
Roche

This presentation contains certain forward-looking statements. These forward-looking statements may be identified by words such as ‘believes’, ‘expects’, ‘anticipates’, ‘projects’, ‘intends’, ‘should’, ‘seeks’, ‘estimates’, ‘future’ or similar expressions or by discussion of, among other things, strategy, goals, plans or intentions. Various factors may cause actual results to differ materially in the future from those reflected in forward-looking statements contained in this presentation, among others:

1 pricing and product initiatives of competitors;
2 legislative and regulatory developments and economic conditions;
3 delay or inability in obtaining regulatory approvals or bringing products to market;
4 fluctuations in currency exchange rates and general financial market conditions;
5 uncertainties in the discovery, development or marketing of new products or new uses of existing products, including without limitation negative results of clinical trials or research projects, unexpected side-effects of pipeline or marketed products;
6 increased government pricing pressures;
7 interruptions in production;
8 loss of or inability to obtain adequate protection for intellectual property rights;
9 litigation;
10 loss of key executives or other employees; and
11 adverse publicity and news coverage.

Any statements regarding earnings per share growth is not a profit forecast and should not be interpreted to mean that Roche’s earnings or earnings per share for this year or any subsequent period will necessarily match or exceed the historical published earnings or earnings per share of Roche.

For marketed products discussed in this presentation, please see full prescribing information on our website www.roche.com

Roche

2023 results

Basel, 1 February 2024

Group

Thomas Schinecker
Chief Executive Officer

Performance

Outlook

2023 guidance exceeded

	Guidance	Results
Group sales growth[1]	Low single digit decline	**+1%** ✓
Core EPS growth[1]	Broadly in line with sales decline	**+6% (+1% excl. resolution of tax disputes in 2023)** ✓
Dividend outlook	Further increase dividend in Swiss francs[2]	**CHF 9.60** ✓

[1] At Constant Exchange Rates (CER); [2] 2023 dividend as proposed by the Board of Directors

2023: Strong base business growth across both divisions

Group sales +1% at CER driven by strong base business of +8%

- Strong Pharma (+9% at CER) and Diagnostics (+7% at CER) base business growth
- COVID-19 sales decreased by CHF -4.3bn and AHR by CHF -1.1bn, in line with guidance
- Core OP margin stable, Core EPS growth +6%, Operating Free Cash Flow of +4% at CHF 18.2bn (all at CER)

Key milestones achieved in Q4

- Pharma regulatory: Approval for Vabysmo in RVO (US) and Tecentriq SC (EU), and US priority review granted for Xolair in food allergy
- Pharma readouts: Positive Ph III (INAVO120) inavolisib in 1L *PIK3CA*-mut HR+ BC, Ph III (EMBARK) results for Elevidys in DMD and positive Ph III (OUtMATCH) Xolair in food allergy
- Diagnostics launches: LightCycler Pro, Anti-HEV IgG/IgM and HBeAg Quant
- Deals: Telavant (anti-TL1A), Carmot (Dual GLP-1/GIP RA) and LumiraDx (PoC technology platform)[1]

Significant newsflow in 2024

- Pivotal readouts: Ph III (SKYSCRAPER-01) tiragolumab in 1L NSCLC, Ph IIIs (STARGLO & SUNMO) Columvi / Lunsumio in 2L+ DLBCL, Ph III (VERONA) Venclexta in 1L MDS, Ph III (REGENCY) Gazyva in LN and Ph III (LUMINESCE) Enspryng in gMG
- Ph III enabling readouts: Ph I/II (Brainshuttle AD) trontinemab in AD, Ph IIb (PADOVA) prasinezumab in PD, Ph II (MANATEE) Evrysdi + GYM329 in SMA, Ph II (GOLDEN STUDY) ASO factor B in GA, Ph II (BARDENAS/ALLUVIUM) vamikibart in DME and Ph II (KARDIA-2) zilebesiran in hypertension
- Diagnostics launches: i601 mass spectrometry, Accu-Chek SmartGuide (CGM), cobas c703 and ISE neo, cobas 6800 / 8800 v2.0, cobas pro serology solution, cobas Liat Respiratory Panel and cobas Respiratory flex

[1]Contingent on deal closing; Growth numbers and rates at CER (Constant Exchange Rates); AHR=Avastin,Herceptin,Rituxan/MabThera; RVO=retinal vein occlusion; HER2+=human epidermal growth factor receptor positive; HR+=hormone receptor positive; PIK3CA-mut=phosphoinositide 3-kinase mutant; BC=breast cancer; anti-HEV IgG/IgM=anti-hepatitis E virus immunoglobulin G/immunoglobulin M; HBeAg=hepatitis B e-antigen; TL1A=TNF-like ligand 1A; GLP-1=glucagon-like peptide 1; GIP RA=glucose-dependent insulinotropic polypeptide receptor agonist; PoC=point of care; NSCLC=non-small cell lung cancer; DLBCL=diffuse large B-cell lymphoma; SC=subcutaneous; MDS=myelodysplastic syndromes; LN=lupus nephritis; gMG=generalized myasthenia gravis; PD=Parkinson's disease; AD=Alzheimer's disease; SMA=spinal muscular atrophy; ASO=antisense oligonucleotide; GA=geographic atrophy; DME=diabetic macular edema; CGM=continuous glucose monitoring; ISE=ion selective electrode; DMD=Duchenne muscular dystrophy

2023: Strong base business growth

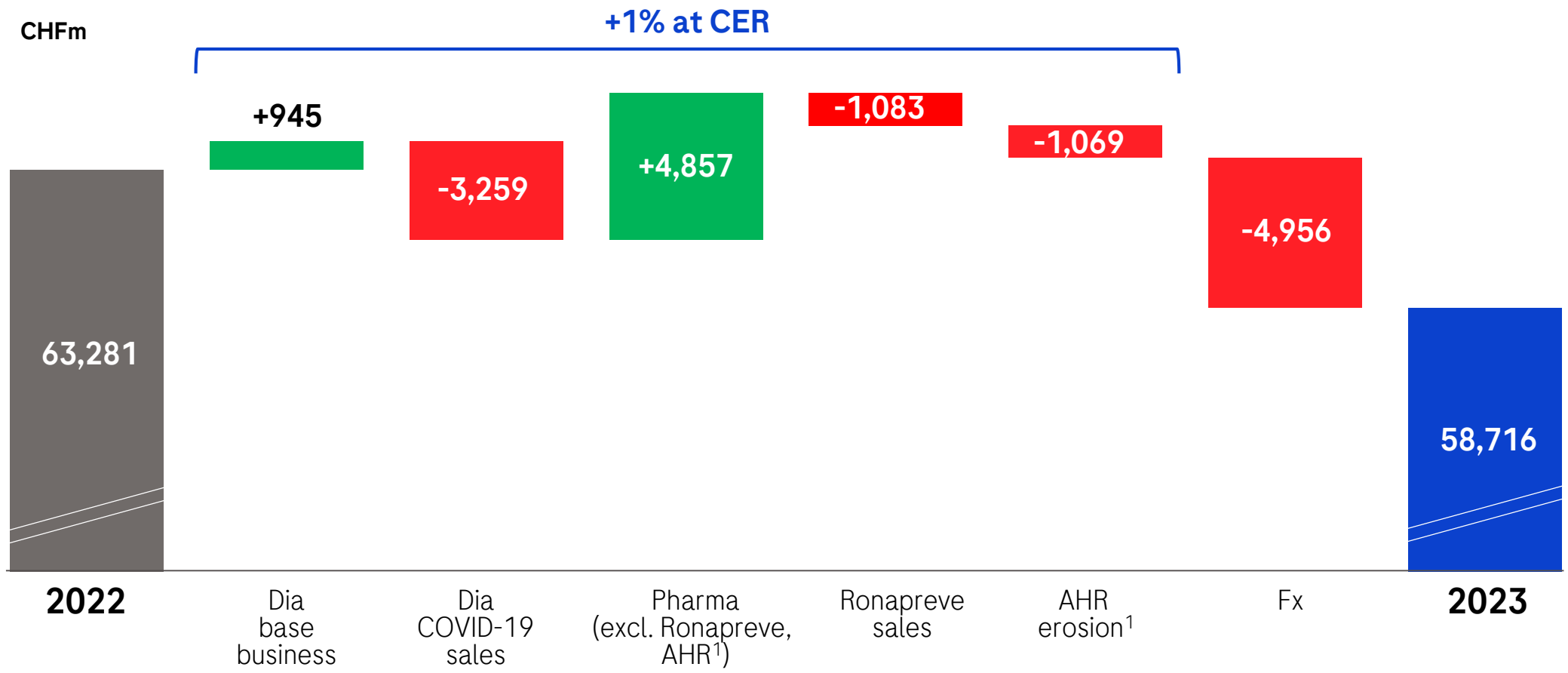
Guidance exceeded with Group sales up by +1% at CER

	2023 CHFbn	2022 CHFbn	Change in % CHF	Change in % CER	Excl. C19[1]
Pharmaceuticals Division	**44.6**	45.6	**-2**	**6**	**9**
Diagnostics Division	**14.1**	17.7	**-20**	**-13**	**7**
Roche Group	**58.7**	63.3	**-7**	**1**	**8**

CER=Constant Exchange Rates; totals may include differences due to rounding; [1] Pharmaceuticals Division sales excluding Ronapreve, Diagnostics Division base business

2023: Base business more than compensates for COVID-19 impact

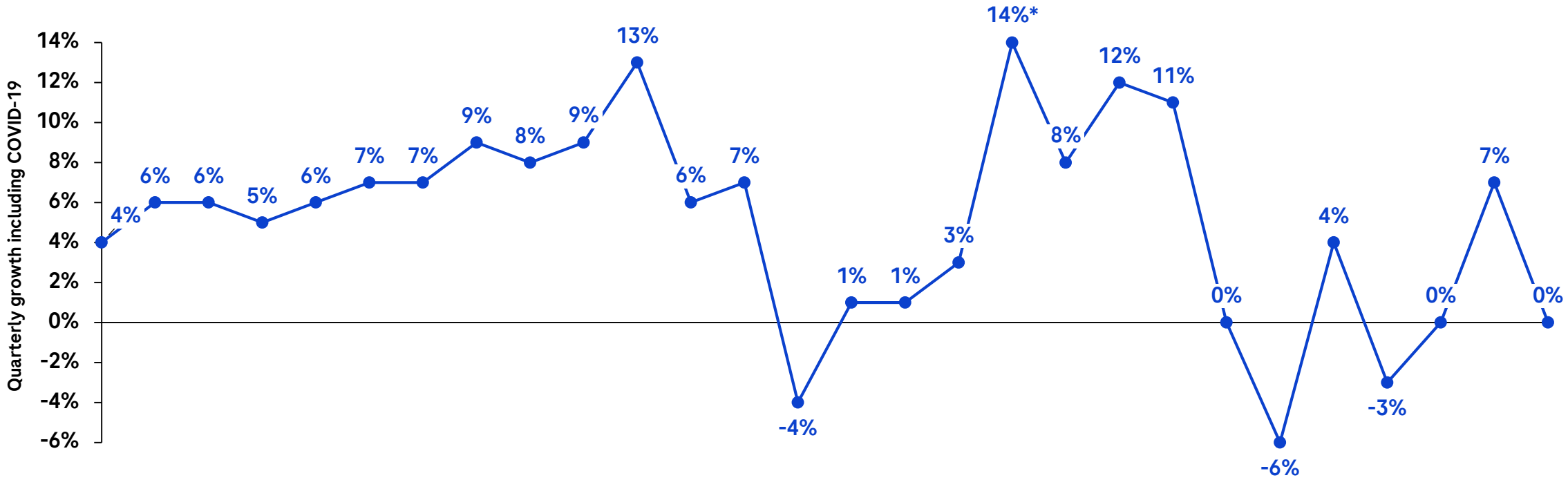
COVID-19 and AHR[1] impact as expected; currency headwinds intensified throughout 2023



CER=Constant Exchange Rates; [1]AHR: Avastin, Herceptin, Rituxan/MabThera

Acceleration of our growth momentum in 2023

Q4 2023 growth impacted by base effect from Ronapreve sales in Japan in 2022



Growth excl. COVID-19	+5%	+7%	+9%	-3%	+3%	+3%	+8%
	Q1 Q2 Q3 Q4	Q1 Q2 Q3 Q4	Q1 Q2 Q3 Q4	Q1 Q2 Q3 Q4	Q1 Q2 Q3 Q4	Q1 Q2 Q3 Q4	Q1 Q2 Q3 Q4
	2017	2018	2019	2020	2021	2022	2023

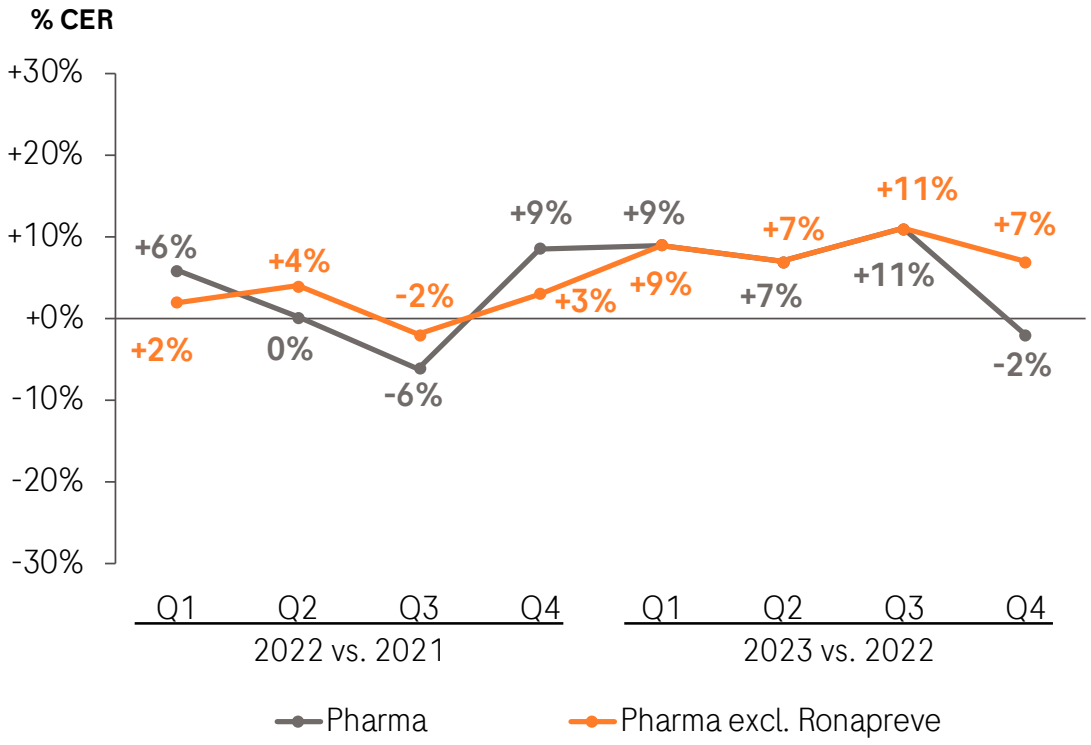
*Q2 2020 sales severely impacted by COVID-19 pandemic onset; Growth rates at CER (Constant Exchange Rates) of the respective year

2023: Base businesses in both divisions growing high single digit

More than offsetting COVID-19 sales (CHF 4.3bn) erosion

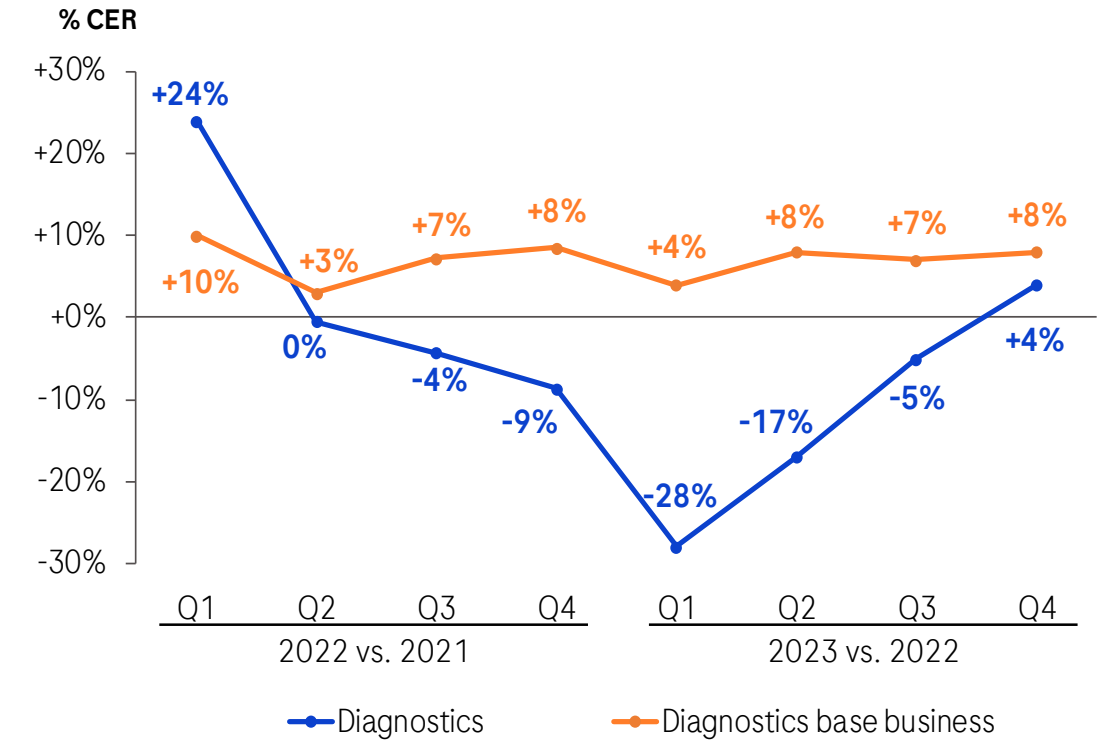
Pharma

Quarterly sales evolution 2022-2023



Diagnostics

Quarterly sales evolution 2022-2023



Growth rates at CER (Constant Exchange Rates) of the respective year

Key growth drivers of the Roche portfolio in 2023

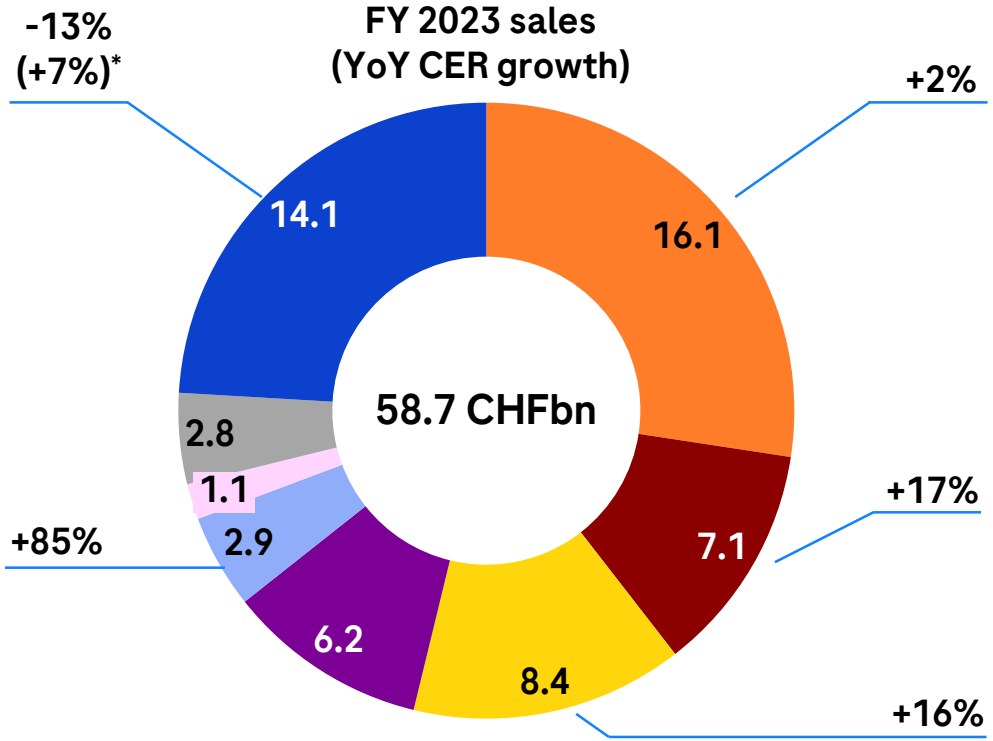
Establishing new leadership positions while further diversifying our portfolio

Core Lab | Molecular Lab | Pathology Lab | Point of care

Diagnostics: +7% base business growth

VABYSMO

Vabysmo reaches CHF 2.4bn



PHESGO

Phesgo reaches CHF 1.1bn

HEMLIBRA

Hemlibra reaches 40% pts share (US/EU5)

POLIVY polatuzumab vedotin-piiq | COLUMVI glofitamab-gxbm | Lunsumio mosunetuzumab-axgb

Polivy becoming new SoC in 1L DLBCL
Columvi/Lunsumio with strong launches in 3L+ DLBCL and FL

OCREVUS ocrelizumab | Evrysdi risdiplam

Ocrevus is global #1 with 24% patient share
Evrysdi is global #1 in total patient share

Definition of Pharmaceuticals TA split used in the FY 2023 Financial Report vs. IR Presentation explained on slide 172; *Diagnostics base business growth at +7%

Strategy and organizational development 2023

Important progress made to set up the organization for continued success

Strategy

Digital Health strategy

- Portfolio focus defined
- One technology platform
- One Center of Excellence for digital product development

Disease area strategies

- Cardiovascular & metabolic and Neurology strategies defined

Group strategy

- To be presented at Pharma Day 2024

Pharma strategy

- To be presented at Pharma Day 2024

Innovation

R&D Excellence

- Productivity analysis
- Six levers defined to accelerate delivery; implementation ongoing
- End-to-end portfolio committee
- Investment in latest technologies to expedite R&D (e.g., AI/ML/LLM, «lab in a loop», IHB)[1]
- Acceleration of promising projects

External opportunities

- Increased focus on de-risked, clinical stage deals (e.g., anti-TL1A)
- Expansion into new therapeutic areas with high disease burden

Organization

Corporate Executive Committee

- All Pharma R&D functions represented from early to late stage and partnering

Operating Model

- Simplify, clarify and align structure, processes & technology

Diagnostics / Diabetes Care integration

- Integration to increase portfolio synergies and operational efficiencies; completed in 2024

Foundation Medicine (FMI)

- Shift to Diagnostics to leverage portfolio synergies

People & Culture

Corporate Executive Committee

- New: Divisional CEOs, Head of Corporate Strategy & Sustainability, Head Global Product Development
- Gender parity achieved

New key executive positions

- Chief Diversity Officer
- Chief Sustainability Officer

Culture

- High employee engagement and company culture scores
- Debate leading to better, faster decisions by empowered people
- Excellence in delivery of ambitious goals

[1]AI=Artificial Intelligence, ML=Machine Learning, LLM=Large Language Model, IHB=Institute of Human Biology

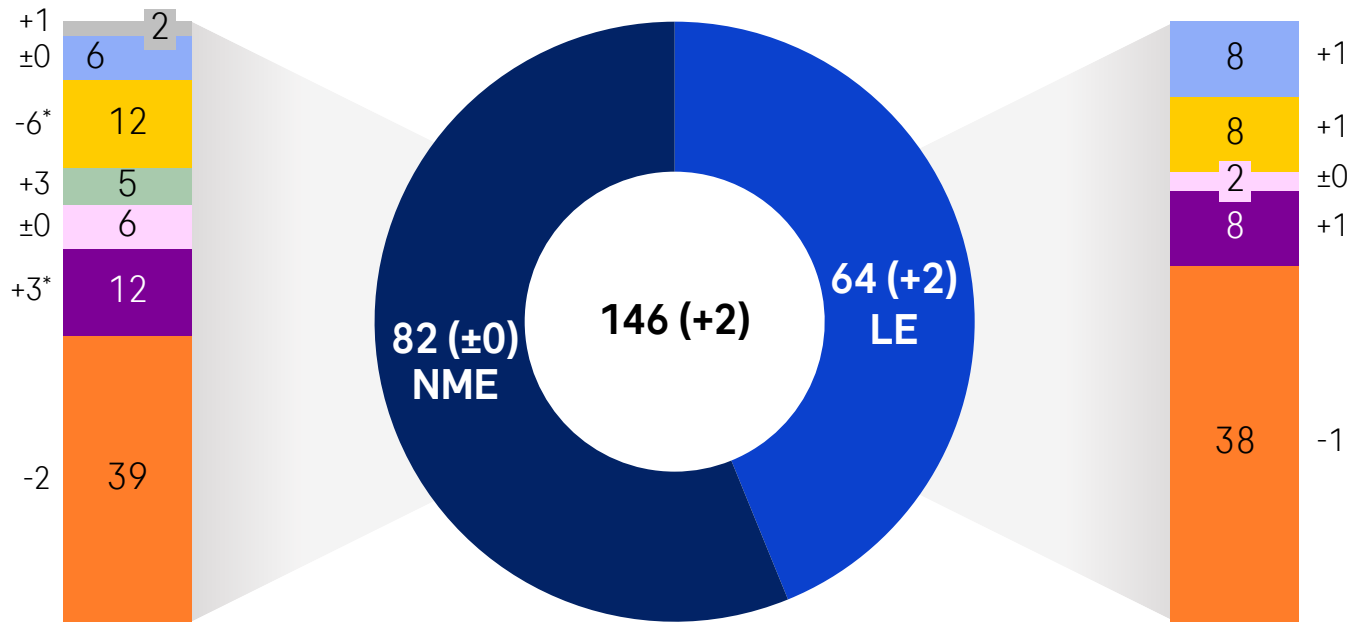
Pipeline update: Strengthening Pharma pipeline

Trade-offs made in Q4 to increase the overall portfolio value and speed up development

NME changes in Q4

		Phase	Indication
+	RG6468	I	Solid tumors
+	RG6457	I	Solid tumors
+	anti-TL1A	II	UC
+	RG6382	I	SLE
+	CT-868	II	T1D + Obesity
+	CT-388	I	Obesity ±T2D
+	CT-996	I	Obesity ±T2D
+	CHU REVN24	I	Acute diseases
–	FAP-CD40	I	Solid tumors
–	EGFRvIIIxCD3	I	Glioblastoma
–	HLA-G CD3 TCB	I	Solid tumors
–	crenezumab	II	AD
–	semorinemab	II	AD
–	balovaptan	II	PTSD
–	basmisanil	II	Dup15q
–	rugonersen	I	Angelman

NME and LE (QoQ change, Q4 vs Q3)



Oncology / Hematology | Immunology | Infectious diseases | Cardiovascular & Metabolism | Neurology | Ophthalmology | Other

*Selnoflast lead indication was changed from Neurology to Immunology, no selnoflast projects were added/terminated; NME=new molecular entity; LE=line extension; UC=ulcerative colitis; SLE=systemic lupus erythematosus; AD=Alzheimer's disease; PTSD=post-traumatic stress disorder; Dup15q=Chromosome 15q11.2-13.1 duplication; CD=Crohn's disease; T1D/T2D=type-1/2 diabetes; Includes all assets from Ph I to Registration

Pipeline acceleration through partnering and acquisitions

Recent deals increasingly focused on de-risked assets with significant potential

Telavant	Alnylam Pharmaceuticals	CARMOT THERAPEUTICS	MediLink Therapeutics	IONIS	Monte Rosa Therapeutics / ORIONIS™ BIOSCIENCES	NVIDIA	lumiraDx*
Anti-TL1A in inflammatory bowel disease	**siRNA targeting AGT** in hypertension	**Dual GLP-1/GIP RA** in obesity ±diabetes	**ADCs** in solid tumors	**RNA therapies** in Alzheimer's and Huntington's disease	**Molecular glue degraders** in oncology and neurology	**Generative AI** for drug discovery	**PoC technology** with multiple diagnostic modalities on a single platform
Immunology	CVM	CVM	Oncology	Neurology	Onco & Neuro	Across diseases	Patient Care
Ph III ready	**Ph II**	**Ph II ready**	**Ph I ready**	**Pre-clinical**	**Pre-clinical**	**Pre-clinical**	**On market**

*Contingent on deal closing; CVM=cardiovascular & metabolism; siRNA=small interfering RNA; AGT=angiotensinogen; TL1A=Tumor necrosis factor-like cytokine 1A; GLP-1=glucagon-like peptide-1; GIP=glucose-dependent insulinotropic polypeptide; RA=receptor agonist; AI=artificial intelligence; ADC=antibody-drug conjugate; PoC=point of care

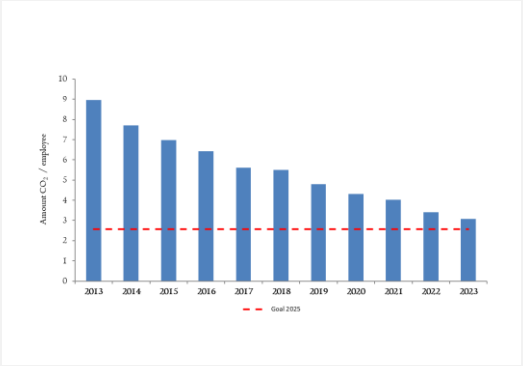
ESG achievements 2023

Sustainability is part of everything we do

Top 3 position in DJSI

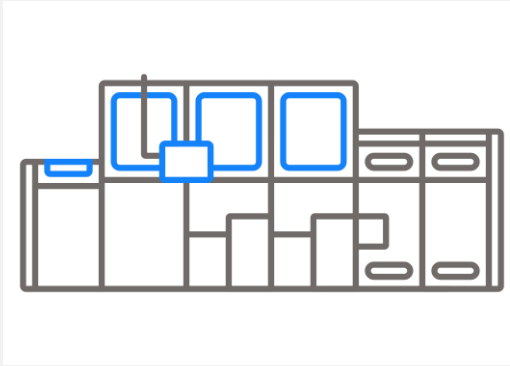
Roche and Chugai ranked as 3rd and 2nd in the DJSI 2023

Reducing Scope 1 & 2 GHG emissions



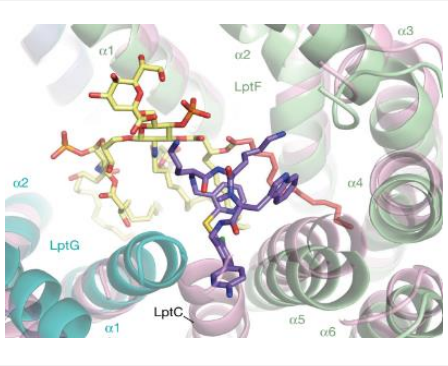
79% reduction in Scope 1 & 2 GHG emissions since 2004

WHO prequalification for HPV molecular test



Will help prevent 74m new cases of cervical cancer in 78 LMICs, supporting WHO goals[1]

Novel antibiotic class with potential anti-CRAB activity[2,3]



pRED & Harvard scientists discovered a potential new antibiotic class for the first time in over 50 yrs

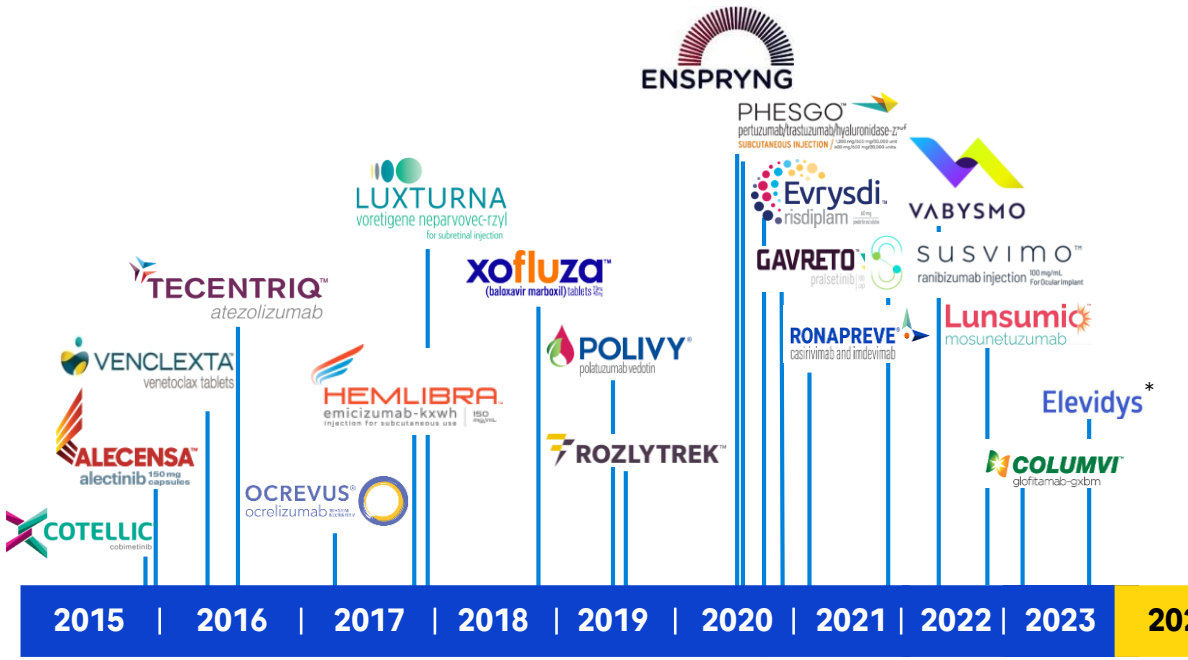
WHO=World Health Organization; HPV=human papillomavirus; LMIC=low and middle income country, DJSI=Dow Jones Sustainability Indices; CRAB=Carbapenem-resistant *Acinetobacter baumannii* classified as a priority 1 critical pathogen by WHO; GHG=greenhouse gases; [1] Global WHO strategy to accelerate the elimination of cervical cancer as a public health problem. Geneva: WHO (2020); [2] Zampaloni et al. Nature (2024); [3] Pahil et al. Nature (2024)

Performance

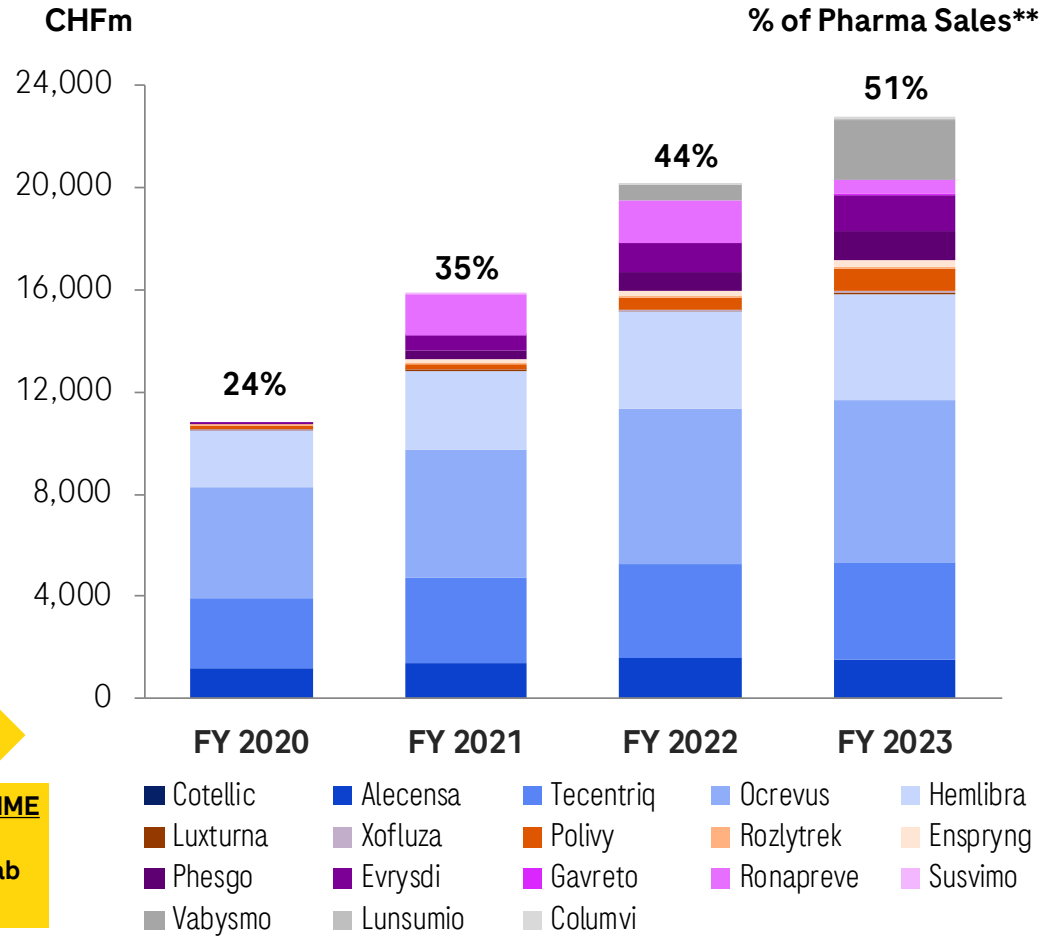
Outlook

Young portfolio to drive growth in the near- to mid-term

Two potential NME approvals expected for 2024: crovalimab in PNH and inavolisib in HR+ breast cancer



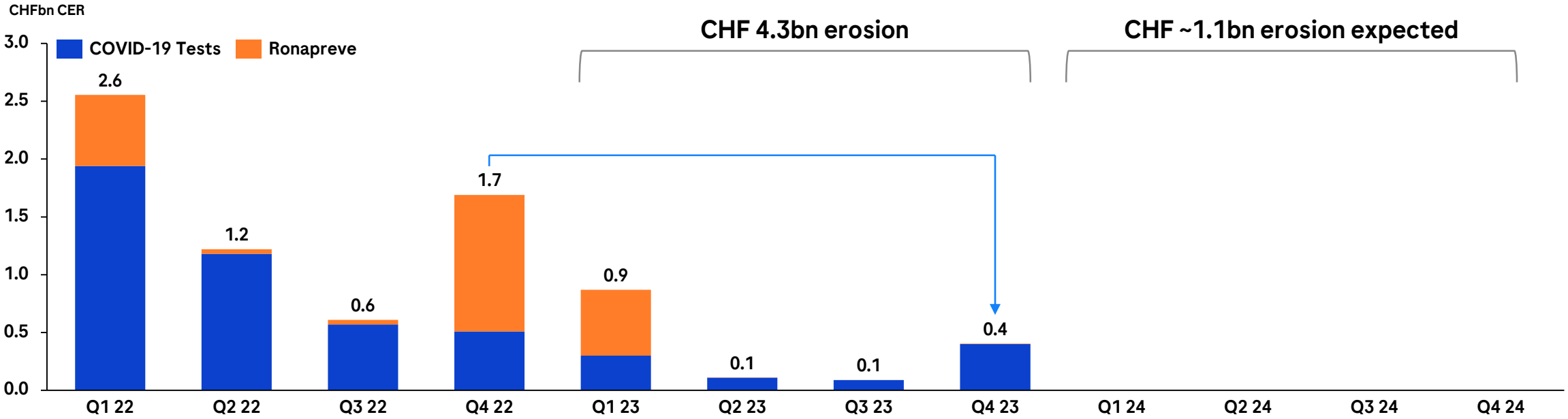
Potential NME launches:
- **crovalimab**
- **inavolisib**



Young portfolio defined as all launches since end of 2015; * Elevidys: Accelerated US approval by partner company Sarepta; ** Venclexta sales booked by AbbVie and therefore not included; NME=new molecular entity; PNH=Paroxysmal Nocturnal Hemoglobinuria; HR=hormone receptor

Declining COVID-19 related headwinds in 2024

Q1 2024 is the final quarter materially impacted by declining COVID-19 sales



Roche had a significant contribution to ending the COVID-19 pandemic

- 16 COVID-19 products
- ~ 3 million patients treated with Ronapreve & Actemra
- ~ 2 billion COVID-19 tests
- ~ CHF 19bn in sales*

*COVID-19 sales referring to COVID-19 diagnostic tests, Ronapreve and Actemra sales; all values at CER (Constant Exchange Rate) of the respective year

Key growth drivers beyond 2025

Many opportunities with significant market potential in both divisions

Pharmaceuticals

	NME	Indication	Newsflow	Timing
Oncology / Hematology	**tiragolumab**	NSCLC	Final Ph III data	H2 2024
	inavolisib	BC	US/EU filing	2024
	divarasib	NSCLC	Ph I/II readout	2024/25
	giredestrant	BC	Ph III readout	2025
Neurology	**Elevidys**	DMD	Ph III readout	2024/25
	prasinezumab	PD	Ph IIb readout	2024
	Evrysdi + GYM329	SMA	Ph II readout	2024
	trontinemab	AD	Ph I/II readout	2024
	fenebrutinib	MS	Ph III readout	2025
Immunology	**Gazyva**	LN	Ph III readout	2024
	anti-TL1A	IBD	Ph III initiation	2024
	astegolimab	COPD	Ph III readout	2025
Ophthalmology	**vamikibart (anti-IL6)**	DME/UME	Ph II/III readout	2024/25
	ASO factor B	GA	Ph II readout	2024
Cardiovascular & Metabolism	**zilebesiran**	HT	Ph II readout	2024
	CT-388/868/996 (GLP-1/GIP)	Obesity	Ph I/II readout	2024

Diagnostics

	Product	Description	Launch
Core Lab	**i601 mass spec**	Total solution for clinical mass spectrometry and first reagent ipack	2024
	cobas pro serology solution	Roche blood safety solution for the US donor screening market	2024
	cobas c703 & ISE neo	High-throughput clinical chemistry and ISE testing on cobas pro	2024
	Elecsys Amyloid Plasma Panel	Rule-out blood-based test for amyloid pathology detection in AD	2025
Molecular Lab	**cobas 6800/8800 v2.0**	Upgrade with increased testing flexibility, throughput and automation	2024
	cobas Respiratory flex	Novel TAGS® multiplex technology for respiratory testing on cobas x800	2024
	Next generation sequencing	Nanopore sequencer with unique sequencing by expansion technology	2025+
Diabetes Care	**Accu-Chek SmartGuide**	Roche's first generation continuous glucose monitoring solution	2024
Point of Care	**cobas Liat Resp. panel**	Detection & differentiation of four most prevalent respiratory targets	2024

Positive 2024 outlook

Sales drivers[1]

Continued strong base business growth in both divisions

COVID-19 sales expected to decline by roughly CHF 1.1bn

LOE[2] impact of roughly CHF 1.6bn expected

Group sales growth[1]	Mid single digit sales growth

[1] At Constant Exchange Rates (CER); [2] LOE impact includes global losses on Avastin, Herceptin, Mabthera/Rituxan, Esbriet, Lucentis and Actemra

2024 guidance

Group sales growth[1]	Mid single digit sales growth
Core EPS growth[1]	Broadly in line with sales growth excl. impact from resolution of tax disputes in 2023
Dividend outlook	Further increase dividend in Swiss francs

[1] At Constant Exchange Rates (CER)

Finance

Alan Hippe
Chief Financial Officer

IR events currently planned for 2024

Additional events driven by readouts

Neurology Update
Mar 11
15:00 - 16:30 CET
Virtual event

- Neurology franchise update
- Elevidys Ph III (EMBARK) in Duchenne muscular dystrophy
- trontinemab Ph I/II (Brainshuttle™ AD) in Alzheimer's disease (cohort 4 dose escalation)
- prasinezumab Ph II (PASADENA) in Parkinson's disease (4 year OLE data)

Diagnostics Day
May 22
13:00 - 15:30 BST
London & virtual

- Deep-dive into the current product portfolio
- Updates on key development projects and upcoming launches, including mass spectrometry, continuous glucose monitoring (CGM), next generation sequencing and other products in development

Pharma Day
Sep 30
tbd
London & virtual

- Update on Group & Pharma strategy
- Deep-dive into the current product portfolio
- Building blocks for future growth: Late stage portfolio update
- Update on R&D excellence

Results

Cash & balance sheet

Reporting changes

Currency guidance & outlook

2023: Group performance

Sales increase of +1% and Core EPS increase of +6%

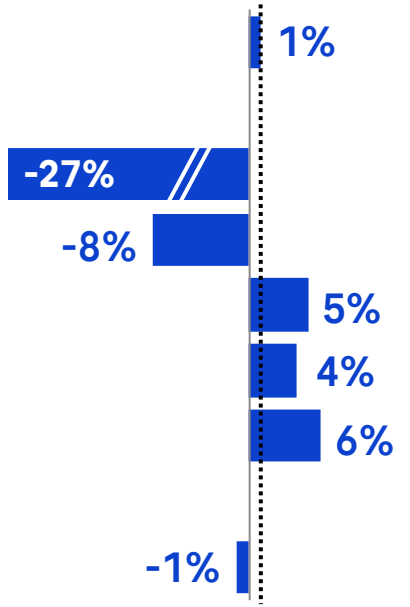
	2023 CHFm	2022 CHFm	Change in % CHF	Change in % CER
Sales	**58,716**	**63,281**	**-7**	**1**
Core operating profit	**19,240**	**22,173**	**-13**	**-1**
as % of sales	*32.8*	*35.0*		
Core net income	**15,804**	**17,530**	**-10**	**3**
as % of sales	*26.9*	*27.7*		
Core EPS (CHF)	**18.57**	**20.30**	**-9**	**6**
IFRS net income	**12,358**	**13,531**	**-9**	**7**
as % of sales	*21.0*	*21.4*		
Operating free cash flow	**15,768**	**17,673**	**-11**	**4**
as % of sales	*26.9*	*27.9*		
Free cash flow	**11,288**	**13,041**	**-13**	**4**
as % of sales	*19.2*	*20.6*		

CER=Constant Exchange Rates; all numbers in CHFm, except Core EPS in CHF

2023: Group operating performance

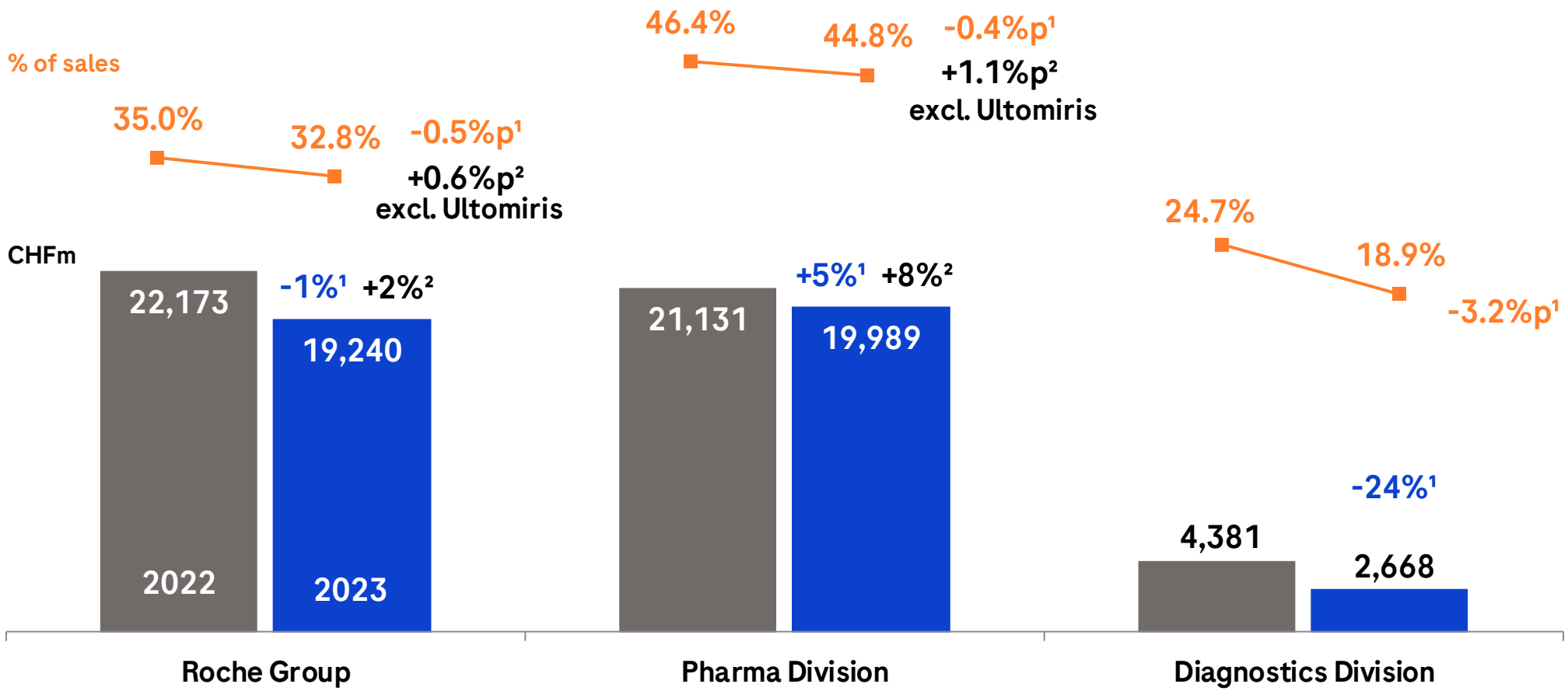
Core OP lower by -1% due to higher operating expenses and lower other revenue (Ultomiris base effect 2022)

	2023 CHFm	2023 abs. CER
Sales	**58,716**	**+391**
Other revenue	1,725	-664
Cost of sales	-15,251	+1,350
R&D	-13,237	-709
SG&A	-13,518	-590
OOI&E	805	+44
Core operating profit	**19,240**	**-178**
Core OP in % of sales	*32.8%*	
At CER	*34.4%*	
	(2022: 34.9%)	



CER=Constant Exchange Rates; OP=Operating Profit; R&D=Research & Development; SG&A=Selling, General & Administration; OOI&E=Other Operating Income & Expense

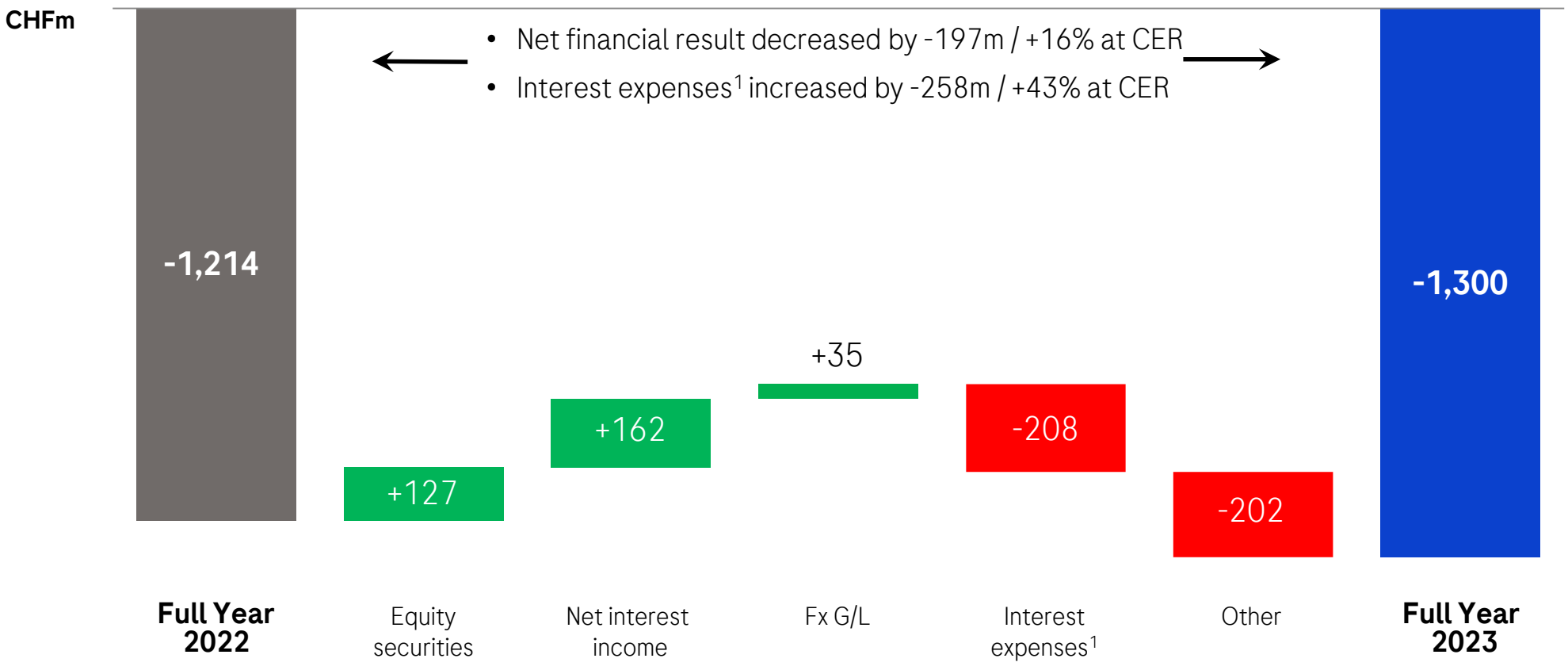
2023: Core operating profit and margin



Note: Group Core operating profit includes -3.4bn from Corporate (-3.3bn in 2022); [1] At CER=Constant Exchange Rates; [2] At CER excluding 2022 Ultomiris patent settlement

2023: Core net financial result

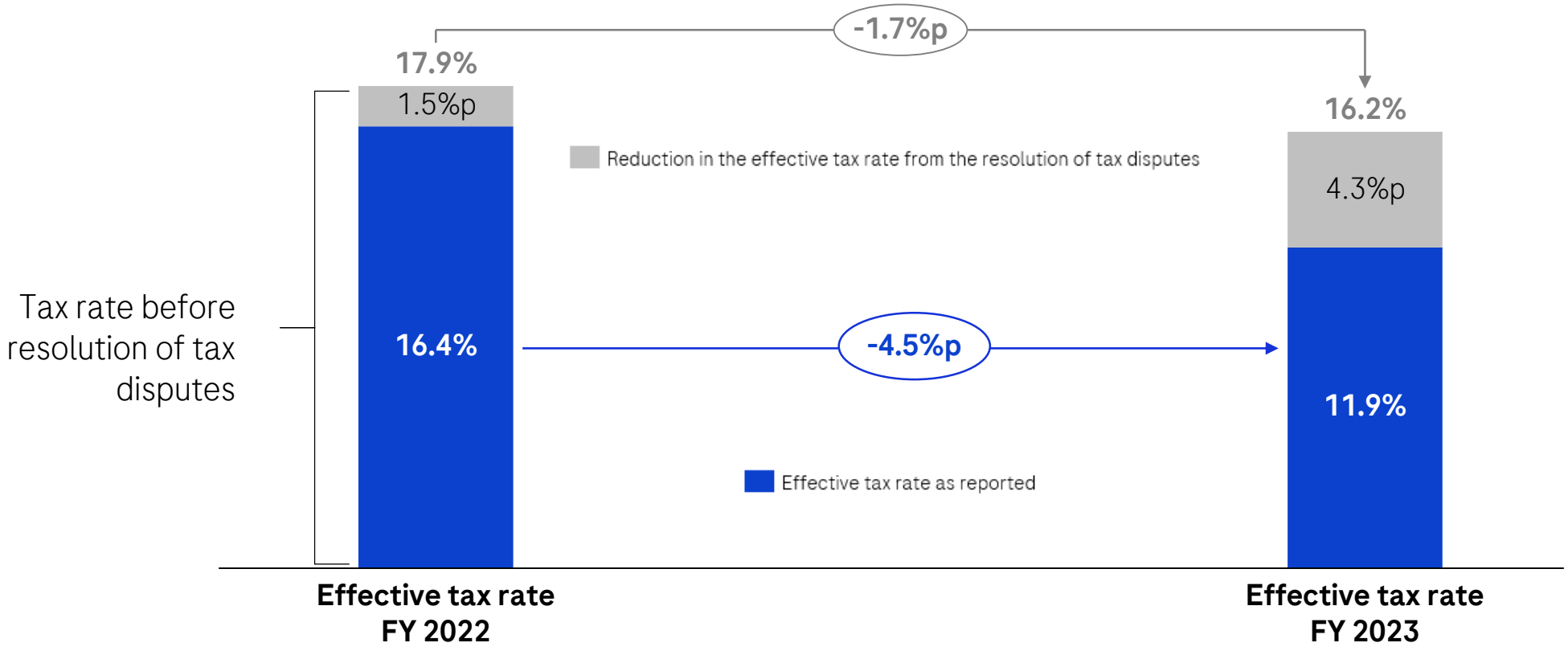
Decrease due to increased interest expenses, partially offset by interest income



CER=Constant Exchange Rates; Fx G/L=exchange rate gains and losses; [1] incl. amortization of debt discount and net gains on interest rate derivatives

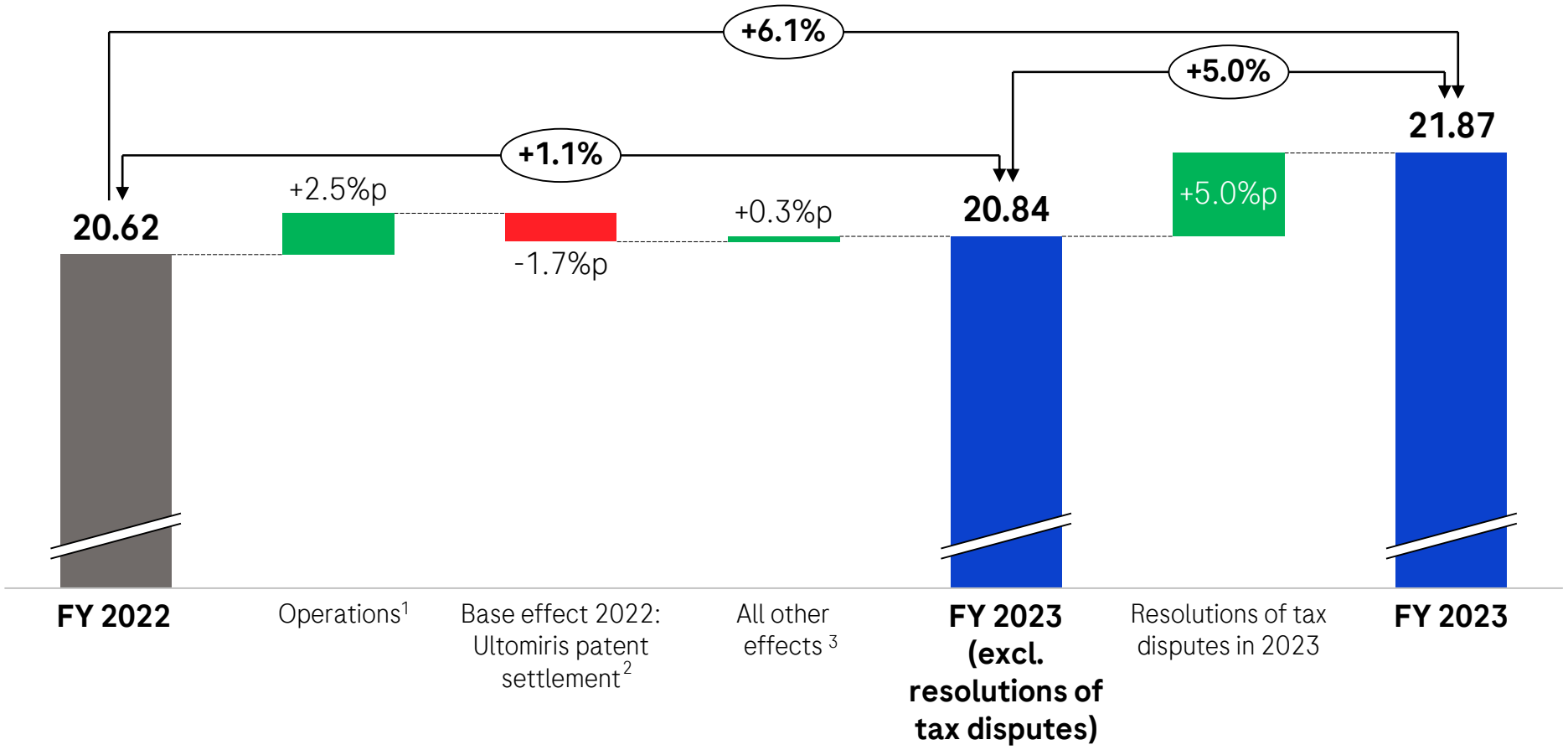
2023: Group Core tax rate

Decrease in core tax rate mainly due to higher impact from the resolution of tax disputes in 2023 compared to 2022 and lower profits from high tax jurisdictions



2023: Core EPS development

Effects of resolutions of tax disputes in 2023 and increase in operations partially offset by Ultomiris base effect



All values at CER=Constant Exchange Rates; [1] Core operating profit excl. impacts from Ultomiris patent settlement; [2] Net impact from the Ultomiris patent settlement: gross income, net of income tax and non-controlling interests; [3] Effects from changes in Non-operating expenses excl. effects from changes in the income tax charges excl. the effect of resolution of tax disputes in 2023 and the effect of the Ultomiris patent settlement on the 2022 tax expense, effects from changes in Non-controlling interest amounts excluding effects of the Ultomiris patent settlement in 2022, effects of changes in number of shares

2023: Non-core and IFRS income

Non-core operating exp. lower vs. PY due to lower impairments of IA partly offset by higher spend in GRP

	2022 CHFm	2023 CHFm	Var. at CER	Change in % CHF	Change in % CER
Core operating profit	**22,173**	**19,240**	**-178**	**-13**	**-1**
Global restructuring plans	-969	-2,038	-1,153		
Amortisation of intangible assets	-933	-711	+189		
Impairment of intangible assets[1]	-2,837	-1,199	+1,566		
M&A and alliance transactions	20	-19	-39		
Legal & Environmental[2]	22	122	+107		
Total non-core operating items	-4,697	-3,845	+670		
IFRS Operating profit	**17,476**	**15,395**	**+492**	**-12**	**+3**
Total financial result & taxes	-3,945	-3,037	+482		
IFRS net income	**13,531**	**12,358**	**+973**	**-9**	**+7**

CER=Constant Exchange Rates; [1] incl. goodwill; [2] incl. pension plan settlements; IA=Intangible Assets; GRP=Group Restructuring Plans

Results

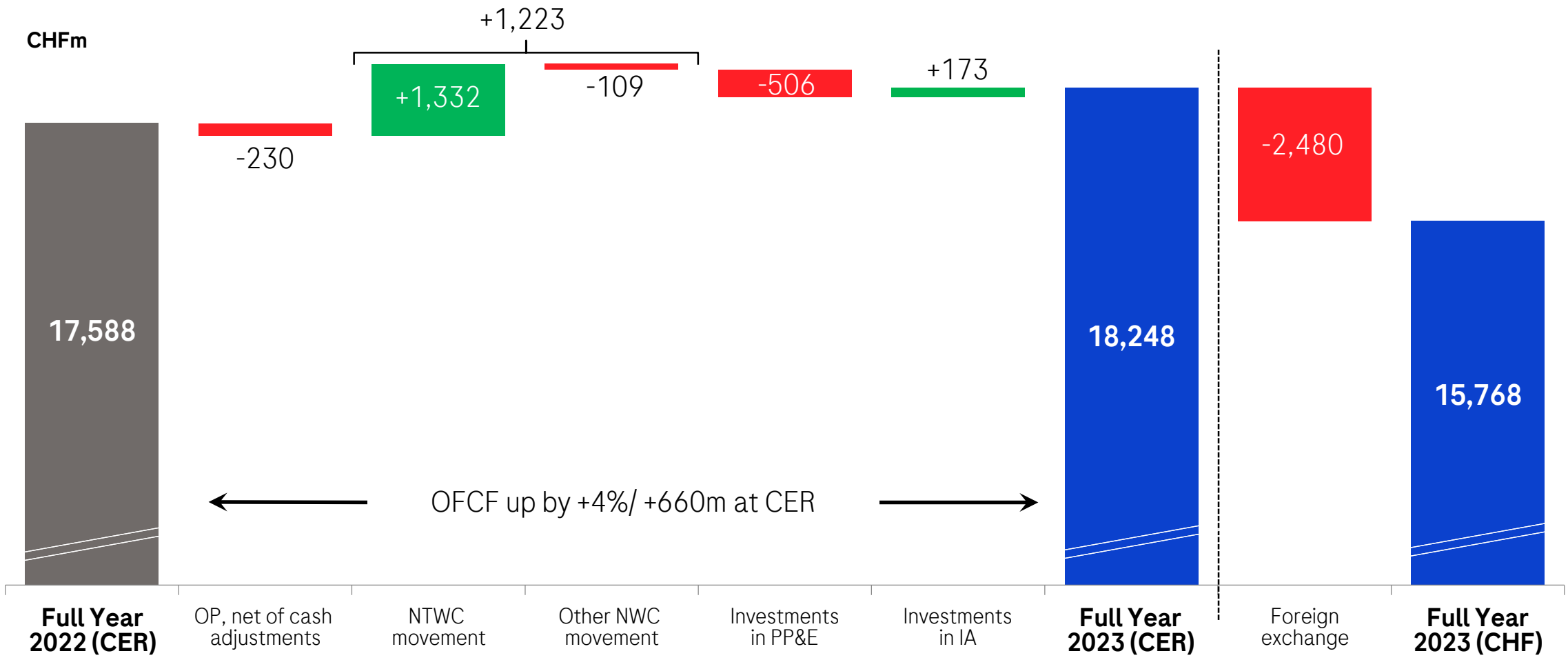
Cash & balance sheet

Reporting changes

Currency guidance & outlook

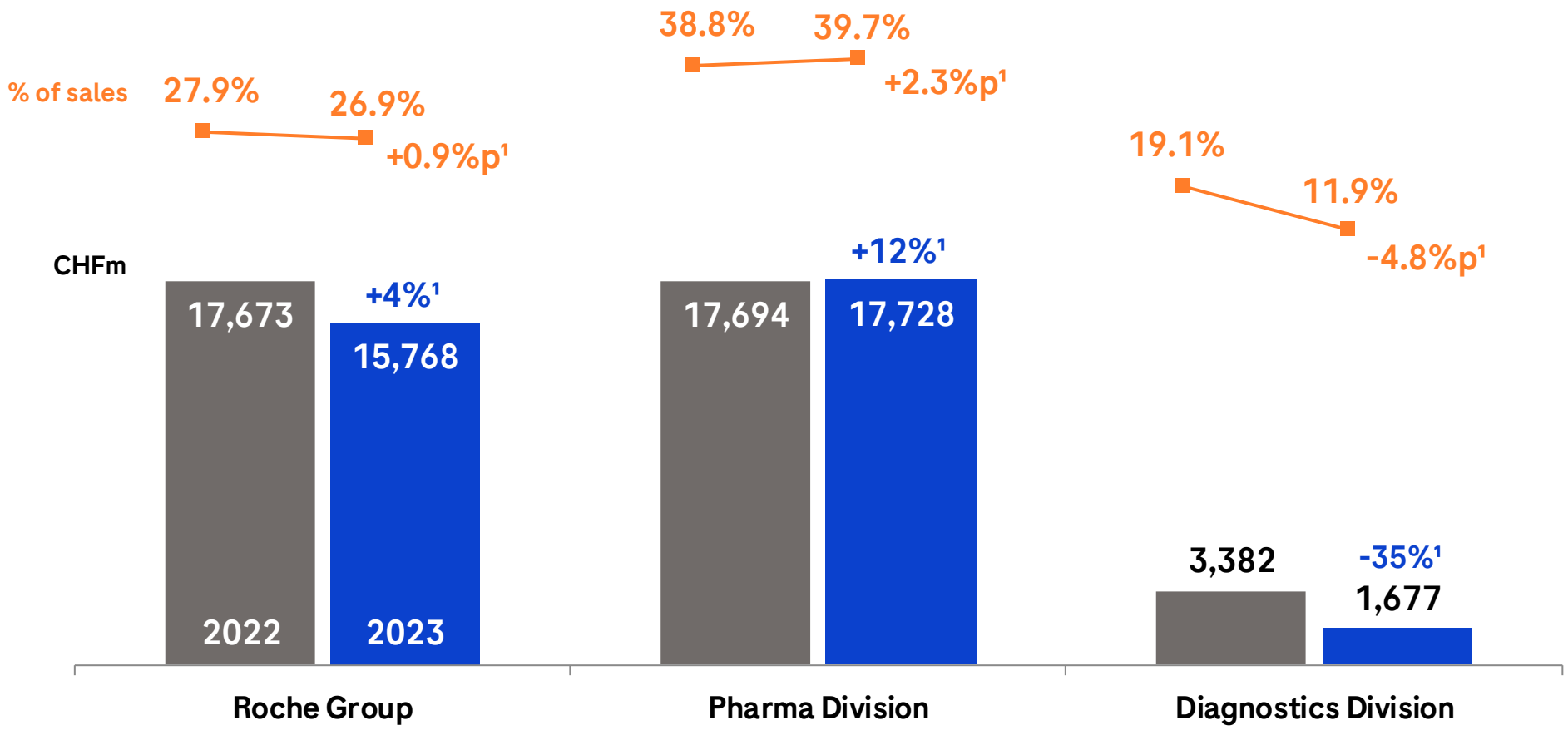
2023: Group Operating Free Cash Flow

OFCF +4%; NWC movement and lower IA investments partly offset by higher inv. in PP&E and declining cash OP



CER=Constant Exchange Rates; OP=Operating Profit; NWC=Net Working Capital; NTWC=Net Trade Working Capital; PP&E=Property, Plant & Equipment incl. lease liability paid; IA=Intangible Assets

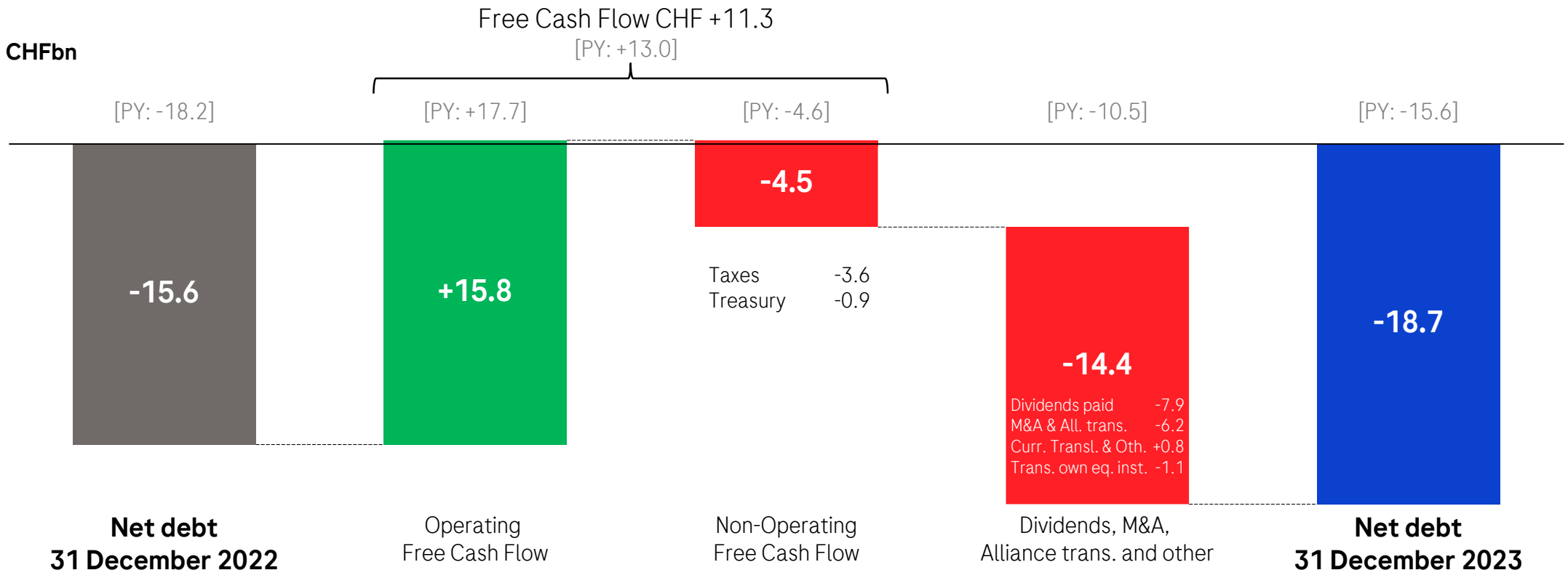
2023: Operating free cash flow and margin



Note: Group Operating free cash flow includes -3.6bn from Corporate (-3.4bn in 2022); [1] At CER=Constant Exchange Rates

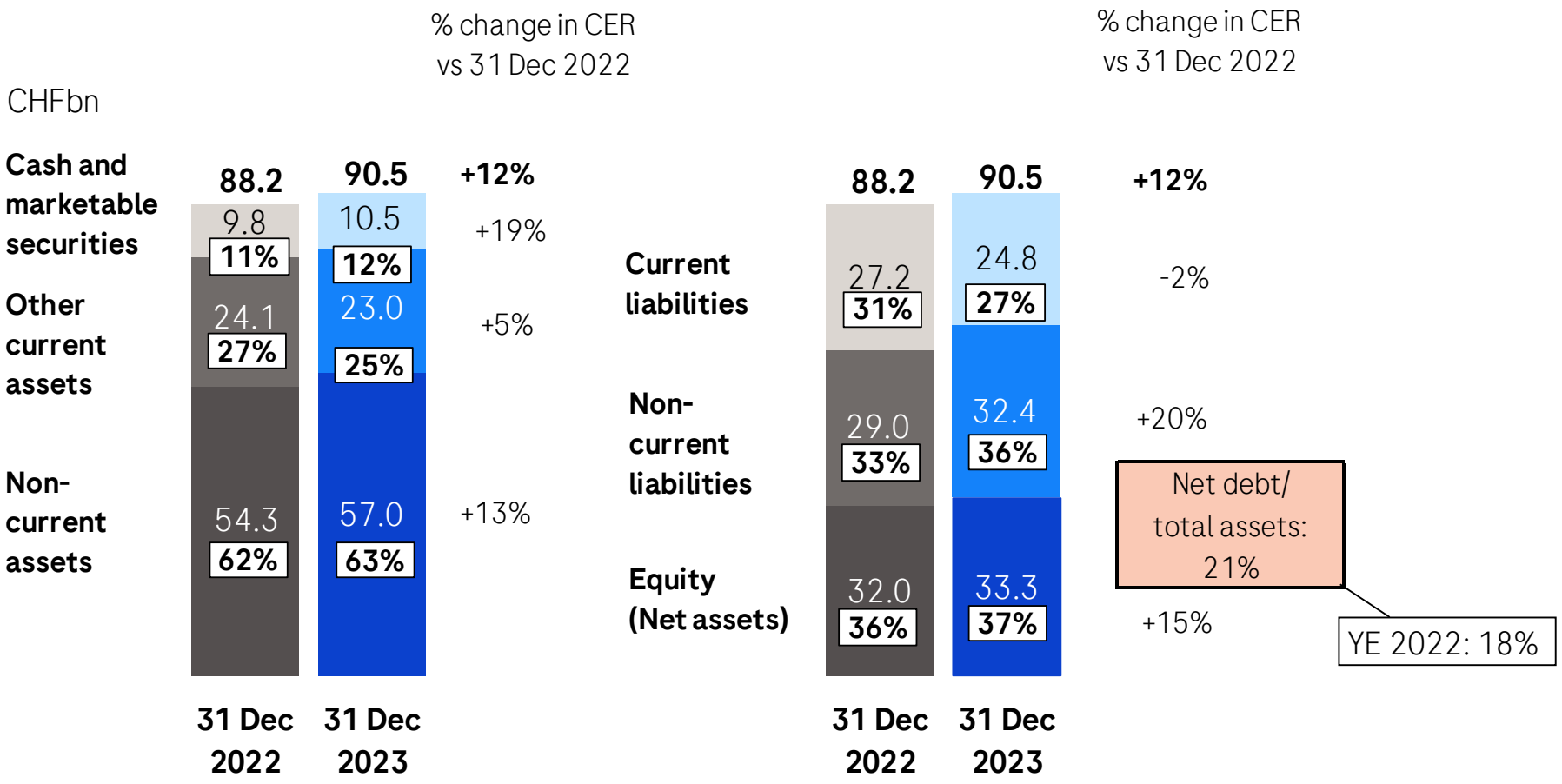
2023: Group net debt development

Net debt higher by CHF 3.1bn vs. YE 2022



Balance sheet 31 December 2023

Equity ratio at 37% (31 Dec 2022: 36%) and net debt to assets at 21% (31 Dec 2022: 18%)



CER=Constant Exchange Rates

Results

Cash & balance sheet

Reporting changes

Currency guidance & outlook

Restatements to be applied in 2024

Foundation Medicine shifted to the Diagnostics Division effective Jan 1, 2024

Income statement (Core)

Pharmaceuticals Division - CHFm	Half Year 2023 Published	Half Year 2023 Delta	Half Year 2023 Restated	Full Year 2023 Published	Full Year 2023 Delta	Full Year 2023 Restated
Sales	22,681	-170	22,511	44,612	-347	44,265
Other revenue	806	-8	798	1,667	-19	1,648
Cost of sales	-4,107	71	-4,036	-8,343	149	-8,194
Research and development	-5,617	110	-5,507	-11,490	204	-11,286
Selling, general and administration	-3,444	136	-3,308	-7,215	263	-6,952
Other operating income (expense)	699	0	699	758	1	759
Core operating profit	**11,018**	**139**	**11,157**	**19,989**	**251**	**20,240**
Core operating profit margin	*48.6%*	*1.0%p*	*49.6%*	*44.8%*	*0.9%p*	*45.7%*

Diagnostics Division - CHFm	Half Year 2023 Published	Half Year 2023 Delta	Half Year 2023 Restated	Full Year 2023 Published	Full Year 2023 Delta	Full Year 2023 Restated
Sales	7,098	170	7,268	14,104	347	14,451
Other revenue	31	8	39	58	19	77
Cost of sales	-3,349	-71	-3,420	-6,908	-149	-7,057
Research and development	-832	-110	-942	-1,747	-204	-1,951
Selling, general and administration	-1,342	-136	-1,478	-2,899	-263	-3,162
Other operating income (expense)	13	0	13	60	-1	59
Core operating profit	**1,619**	**-139**	**1,480**	**2,668**	**-251**	**2,417**
Core operating profit margin	*22.8%*	*-2.4%p*	*20.4%*	*18.9%*	*-2.2%p*	*16.7%*

Results

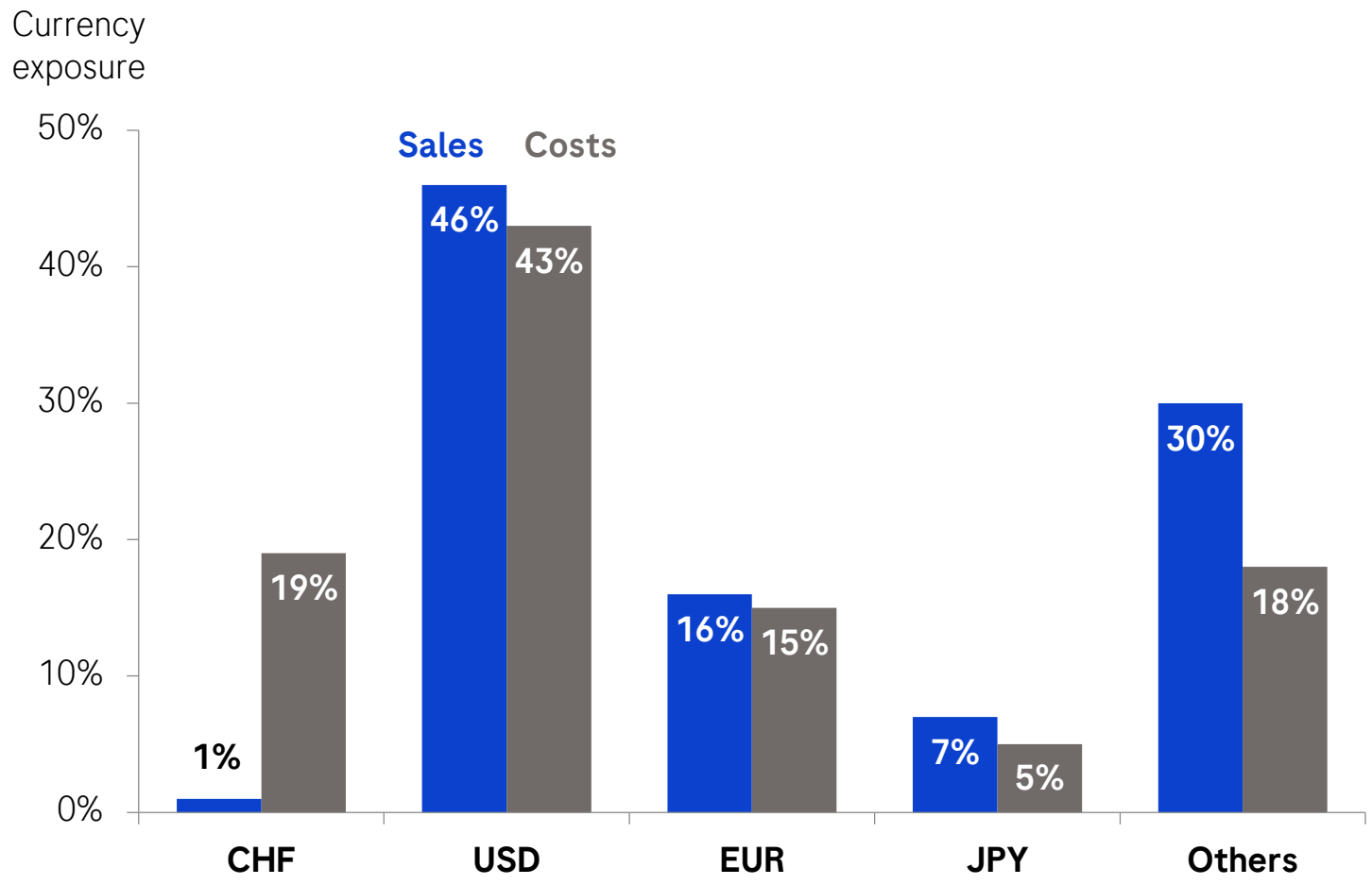
Cash & balance sheet

Reporting changes

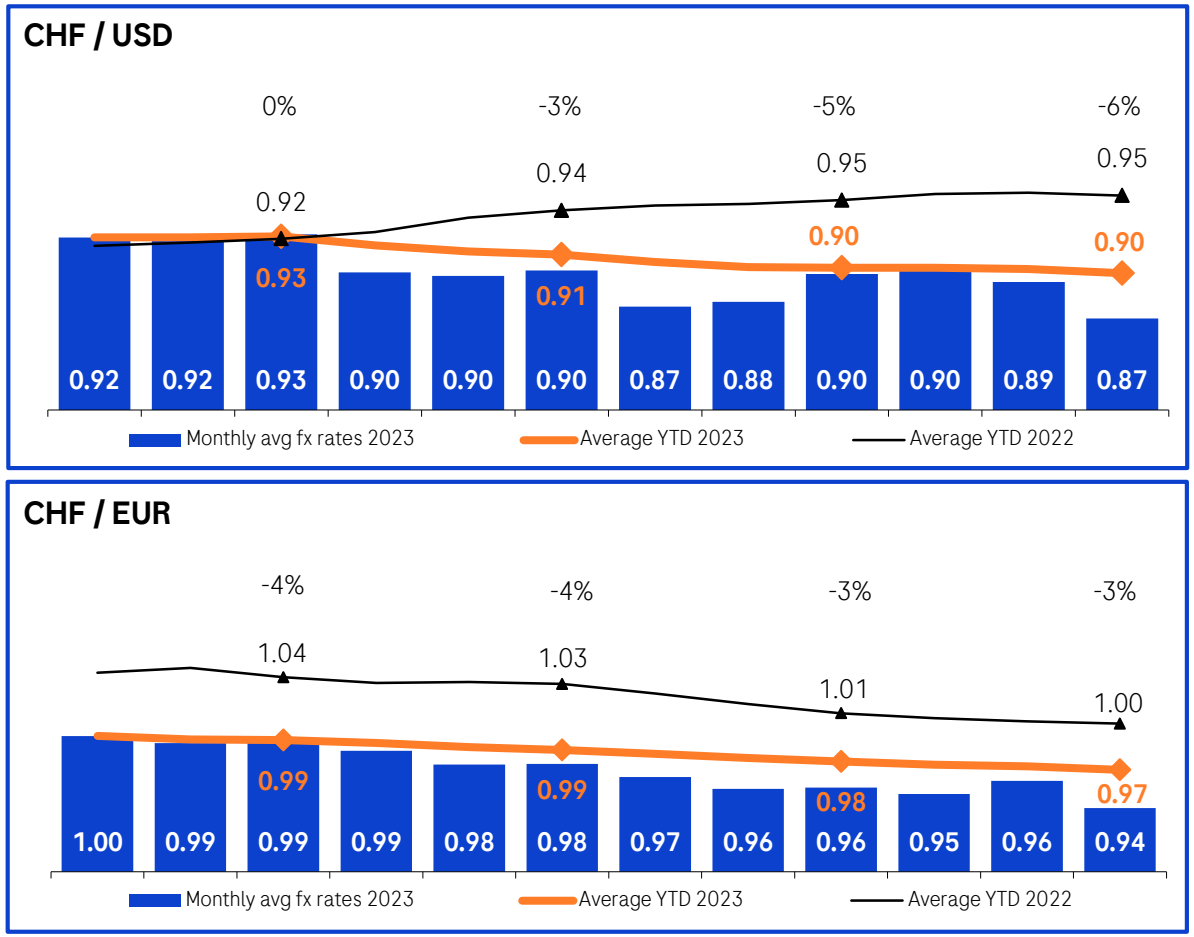
Currency guidance & outlook

2023: Group currency exposure

Overall solid natural hedge



2023: Currency impact and outlook



In 2023 impact[1] is (%p):

	Q1	HY	Sep YTD	FY
Sales	-4	-6	-7	**-8**
Core operating profit		-8		**-12**
Core EPS		-9		**-15**

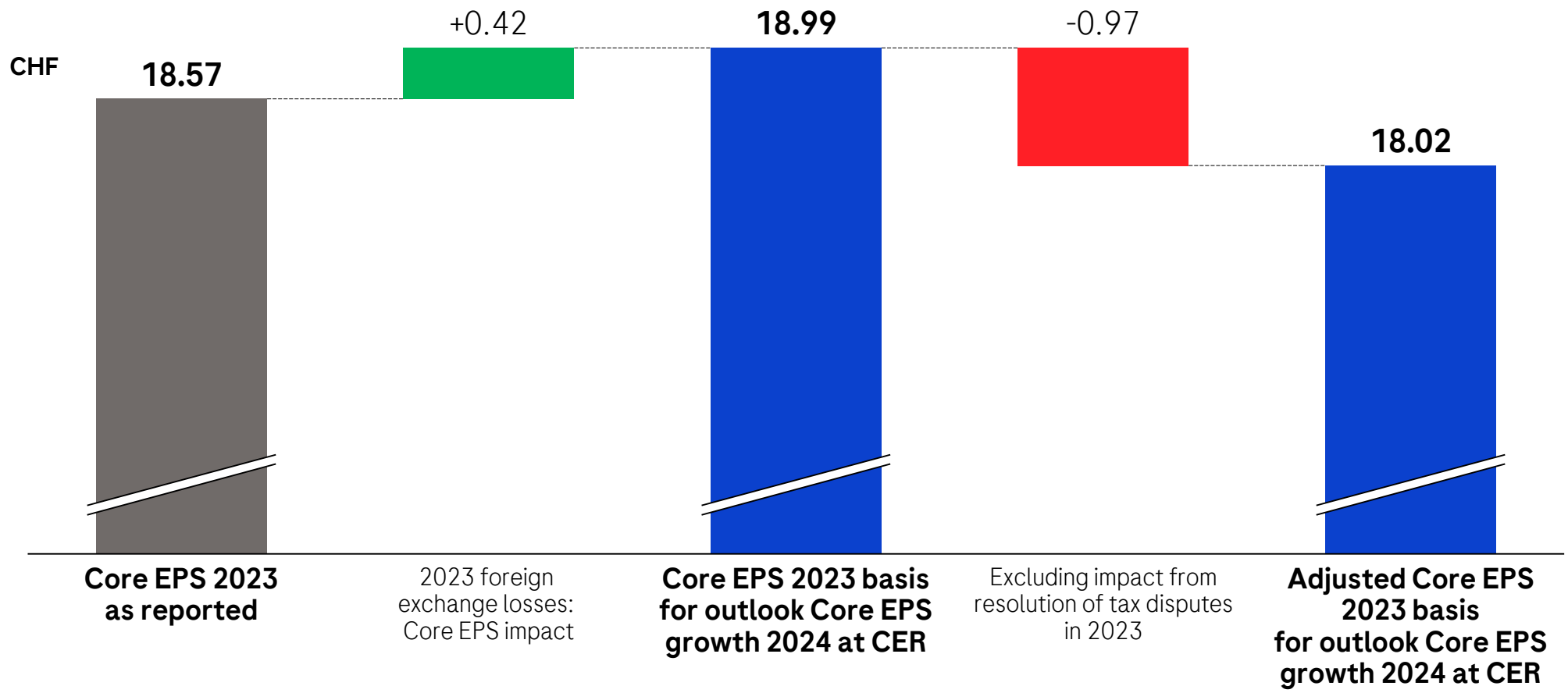
2024 currency impact expected[1] *(based on 29 Dec 2023 FX rates):*

Around -6%p on Sales, -8%p on Core OP and -9%p on Core EPS

[1] On group growth rates

2023: Core EPS

2023 Core EPS adjusted to CHF 18.02 is basis for Core EPS outlook 2024 at CER



CER=Constant Exchange Rates

2024 guidance

Group sales growth[1]	Mid single digit sales growth
Core EPS growth[1]	Broadly in line with sales growth excl. impact from resolution of tax disputes in 2023
Dividend outlook	Further increase dividend in Swiss francs

[1] At Constant Exchange Rates (CER)

Pharmaceuticals Division

Teresa Graham
CEO Roche Pharmaceuticals

2023: Pharmaceuticals sales

All regions ex-Japan delivering strong growth, intensifying currency headwinds throughout 2023

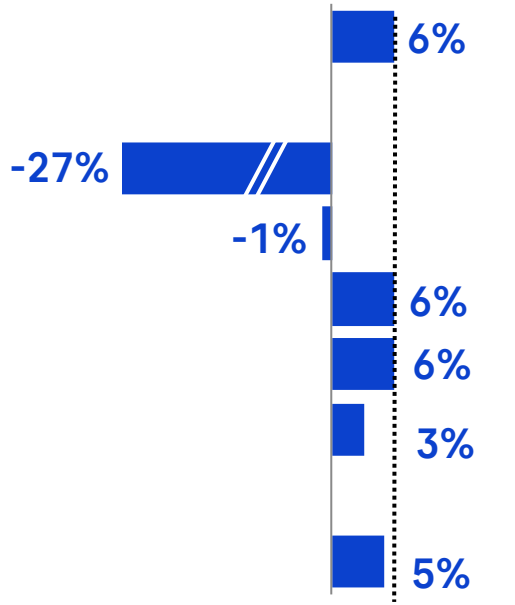
	2023 CHFm	2022 CHFm	Change in % CHF	Change in % CER	CER w/o Ronapreve
Pharmaceuticals Division	**44,612**	**45,551**	**-2**	**6**	**9**
United States	23,606	23,322	1	8	8
Europe	8,306	8,143	2	6	7
Japan	3,745	4,949	-24	-14	6
International	8,955	9,137	-2	13	14

CER=Constant Exchange Rates

2023: Pharmaceuticals core operating profit

Core operating profit broadly in line with sales growth

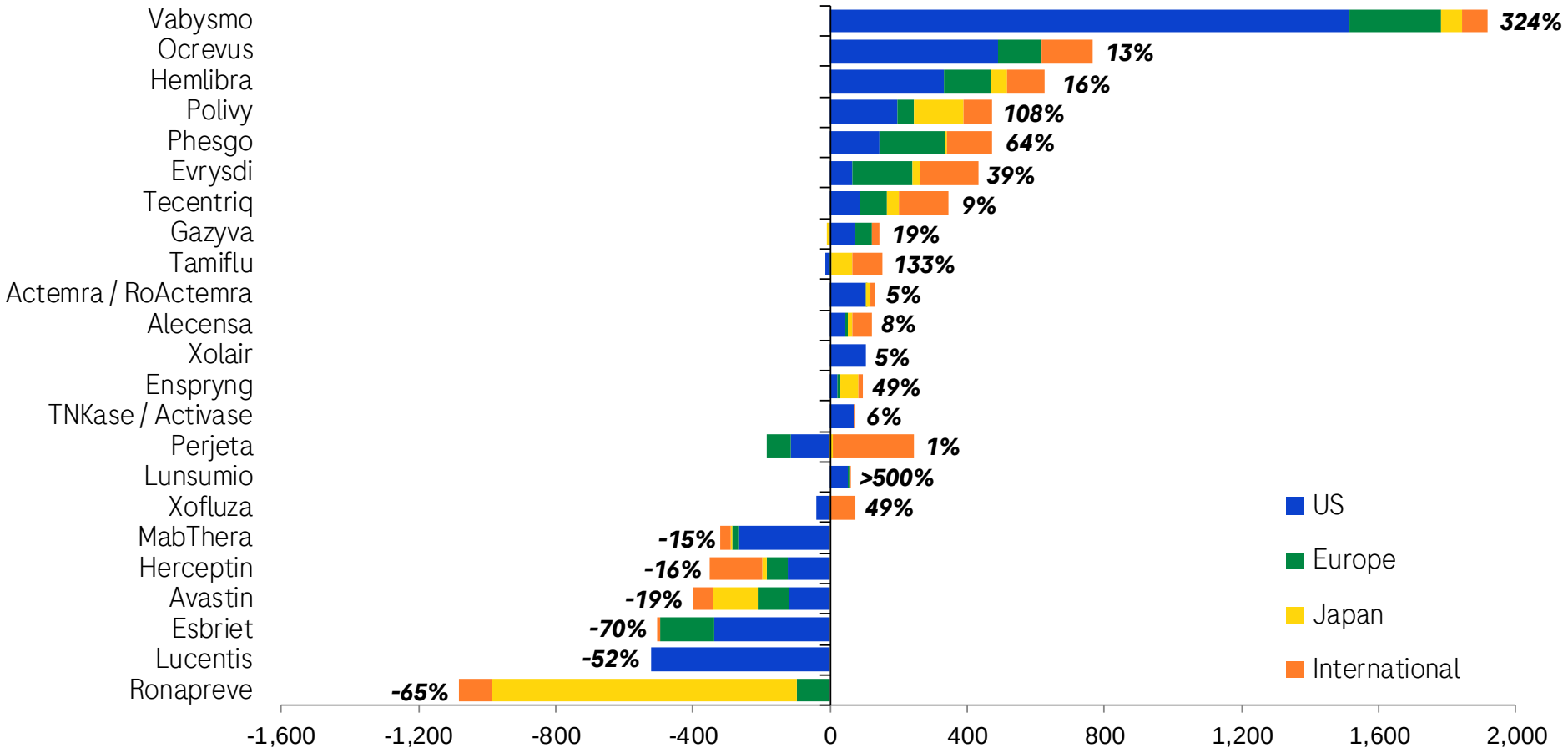
	2023 CHFm	2023 abs. CER
Sales	**44,612**	**+2,705**
Other revenue	1,667	-656
Cost of sales	-8,343	+114
R&D	-11,490	-725
SG&A	-7,215	-409
OOI&E	758	+25
Core operating profit	**19,989**	**+1,054**
Core OP in % of sales	*44.8%*	
At CER	*45.8%*	
	(2022: 46.2%)	



CER=Constant Exchange Rates; R&D=Research & Development; SG&A=Selling, General & Administration; OOI&E=Other Operating Income & Expense

2023: Young portfolio delivering strong growth

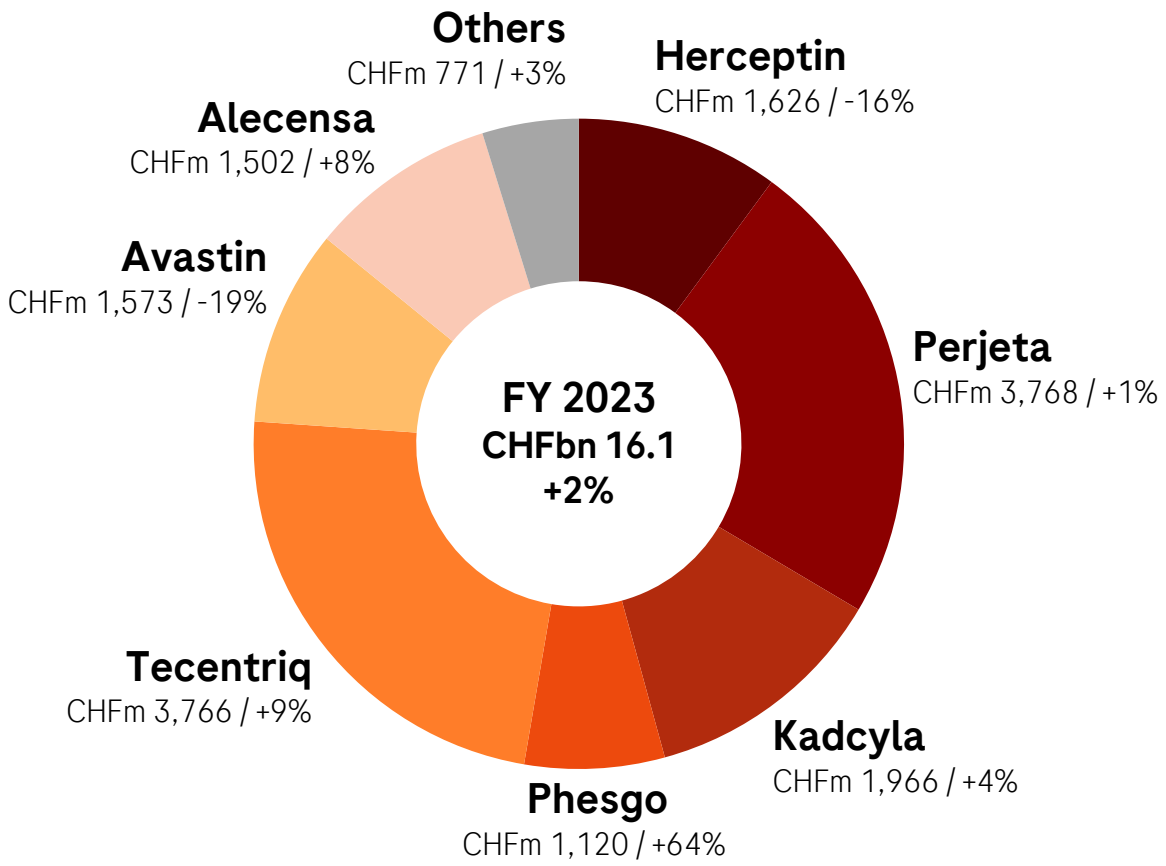
Vabysmo sales exceed CHF 2bn and Phesgo achieves blockbuster status



Absolute values and growth rates at Constant Exchange Rates (CER)

Strong Phesgo launch continues, now at 39% conversion rate*

Tecentriq SC achieves EU approval



CHFm / YoY CER growth

Q4 update

- Perjeta: growth driven by International; Q4 sales impacted by an adjustment in the reserves related to US government programs
- Tecentriq: growth driven by adjuvant NSCLC and 1L HCC
- Kadcyla: growth in International compensating for US/EU
  - 7-years KATHERINE data reinforces OS and IDFS benefit in adj. HER2+ BC
- Alecensa: global market leader in 1L ALK+ mNSCLC
- Positive Ph III (INAVO120) for inavolisib + palbociclib + fulvestrant in 1L *PIK3CA*-mut HR+ BC

Outlook 2024

- Tecentriq SC for various indications: US approval
- Alecensa in adj. ALK+ NSCLC: US/EU approval
- Inavolisib in 1L *PIK3CA-mut* HR+ BC: US/EU filing
- Ph III (SKYSCRAPER-01) tiragolumab + Tecentriq in 1L PD-L1+ NSCLC final OS results expected in H2 2024

Definition of Pharmaceuticals TA split used in the FY 2023 Financial Report vs. IR Presentation explained on slide 172; *Perjeta/Phesgo conversion rate calculated using volumes, currently taking 46 launch countries into account; CER=Constant Exchange Rates; *PIK3CA*-mut=phosphatidylinositol 3-kinase, catalytic, alpha polypeptide mutated; HR=hormone-receptor; BC=breast cancer; OS=overall survival; IDFS=invasive disease-free survival; SCCHN=squamous cell carcinoma of head and neck; NSCLC=non-small cell lung cancer; SC=subcutaneous; PDUFA=prescription drug user fee act; ALK=anaplastic lymphoma kinase

Inavolisib more than doubles PFS in 1L *PIK3CA*-mut HR+ breast cancer

Additional Ph III trials ongoing, including head-to-head vs. alpelisib and in combination with Phesgo

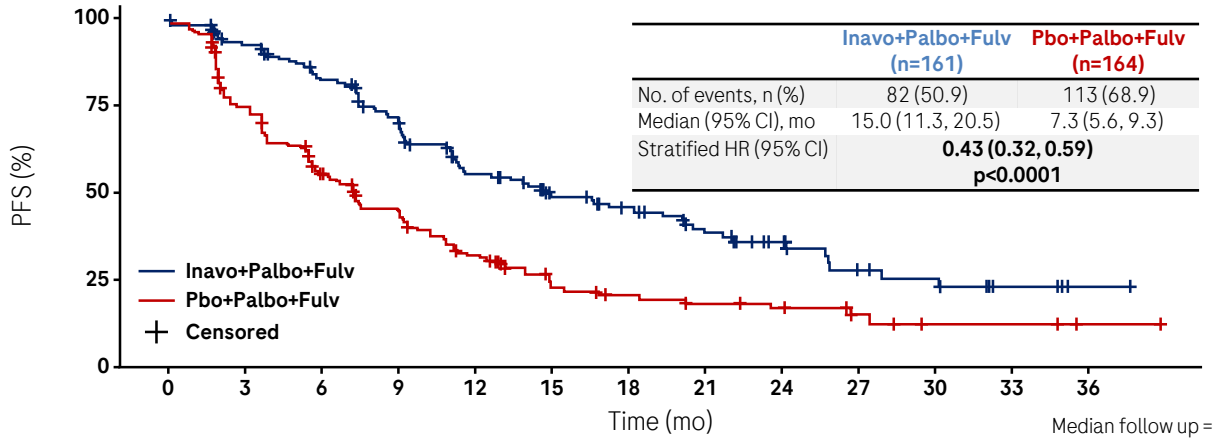
Ph III development program

Inavolisib (INAVO120)	1L *PIKC3A*-mut HR+ HER2- mBC
Inavolisib (INAVO121)	Post CDK4/6i *PIK3CA*-mut/HR+/HER2- BC
Inavolisib (INAVO122)	1L *PIK3CA*-mut/HER2+ BC
Giredestrant (perservERA)	1L ER+/HER2- mBC endocrine sensitive
Giredestrant (pionERA)	1L ER+/HER2- mBC endocrine resistant
Giredestrant (lidERA)	Adjuvant ER+/HER2- BC
Giredestrant (heredERA)	1L maint ER+/HER2+ BC

✔ Positive data

Ph III (INAVO120) inavolisib in 1L *PIK3CA*-mut HR+ mBC[1]

PFS (investigator assessed)



	Inavo+Palbo+Fulv (n=161)	Pbo+Palbo+Fulv (n=164)
No. of events, n (%)	82 (50.9)	113 (68.9)
Median (95% CI), mo	15.0 (11.3, 20.5)	7.3 (5.6, 9.3)
Stratified HR (95% CI)	**0.43 (0.32, 0.59) p<0.0001**	

Median follow up = 21.3 mo

Patients at risk:

Inavo+Palbo+Fulv	161	134	111	92	66	48	41	31	22	13	11	5	1
Pbo+Palbo+Fulv	164	113	77	59	40	23	19	16	12	6	3	3	1

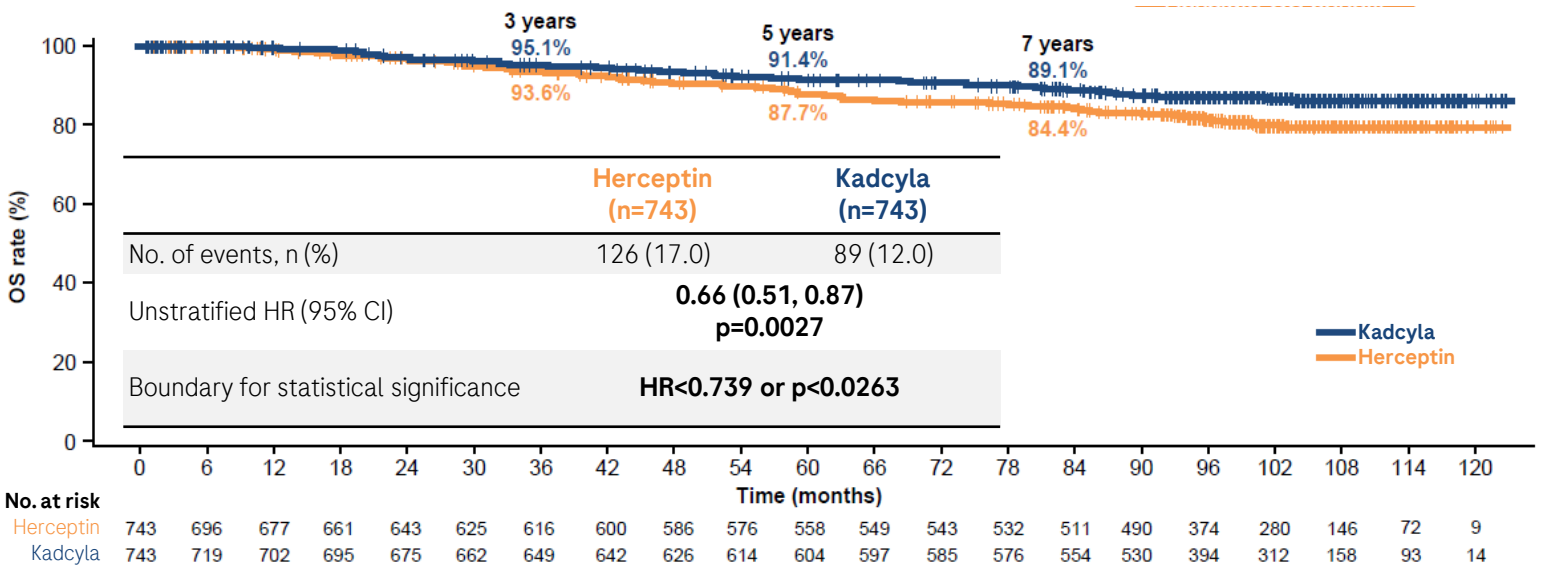
- Inavolisib combination reduced the risk of disease progression by 57% (HR=0.43); OS was immature, but with clear positive trend (HR=0.64)
- Data to be submitted to health authorities, with the view of bringing a potential new SoC to HR+ breast cancer patients with *PIK3CA* mutations
- Two additional Ph III in *PIK3CA*-mut breast cancer ongoing: inavolisib + fulvestrant vs. alpesilib + fulvestrant (INAVO121) in post-CDKi 1/2/3L HR+ HER2- breast cancer and inavolisib + Phesgo (INAVO122) in 1L HER2+ breast cancer

[1]Jhaveri KL et al., SABCS 2023; PFS=progression-free survival; PIK3CA-mut=phosphatidylinositol 3-kinase, catalytic, alpha polypeptide mutated; HR+=hormone-receptor positive; ER+=estrogen receptor positive; HER2=human epidermal growth factor receptor 2; (m)BC=(metastatic) breast cancer; CDK=cyclin-dependent kinase; inavo=inavolisib; Palbo=palbociclib; fulv=fulvestrant; Pbo=placebo; mo=months; HR=hazard ratio; CI=confidence interval; OS=overall survival

Kadcyla as SoC in early HER2+ BC with residual invasive disease

First targeted therapy to show significant OS benefit in this patient population

Ph III (KATHERINE) Kadcyla in HER2+ early-stage breast cancer 7-year OS data[1]

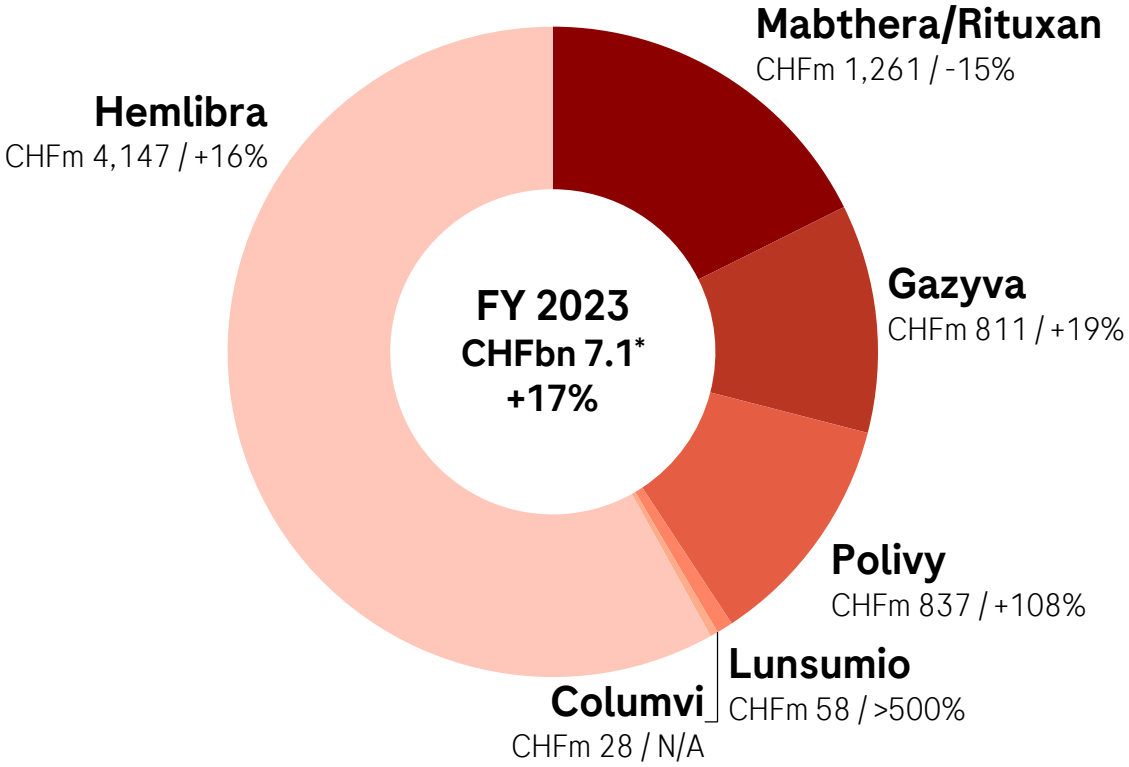


- Kadcyla achieved an OS improvement (HR=0.66) with an absolute OS benefit of 4.7% at 7 years vs. Herceptin in early-stage breast cancer, further substantiating it's SoC status in this setting with >80k patients treated globally
- Long-term data showed continued IDFS benefit (HR=0.54) with an absolute IDFS benefit of 13.7% at 7 years vs. Herceptin
- Kadcyla's safety profile was consistent with previous findings and no new safety signals were identified

[1]Loibl S et al., SABCS 2023; SoC=standard of care; OS=overall survival; IDFS=invasive disease-free survival; HER=human epidermal growth factor receptor; HR=hazard ratio; CI=confidence interval

Hemlibra reaches 40% patient share in US/EU5

Polivy US patient share in 1L DLBCL (IPI 0-5) climbing to 21%



CHFm / YoY CER growth

Q4 update

- Hemlibra: continued penetration across all approved pts segments with ~24,000 patients treated globally
  - Positive Ph III (HAVEN 7) results in infants with Hemophilia A presented at ASH 2023
- Polivy: strong 1L DLBCL uptake in all major markets
  - US: NCCN guidelines updated to category 1 recommendation for Polivy in all stages of 1L DLBCL**
- Gazyva: growth driven by combinations in 1L CLL
- Lunsumio: driven by strong 3L+ FL launch
- Columvi: driven by strong 3L+ DLBCL launch

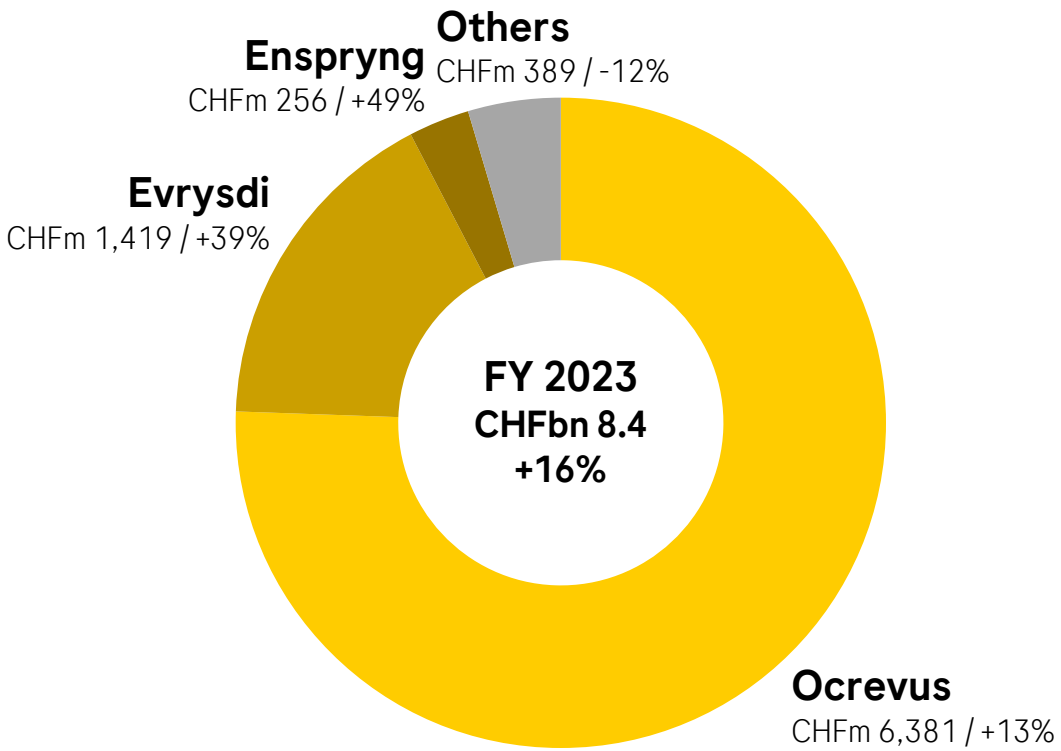
Outlook 2024

- Crovalimab in PNH: US/EU approval
- Ph III (STARGLO) Columvi + GemOx in 2L+ DLBCL readout
- Ph III (SUNMO) Lunsumio + Polivy in 2L+ DLBCL readout
- Ph III (VERONA) Venclexta + azacitidine in 1L MDS readout

Definition of Pharmaceuticals TA split used in the FY 2023 Financial Report vs. IR Presentation explained on slide 172; *Venclexta sales booked by AbbVie and therefore not included; **NCCN guidelines for B Cell Lymphomas (V1.2024); CER=Constant Exchange Rates; R/R=relapsed or refractory; DLBCL=diffuse large B cell lymphoma; FL=follicular lymphoma; SC=subcutaneous; MM=multiply myeloma; PNH=paroxysmal nocturnal hemoglobinuria; MDS=myelodysplastic syndromes; IPI=international prognostic index

Ocrevus market leader in US/EU5 with 24% global patient share

Elevidys Ph III (EMBARK) results to be shared with health authorities



CHFm / YoY CER growth

Q4 update

- Ocrevus: >300k patients treated globally; higher retention rate than other MS medicines
- Evrysdi: global market leader in pts share (>45% in US, Japan and EU5); >11,000 patients treated globally
- Ph III (EMBARK) of Elevidys in DMD did not reach primary endpoint, but showed positive efficacy outcomes on all timed functional key endpoints

Outlook 2024

- Ocrevus 6m SC: US/EU approval
- Ph III (EMBARK) Elevidys data to be presented at MDA, and to be shared with EMA
- Ph III (LUMINESCE) Enspryng in gMG readout
- Ph II (MANATEE) Evrysdi + GYM329 in SMA interim readout
- Ph IIb (PADOVA) prasinezumab in PD readout
- Ph Ib/IIa (Brainshuttle™ AD) trontinemab in AD updated data

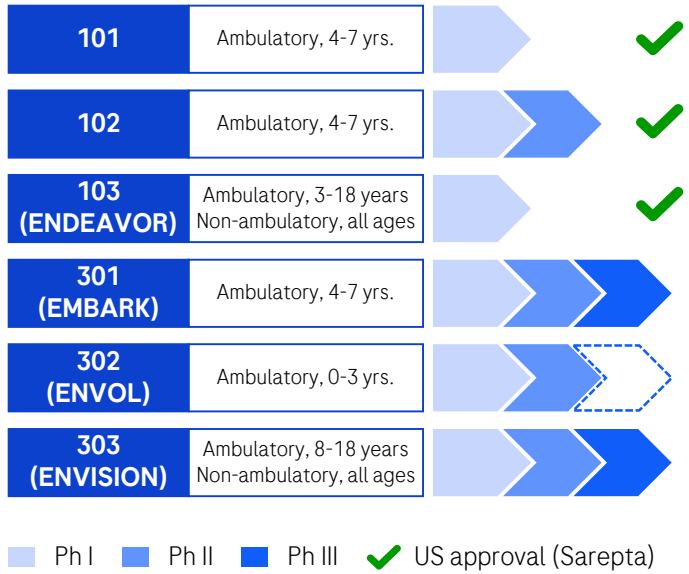
CER=Constant Exchange Rates; DMD=Duchenne muscular dystrophy; MS=multiple sclerosis; SC=subcutaneous; gMG=generalized myasthenia gravis; SMA=spinal muscular atrophy; PD=Parkinson's disease; AD=Alzheimer's disease

Elevidys providing clinically meaningful benefits in DMD

Ph III (EMBARK) results favoring Elevidys treatment on all key secondary endpoints

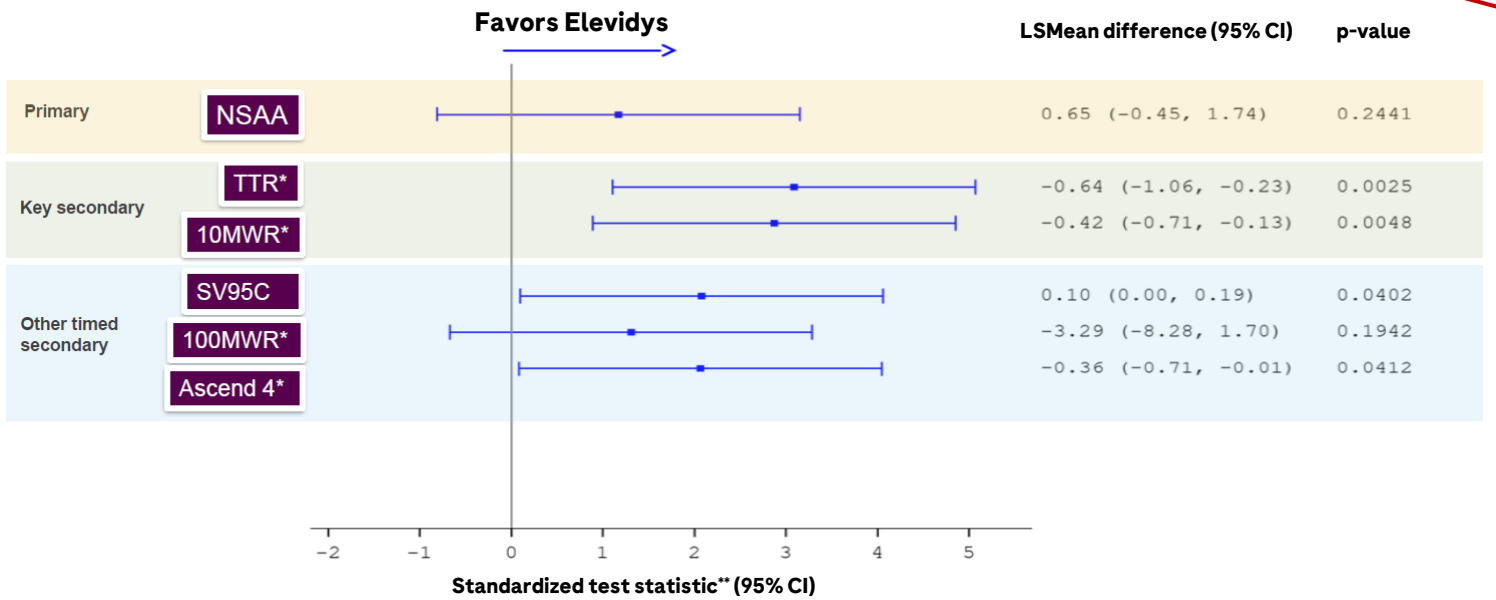
IR Neurology Update on Mar 11th

Development program



- Ph III (ENVISION) in older ambulatory and all ages non-ambulatory patients is ongoing
- Ph II (ENVOL) in 0-3 year old ambulatory patients initiated in Q4

Ph III (EMBARK) in DMD topline results



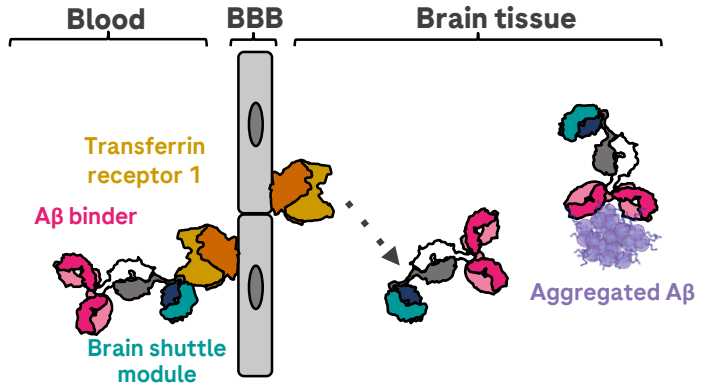
- NSAA increased compared to placebo at 52 weeks but the primary endpoint was not met
- For all key pre-specified secondary functional endpoints, TTR and 10MWR, clinically meaningful and statistically significant treatment benefits were observed across age groups
- No new safety signals observed, reinforcing the favorable and manageable safety profile
- EMA and other global regulators to be engaged

*Timed function tests sign reversed to align favorable directions among effect endpoints; **Blue lines plot standardized t test statistic (+/- 1.96) after dividing LSMean (95% CI) by standard error; DMD=Duchenne muscular dystrophy; NSAA=North Star Ambulatory Assessment; TTR=time to rise; 10MWR/100MWR=10/100-m walk/run velocity; SV95C=stride velocity 95th centile; Ascend 4=time to ascend 4 steps; LSM=least-squares mean; CI=confidence interval; Elevidys in collaboration with Sarepta

Trontinemab in AD clears Aβ more rapidly than conventional mAbs

First Aβ-targeting antibody Brainshuttle™ with Ph Ib/IIa in Alzheimer's disease currently ongoing

Trontinemab (Brainshuttle™ anti-Aβ mAb)

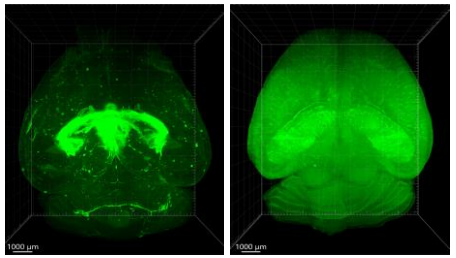


Active TfR1 transport at the capillary level

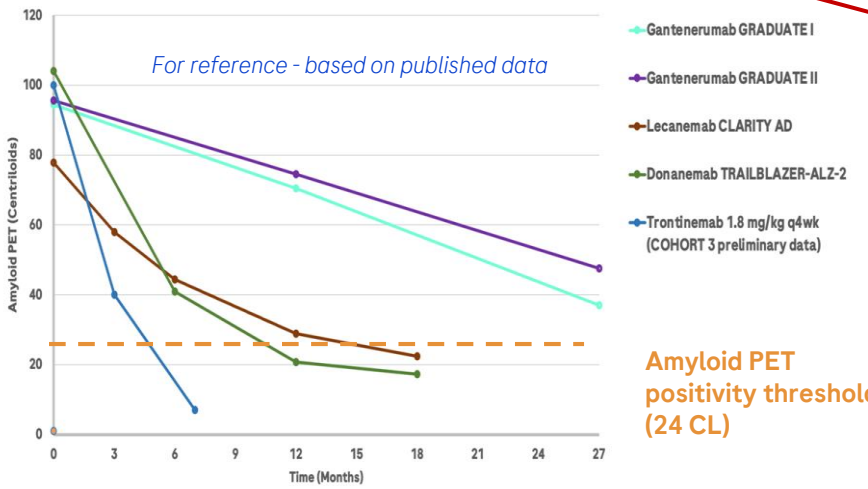
- Trontinemab uses Roche`s proprietary Brainshuttle™ technology, combining an Aβ binding mAb with a transferrin receptor (TfR1) shuttle module
- Designed for efficient transport across the BBB to target aggregated forms of Aβ and remove amyloid plaques in the brain

Trontinemab clearly differentiated from other anti-Aβ mAbs

Homogeneous brain exposure[1]



Ph Ib/IIa (Brainshuttle™ AD) trontinemab results vs. other anti-Aβ mAb Ph III[1]

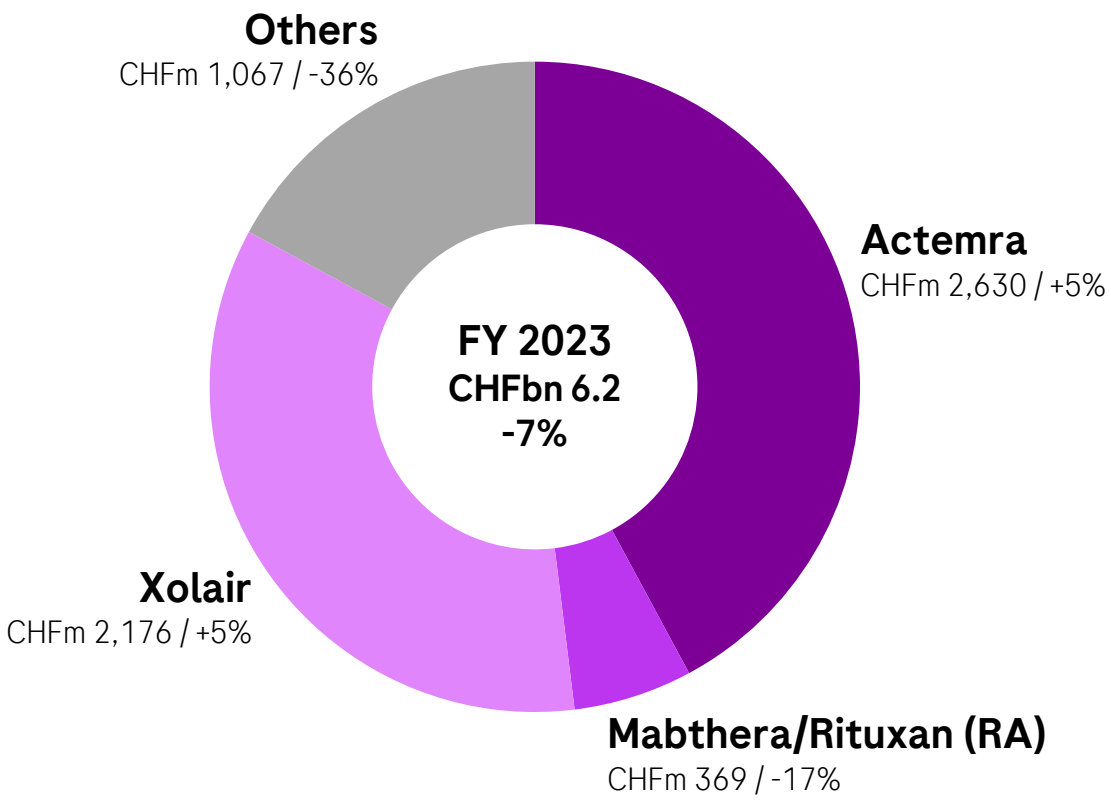


- Trontinemab demonstrated rapid and robust amyloid plaque reduction at relatively low doses (1.8 mg/kg Q4W), compared with standard anti-Aβ mAb
- Interim PD and safety data (including a low ARIA incidence) support further investigation in the ongoing Ph Ib/IIa (Brainshuttle™ AD) study
- Updated Ph Ib/IIa data to be presented at upcoming conference (AD/PD)

[1]Kulic L et al., CTAD 2023; Gantenerumab GRADUATE I /II: presentation at CTAD 2022, publication in preparation; Lecanemab CLARITY AD: N Engl J Med 2023; 388:9-21; Donanemab TRAILBLAZER-ALZ-2: JAMA. 2023;330(6):512-527; AD=Alzheimer's disease; CL=centiloid unit; PET=positron emission tomography; mAb=monoclonal antibody; Aβ=amyloid β; q4w=every 4 weeks; PD=pharmacodynamics; NME=new molecular entity; ARIA=amyloid-related imaging abnormalities; BBB=blood-brain barrier

Xolair in food allergy filed in the US, approval expected in Q1 2024

Gazyva Ph III (REGENCY) in lupus nephritis to readout in 2024



CHFm / YoY CER growth

Q4 update

- Xolair: growth driven by strong CSU performance; market shares in Asthma declining
- Actemra: strong US performance in RA
- Updated positive Ph II data for ASO Factor B in IgA nephropathy presented at ASN Kidney Week 2023

Outlook 2024

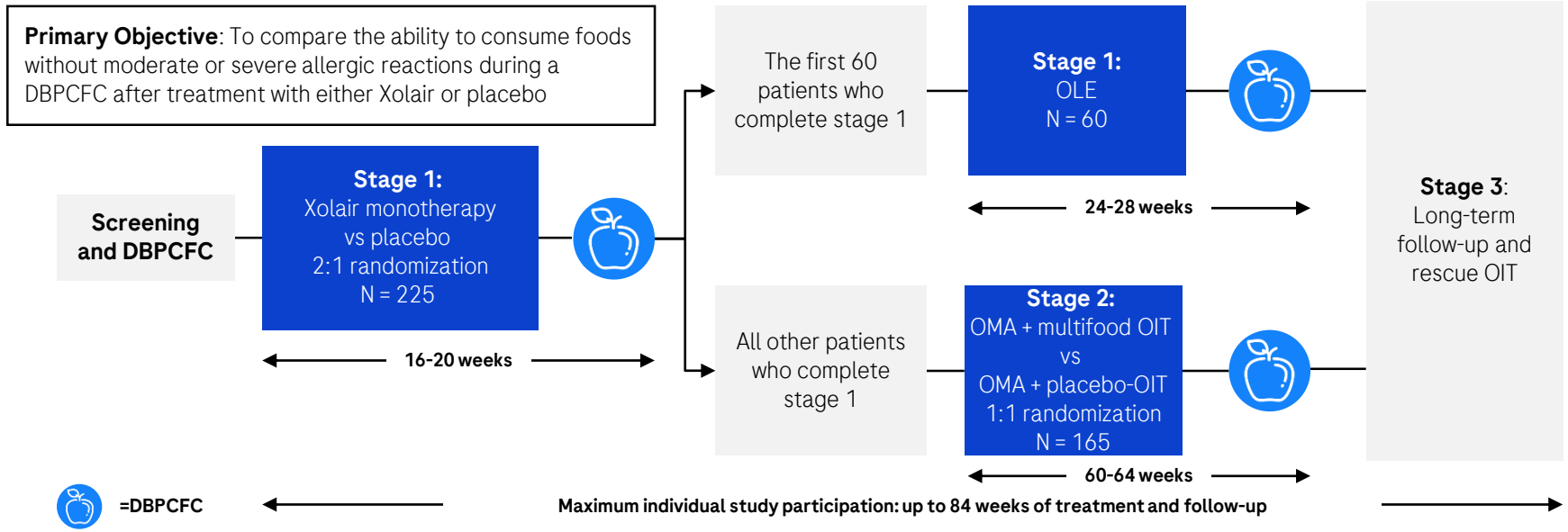
- Xolair: US approval in food allergy expected in Q1
- Actemra biosimilars expected in the US
- Ph III (REGENCY) Gazyva in lupus nephritis readout
- Ph III trials of anti-TL1A in IBD to be initiated

CER=Constant Exchange Rates; IgA=immunoglobulin A; RA=rheumatoid arthritis; IBD=inflammatory bowel disease; TL1A=Tumor necrosis factor-like cytokine 1A; CSU=chronic spontaneous urticarial; ASO=antisense oligonucleotide; ASO factor B in collaboration with Ionis

Xolair: first medicine to reduce allergic reactions to multiple foods

FDA priority review ongoing and decision expected for Q1 2024

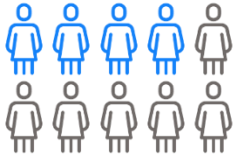
Ph III (OUtMATCH) in food allergy study design*



Unmet need[1,2,3]

17m Pts with confirmed food allergy in the US

>40% Of children with food allergies experience severe reaction at least once



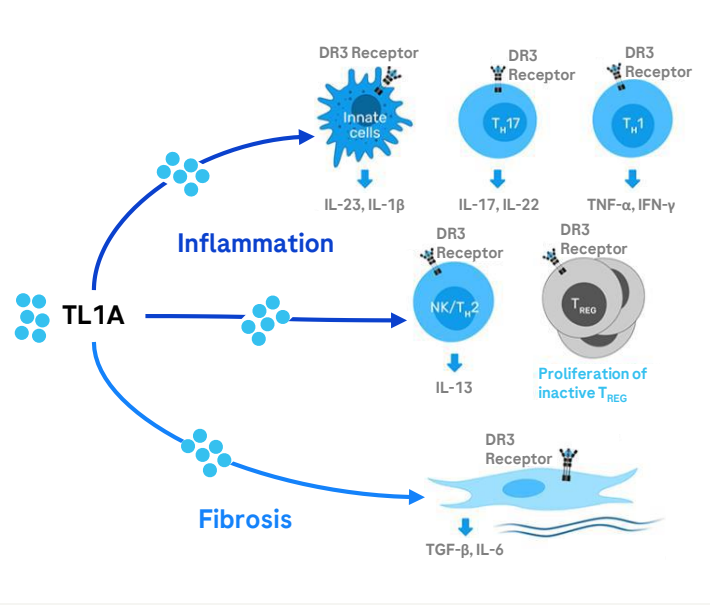
- Interim analysis from first-of-its-kind Ph III (OUtMATCH) showed Xolair significantly increased the amount of peanut, milk, egg and cashew needed to cause an allergic reaction
- 17m people in the US have confirmed food allergies; more than 40% of children and more than half of adults with food allergies have experienced a severe reaction at least once
- If approved, Xolair would be the first medicine to reduce allergic reactions to multiple foods following an accidental exposure

*The phase III OUtMATCH study is being sponsored and funded by the National Institute of Allergy and Infectious Diseases (NIAID), part of the NIH, and conducted by the NIAID-funded Consortium of Food Allergy Research (CoFAR) across 10 clinical sites throughout the U.S. The study is also supported by Genentech, a member of the Roche Group, and Novartis Pharmaceuticals Corporation. Detailed results from the OUtMATCH study have been submitted by NIAID and CoFAR to a peer-reviewed journal;[1]Gupta RS et al. JAMA Netw Open. 2019; [2]Warren CM et al. Curr Allergy Asthma Rep. 2020; [3]Gupta RS et al. Pediatrics. 2018; DBPCFC=double-blind, placebo-controlled food challenge; OIT=oral immunotherapy; OLE=open label extension; OMA=omalizumab.

Anti-TL1A with first-in-class and best-in-disease potential in IBD

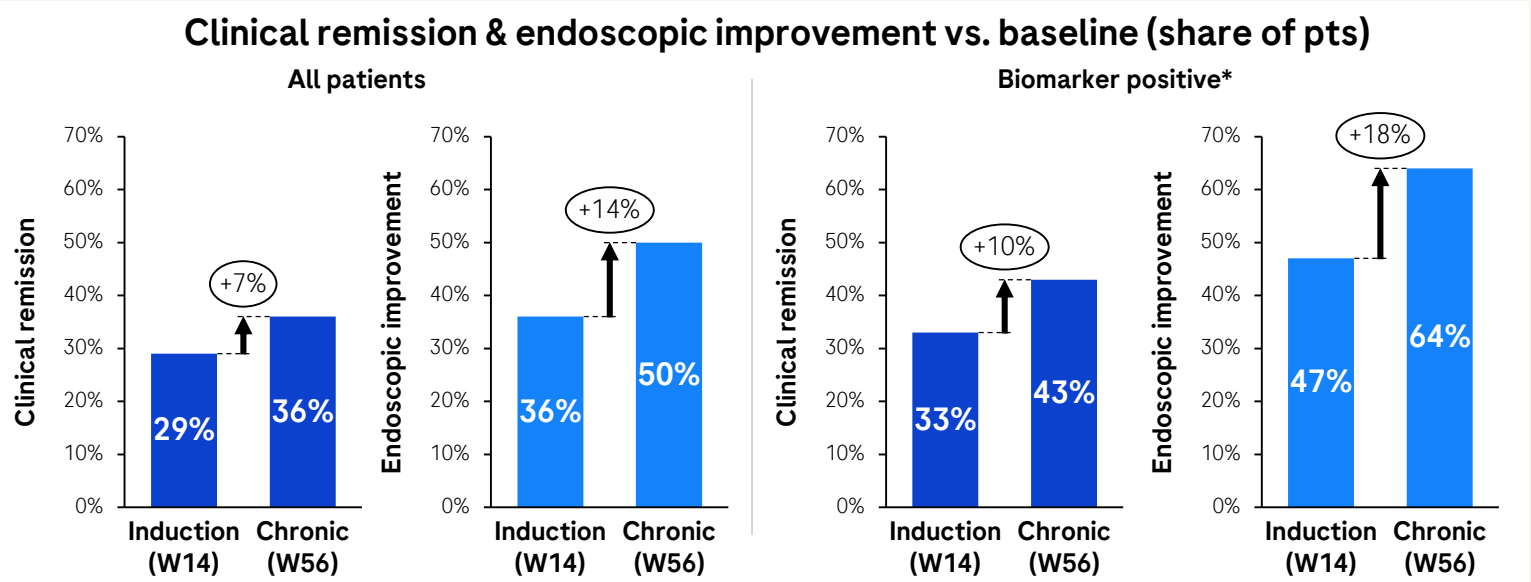
Initiation of Ph III studies in IBD ongoing; additional potential in several other auto-immune diseases

anti-TL1A (RVT-3101)



- TL1A binds to DR3 receptor, stimulating downstream inflammation and fibrosis processes
- Dysregulated TL1A with clinical links to multiple immune-mediated diseases

Ph IIb (TUSCANY-2) anti-TL1A in ulcerative colitis

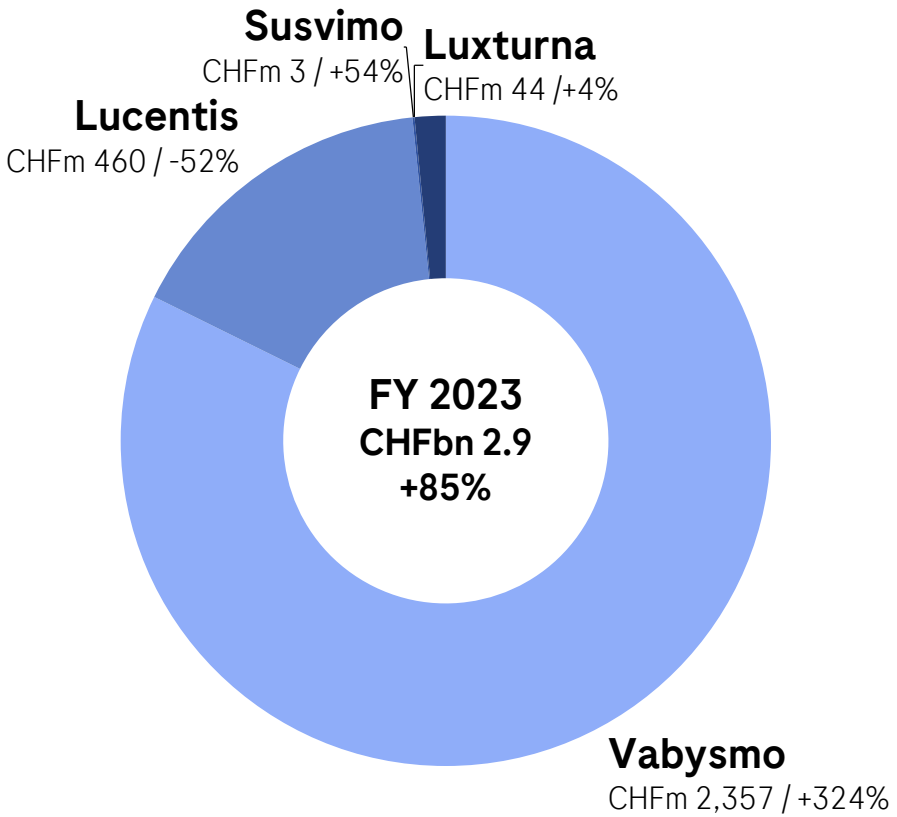


- Strong Ph IIb ulcerative colitis data for all-comers and biomarker positive pts; sustained clinical remission (75%) and endoscopic improvement (80%) from induction to chronic phase
- Favorable safety and tolerability profile
- Ph III trials in IBD to be initiated in 2024
- Anti-TL1A has potential for improved clinical outcomes in multiple auto-immune diseases

*biomarker not yet disclosed; TL1A=Tumor necrosis factor-like cytokine 1A; DR3 receptor=dopamine 3 receptor; IBD=inflammatory bowel disease; RA=rheumatoid arthritis; SoC=standard of care

Vabysmo reaching US market share of 22% in nAMD and 15% in DME*

US approval for Vabysmo's third indication RVO achieved



CHFm / YoY CER growth

Q4 update

- Vabysmo: 42% of US new patient starts are naive
- US approval for Vabysmo in RVO achieved, 2 months ahead of PDUFA date
- Vabysmo reimbursement achieved in all EU5
- New long-term data for Vabysmo in RVO shows sustained retinal drying, driving extended durability and sustained vision improvements
- Ph III (SatraGO1/2) of Enspryng in TED initiated

Outlook 2024

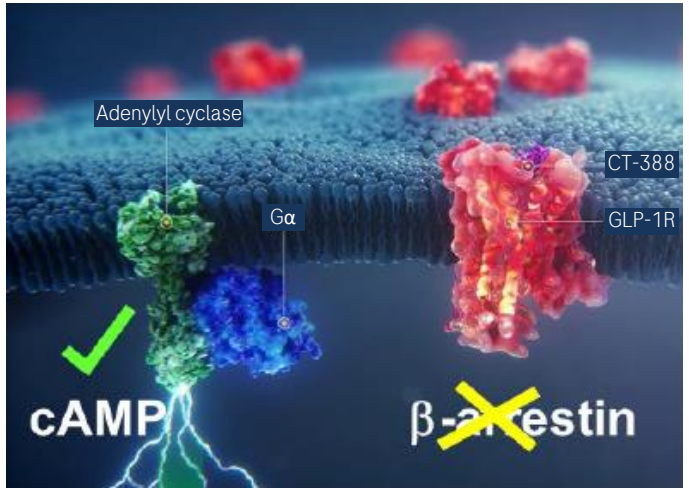
- Vabysmo in RVO: EU approval
- Susvimo in nAMD: US commercial relaunch
- Susvimo in DME/DR: US filing
- Ph II (BARDENAS/ALLUVIUM) vamikibart (anti-IL6) in DME readout
- Ph II (GOLDEN STUDY) ASO factor B in GA readout

*based on November 2023 Verana patient claims data; CER=Constant Exchange Rates; nAMD=neovascular age-related macular degeneration; DME=diabetic macular edema; RVO=retinal vein occlusion; TED=thyroid eye disease; GA=geographic atrophy; ASO=antisense oligonucleotide; ASO factor B in collaboration with Ionis

Dual GLP-1/GIP agonist (CT-388) with best-in-class potential in obesity

Early stage readouts for all incretins expected in 2024; new trials to be initiated

GLP-1/GIP RA (CT-388)



- Elimination of β-arrestin coupling minimizes/avoids receptor degradation
- cAMP biased molecules show synergy between GLP-1 and GIP, leading to reduced blood glucose, food intake and body weight

Development program

Molecule	Indication	Admin.	Development stage	2024 readouts*
CT-388 (GLP-1/GIP RA)	Obesity +/- T2D	(QW)	Ph I	Final Ph I data
CT-868 (GLP-1/GIP RA)	T1D w. Obesity as adjunct treatment	(QD)	Ph II	Ph II interim data
CT-996 (GLP-1 RA)	Obesity +/- T2D	(QD)	Ph I	Ph I interim data

Subcutaneous · Oral · Ph I · Ph II

- Broad development program in obesity with promising initial results; potential to combine with different Roche molecules
- CT-388's differentiated molecular pharmacology may enable more patients to achieve >15-20% weight loss with good tolerability via optimized dosing and titration scheme
  - Early Ph I results of up to -8% weight reduction at 4 weeks; Final readout end of 2024
  - Ph II in obesity +/- T2D to be initiated in 2024

*Outcome studies are event-driven: timelines may change; GLP-1=glucagon-like peptide-1; GIP=glucose-dependent insulinotropic polypeptide; RA=receptor agonist; T2D=type-2 diabetes; T1D=type-1 diabetes; QW=once weekly; QD=once daily

2023: Key newsflow*

	Compound	Indication	Milestone	
Regulatory	**Hemlibra**	Moderate hemophilia A	EU approval	✓
	Polivy + R-CHP	1L DLBCL	US approval	✓
	Vabysmo	RVO	US approval/EU filing	✓
	Tecentriq	Subcutaneous administration	US approval/EU filing	*US 2024 /* ✓ **EU filing**
	Columvi (glofitamab)	3L+ DLBCL	US/EU approval	✓
	Xofluza	Influenza (paediatric 1+ yrs.)	EU approval	✓
Clinical results	**Tecentriq + Avastin**	Adjuvant HCC	Ph III IMbrave050	✓
	Tecentriq + chemo	Neoadjuvant / adjuvant TNBC	Ph III GeparDouze/NSABP B-59	*2024*
	Tecentriq	Adjuvant SCCHN	Ph III IMvoke010	✗
	Tecentriq + chemo	Adjuvant TNBC	Ph III IMpassion030	✗
	Tiragolumab + Tecentriq	1L PDL1+ NSCLC	Ph III SKYSCRAPER-01	*H2 2024*
	Tiragolumab + Tecentriq + chemo	1L esophageal cancer	Ph III SKYSCRAPER-08 (China only)	✓
	Venclexta + dexamethasone	t(11;14) R/R MM	Ph III CANOVA	✗
	Venclexta + azacitidine	1L high risk MDS	Ph III VERONA	*2024*
	Alecensa	Adjuvant ALK+ NSCLC	Ph III ALINA	✓
	Phesgo OBI (on body injector)	HER2+ BC	Ph I *(pivotal)*	✓
	Crovalimab	PNH	Ph III COMMODORE 1/2	✓
	Columvi + GemOx	2L+ DLBCL	Ph III STARGLO	*2024*
	Lunsumio + Polivy	2L+ DLBCL	Ph III SUNMO	*2024*
	Elevidys (Delandistrogene moxeparvovec)	DMD	Ph III EMBARK	*Full data to be shared*
	Ocrevus 6m SC	RMS / PPMS	Ph III OCARINA II	✓
	TNKase	Stroke patients 4.5-24h	Ph III TIMELESS	✗
	Susvimo	DME	Ph III PAGODA	✓
	Susvimo	DR	Ph III PAVILION	✓
	Xolair	Food allergy	Ph III OUtMATCH	✓

Additional 2023 newsflow:

- **Fenebrutinib** Positive Ph II (FENopta) results in RMS
- **Elevidys** US approval in DMD for 4 and 5 years old (Sarepta)
- **Zilebesiran** Ph II (KARDIA-1) positive topline results
- **Tiragolumab + Tecentriq + Avastin**: Positive Ph I/II (MORPHEUS) results in 1L HCC
- **Inavolisib + palbociclib + fulvestrant** Positive Ph III (INAVO120) results in 1L HR+ *PIK3CA*-mut BC

*Outcome studies are event-driven: timelines may change

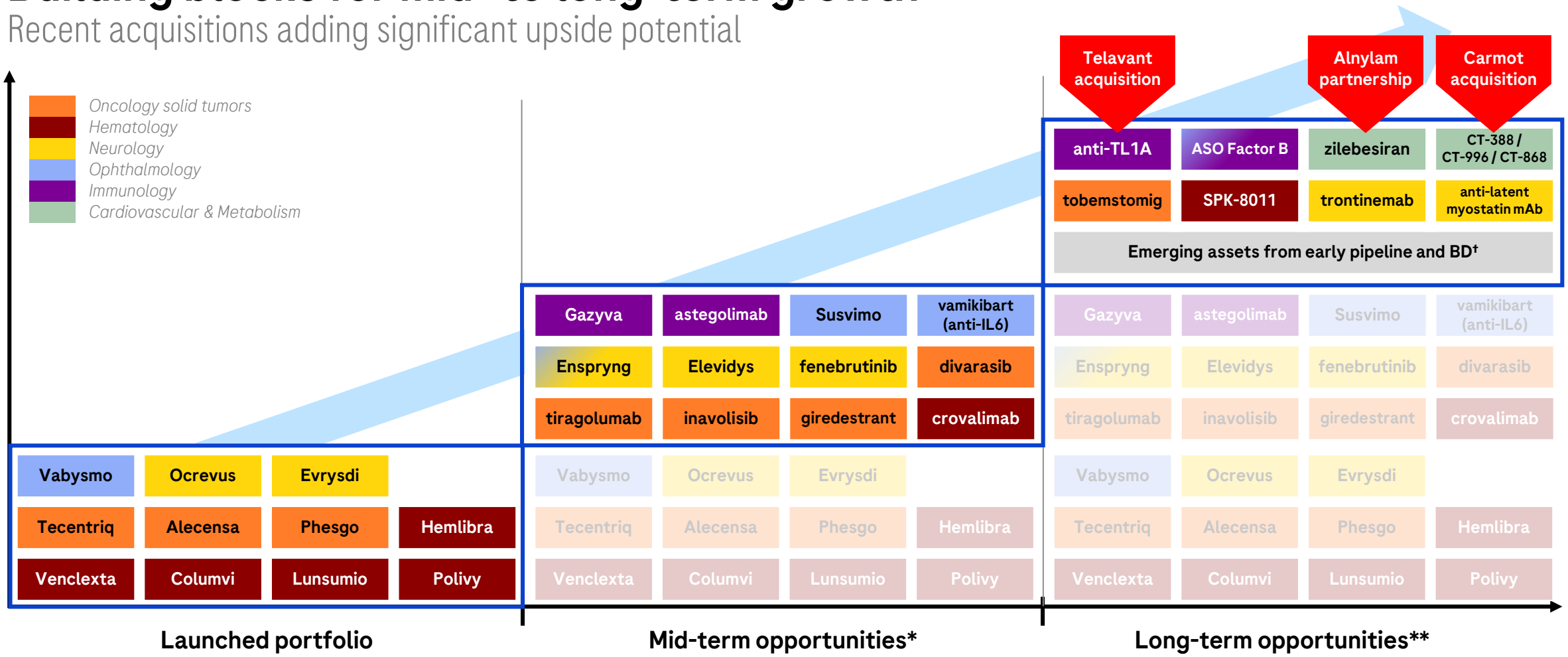
2024: Key newsflow*

	Compound	Indication	Milestone
Regulatory	**Alecensa**	Adjuvant ALK+ NSCLC	US/EU approval
	inavolisib + palbociclib + fulvestrant	1L *PIK3CA*-mut HR+ BC	US/EU filing
	Tecentriq	Subcutaneous administration	US/EU approval ✔ EU
	crovalimab	PNH	US/EU approval
	Elevidys	DMD	EMA interaction ongoing
	Ocrevus 6m SC	RMS/PPMS	US/EU approval
	Susvimo	DME/DR	US filing
	Vabysmo	RVO	EU approval
	Xolair	Food allergy	US approval
Clinical results	**tiragolumab + Tecentriq**	1L PDL1+ NSCLC	Ph III SKYSCRAPER-01
	Venclexta + azacitidine	1L high risk MDS	Ph III VERONA
	Columvi + GemOx	2L+ DLBCL	Ph III STARGLO
	Lunsumio + Polivy	2L+ DLBCL	Ph III SUNMO
	Gazyva	Lupus nephritis	Ph III REGENCY
	Enspryng	generalized Myasthenia gravis	Ph III LUMINESCE
	Evrysdi + GYM329	SMA	Ph II MANATEE
	prasinezumab	Parkinson's disease	Ph IIb PADOVA
	trontinemab	Alzheimer's disease	Ph Ib/IIa Brainshuttle™ AD
	vamikibart (anti-IL6)	DME	Ph II BARDENAS/ALLUVIUM
	ASO factor B	Geographic atrophy	Ph II GOLDEN STUDY
	zilebesiran	Hypertension	Ph II KARDIA-2
	CT-388	Obesity w/wo T2D (QW SC)	Ph I
	CT-868	T1D w. Obesity (QD SC)	Ph II
	CT-996	Obesity w/wo T2D (QW oral)	Ph I

*Outcome studies are event-driven: timelines may change

Building blocks for mid- to long-term growth

Recent acquisitions adding significant upside potential



*mid-term defined as filing 2024-2026, **long-term defined as filing after 2026, BD=business development; †including GSM=Gamma-secretase modulator (GSM)

Diagnostics Division

Matt Sause
CEO Roche Diagnostics

2023: Diagnostics sales

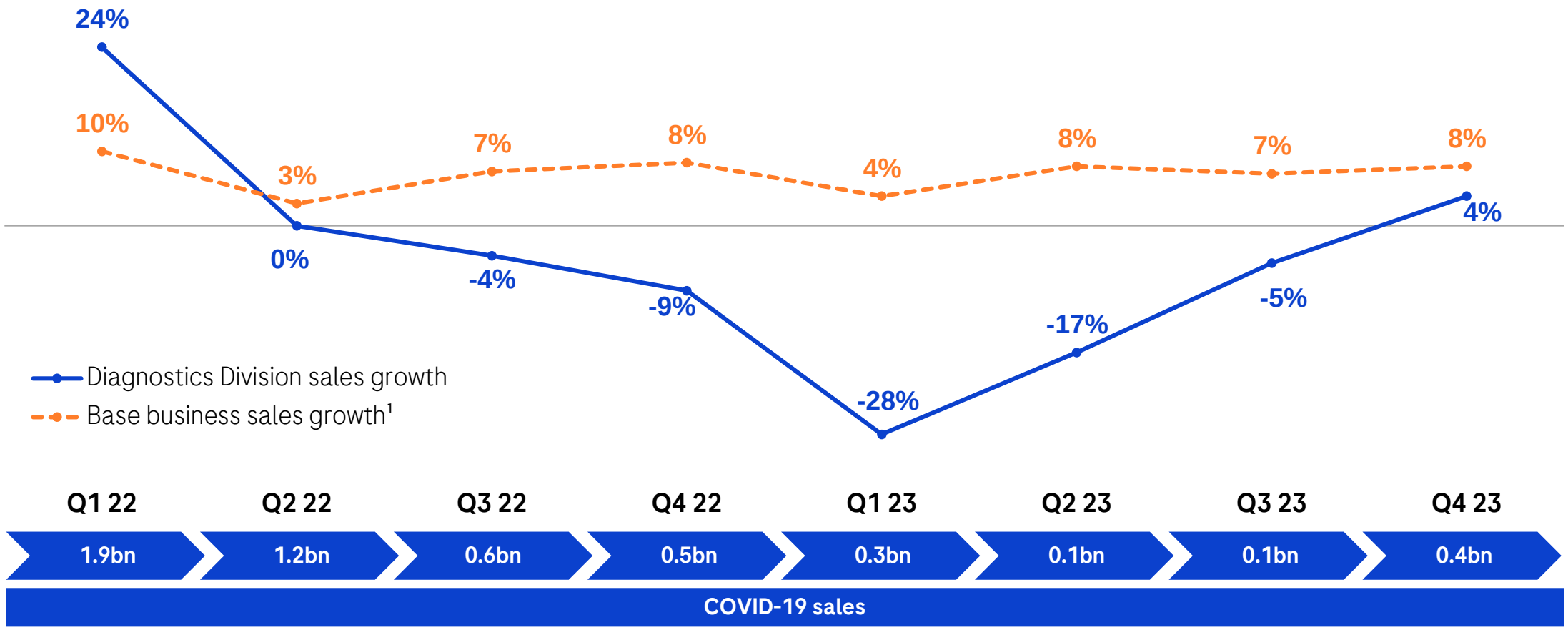
Strong base business growth, partially offsetting COVID-19 sales decrease

	2023 CHFm	2022 CHFm	Change in % CHF	Change in % CER	Excl. C19[1]
Diagnostics Division	**14,104**	**17,730**	**-20**	**-13**	**7**
Core Lab	7,750	7,775	0	9	
Molecular Lab	2,220	3,450	-36	-30	
Pathology Lab	1,388	1,318	5	14	
Point of Care	1,379	3,589	-62	-58	
Diabetes Care	1,367	1,598	-14	-4	

CER=Constant Exchange Rates; [1]Diagnostics Division base business

Diagnostics sales growth by quarter

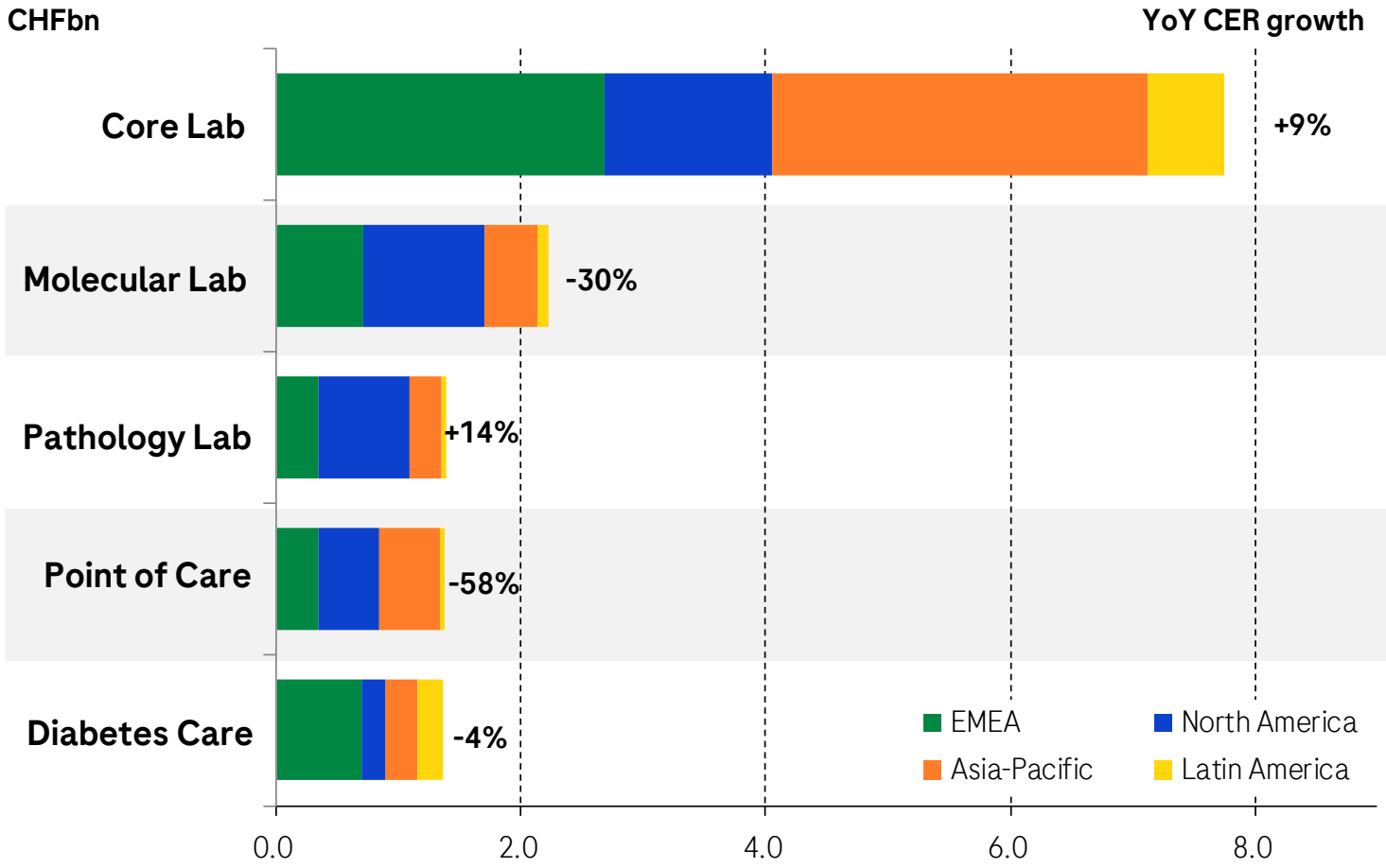
Strong base business growth in Q4 2023



Growth rates and absolute values at CER (Constant Exchange Rates) of the respective year; [1] Quarterly sales growth excluding COVID-19 sales

2023: Diagnostics highlights

Strong base business growth, partially offsetting COVID-19 sales decrease



- Immunodiagnostics (+10%)
- Clinical Chemistry (+10%)
- Custom biotech (-7%)

- Cervical Cancer (+23%)
- Blood Screening (+13%)
- Virology base business (+6%)
- COVID-19 (-88%)

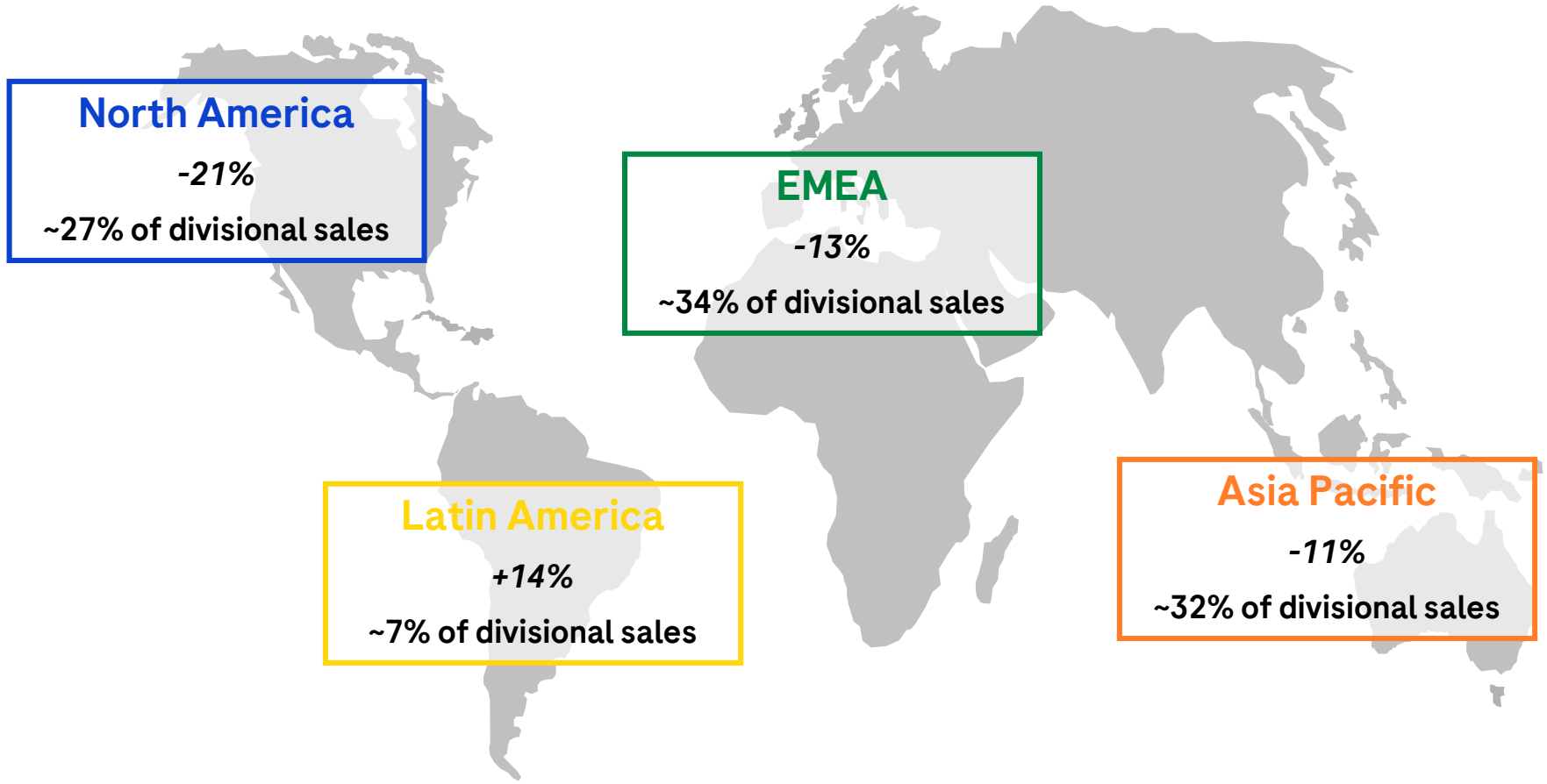
- Advanced staining (+12%)
- Companion diagnostics (+20%)

- PoC Immunodiagnostics (-75%)
- PoC Molecular (-42%)

CER=Constant Exchange Rates; PoC=Point of Care; EMEA=Europe, Middle East and Africa

2023: Diagnostics regional sales

Strong base business growth across all regions; significantly lower COVID-19 sales

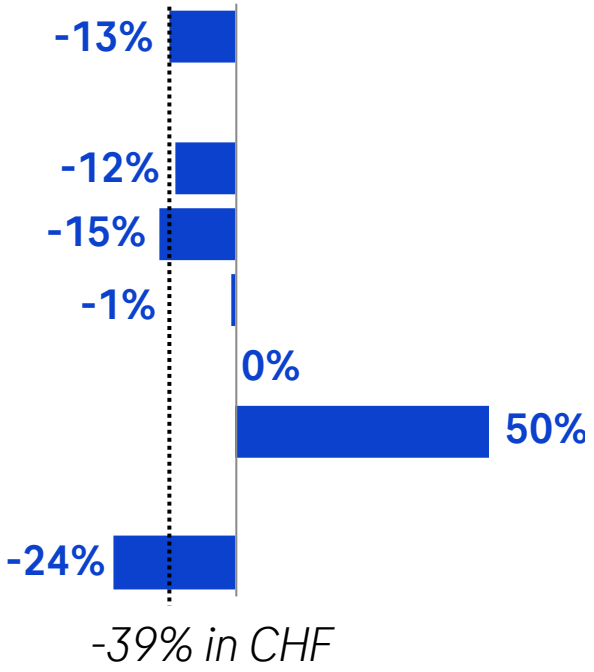


Growth rates at CER (Constant Exchange Rates); EMEA=Europe, Middle East and Africa

2023: Diagnostics core operating profit

Decline due to drop in COVID-19 sales

	2023	
	CHFm	abs. CER
Sales	**14,104**	**-2,314**
Other revenue	58	-8
Cost of sales	-6,908	+1,236
R&D	-1,747	+16
SG&A	-2,899	-12
OOI&E	60	+22
Core operating profit	**2,668**	**-1,061**
Core OP in % of sales	*18.9%*	
At CER	*21.5%*	
	(2022: 24.7%)	

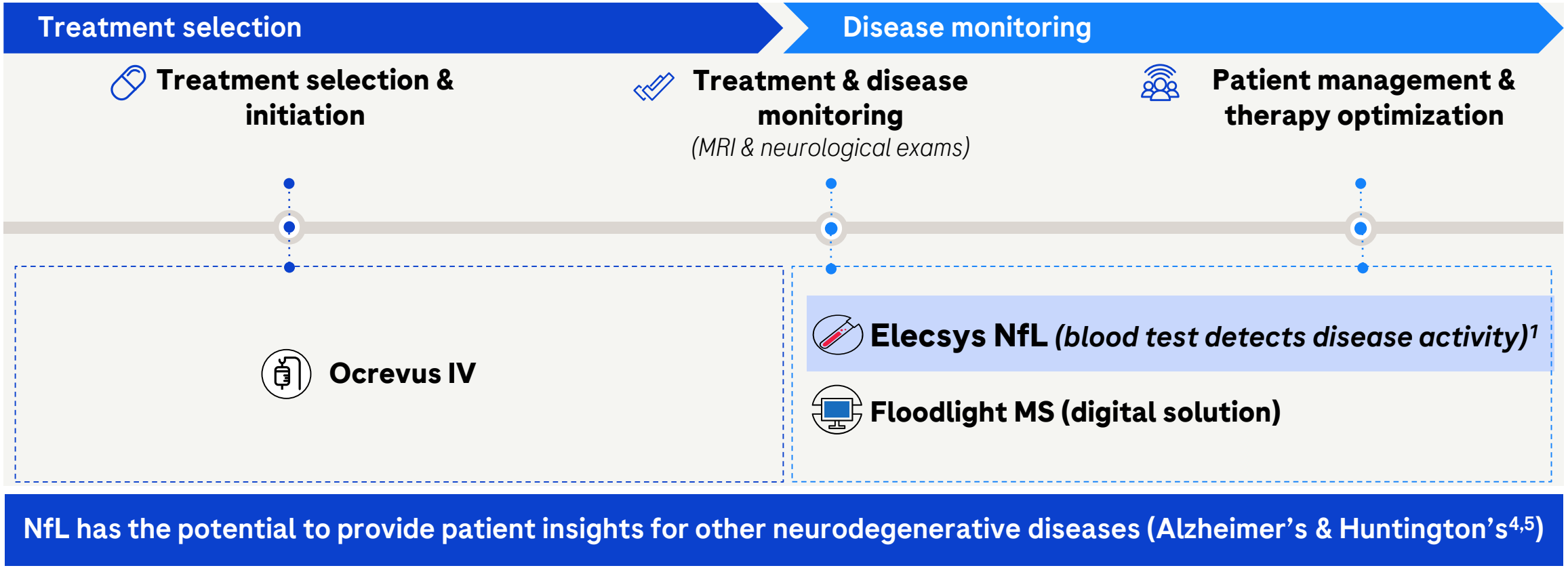


CER=Constant Exchange Rates; R&D=Research & Development; SG&A=Selling, General & Administration; OOI&E=Other Operating Income & Expense

FDA Breakthrough Device Designation status for Elecsys NfL

Aids in detection of disease activity and progression of Multiple Sclerosis

Role of NfL along patient journey for MS (disease burden ~3 million people[2,3])



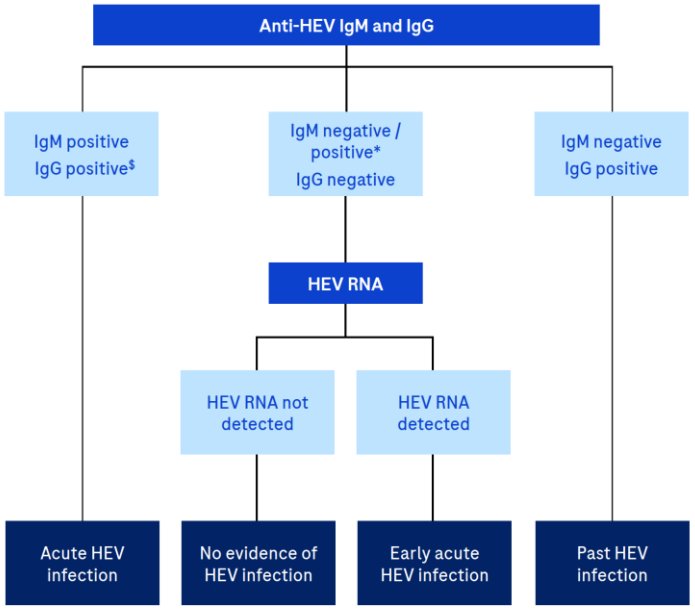
NfL has the potential to provide patient insights for other neurodegenerative diseases (Alzheimer's & Huntington's[4,5])

NfL=neuro filament light chain; MRI=magnetic resonance imaging; [1]Research Use Only (RUO) not linked to any specific indication; [2]Walton C, King R, Rechtman L, et al. Insights from the Atlas of MS, third edition; [3]MS Society UK (2024) mssociety.org.uk/about-ms/types-of-ms/relapsing-remitting-ms; [4]Mayo Clinic Laboratories NFLC (2024) mayocliniclabs.com/api/sitecore/TestCatalog/DownloadTestCatalog?testId=616854; [5]post critical-care applications are under exploration

Elecsys®Anti-HEV IgM & Anti-HEV IgG

Combination test will enable diagnosis of acute and chronic infections for better patient management

Interpretation of testing for HEV[1]



* Detection of anti-HEV IgM alone does not diagnose HEV infection; $ rising anti-HEV IgG titer
HEV, hepatitis E virus; IgG, immunoglobulin G; IgM, immunoglobulin M; RNA: ribonucleic acid.

Unmet medical need

- 20 million new annual infections, resulting in more than 70,000 deaths[1,2]
- ⅓ of global population at risk of HEV infection[1]
- Anti-HEV IgM for the detection of acute HEV added to the WHO Essential Diagnostics List in Q4 2023[3]

Medical Value

- Early identification in vulnerable groups (pregnant women, patients with chronic liver disease)
- Differential diagnosis in people with symptoms of acute hepatitis
- Confirming possible cause of other disorders accompanying hepatitis

The tests complete Roche's panel for differential diagnosis of acute viral hepatitis (HAV, HBV, HCV, HEV)

[1]Public Health England. Public health operational guidelines for hepatitis E. Health protection response to reports of hepatitis E infection. 2019 Guidelines; [2]Webb GW, Dalton HR. Hepatitis E: an underestimated emerging threat. Ther Adv Infect Dis. 2019;6:1-18; [3]The selection and use of essential in vitro diagnostics: report of the fourth meeting of the WHO Strategic Advisory Group of Experts on In Vitro Diagnostics, 2022 (including the fourth WHO model list of essential in vitro diagnostics). Geneva: World Health Organization; 2023 (WHO Technical Report Series, No. 1053). Elecsys® Anti-HEV IgG method sheet 2023-09, V1;Elecsys® Anti-HEV IgM method sheet 2023-09, V1. Not all products are available for sale in all countries. Contact your local sales representative for details; HAV=hepatitis A virus; HBV=hepatitis B virus; HCV=hepatitis C virus; HEV=hepatitis E virus; IgG=immunoglobulin G; IgM=immunoglobulin M

navify Algorithm Suite

Providing trusted decision support for clinicians

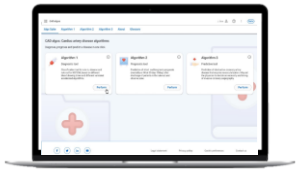
Algorithms

Roche

3rd party Partners

Algorithm library

- ✓ 15 certified & CE-marked algorithms available
- ✓ 20 algorithms in pipeline
- ✓ Key focus on cardiology & oncology



Algorithm output

LAB

Integrated into LIS[1] or EMR[2] workflow

Healthcare Providers

Informs clinical decision making

Patients

Digital platform offering lab customers & clinicians a broad menu of medical algorithms used to inform clinical decisions

[1]Laboratory Information System; [2]Electronic Medical Record (in development)

LightCycler PRO®

First system labeled for research and IVD with broad portfolio of molecular diagnostics tests

Differentiation

Higher multiplexing capabilities (7 channels) to increase complexity of tests per run and throughput

Better **precision**, **scalability** and **data analytics**

Best-in-class flexibility for **clinical research & IVD**

Key applications

- Rapid response to outbreaks and new pathogens
- Immuno-oncology routine testing
- Applied research and biomarker discovery
- Human genetics and population genomics

Market opportunity

- Launched in Q4 2023 for IVD use in CE mark countries and the US
- Supports 200+ assays from TiB Molbiol[1]
- Addressable lab developed test market CHF 500 million, instrument market CHF 200 million

LightCycler PRO + TiB Molbiol is a groundbreaking & cost effective offering for the innovators' PCR segment

IVD=*In vitro* diagnostics; [1]TiB Molbiol=company acquired by Roche in 2021

Diagnostics key launches 2023

	Area	Product	Description	Markets	Status
Instruments Automation	Core Lab	CCM Vertical	Modular transportation system, integrated into the existing cobas connection modules, allowing for overhead sample transportation over different work areas or different floors enabling effective use of lab space	Global	✓
		cobas pro integrated solutions	Scalable and modular serum work area analyzer for mid to high volume clinical chemistry and immunochemistry testing	China	✓
		cobas pure integrated solutions	Serum work area analyzer for low to mid volume clinical chemistry and immunochemistry testing on a footprint of two square meters	China	✓
	Molecular Lab	LightCycler Pro	Flexible real-time PCR instrument with dual IVD and research mode as well as enhanced system features	US & CE	✓
	Point of Care	cobas pulse	Handheld device combining professional glucose meter and a digital platform to host digital clinical decision support applications (from Roche and third parties)	US	2024
Tests	Pathology Lab	IDH1 R132H (IDH Glioma)	Neuropathology Immunohistochemistry (IHC) solution supporting the detection of tumor cells with the IDH1 R132H mutation aiding pathologists to render a diagnosis of gliomas	US	✓
	Core Lab	Anti-HEV IgG and Anti-HEV IgM	Anti-HEV IgM: Immunoassay aiding in the diagnosis of acute HEV infection in clinical settings; Anti-HEV IgG: Immunoassay aiding in the detection of a recent or past HEV infection and enabling accurate seroprevalence determinations. The two assays expand the hepatitis panel (HAV, HBV, HCV, HEV) on the same analytical platform	CE	✓
		HBeAg Quant	Immunoassay aiding in diagnosis, monitoring and predicting treatment response for patients with hepatitis B viral infection	CE	✓
		IL-6 Neonatal sepsis (claim extension)	Only immunoassay available on the market with dedicated claim and supporting evidence aiding in diagnosis of sepsis in neonates, with potential to reduce newborn mortality	CE	✓
		RUO Amyloid Plasma Assays (pTau181 & ApoE4)	Two qualitative immunoassays measuring the phosphorylated Tau 181 protein and apolipoprotein E4 in human plasma for research use only	US	✓
Digital Solutions	Pathology Lab	RUO Digital Pathology Algorithm: PD-L1 SP142	Digital pathology algorithm aiding pathologists in scoring PD-L1 (SP142) breast samples, ensuring a standardized approach and an adjunctive tool to augment diagnostic confidence for research use only	Global	✓
	Lab Insights	navify Algorithm Suite	Digital solution providing access to an open library of certified IVD-based clinical algorithms	Selected markets[1]	✓
		Menu for navify Algorithm Suite	Certified clinical algorithms for oncology applications such as colon and liver cancers	Selected markets[1]	✓
		cobas infinity lab 3.05	Next-generation lab middleware enabling ecosystem of cloud-based solutions for quality control and instrument maintenance	Global	✓
		navify Marketplace	Digital marketplace offering lab customers full range of innovative applications (from Roche and third parties)	Selected markets[1]	✓
		navify Sample Tracking	Open digital solution offering sample tracking beyond the lab setting (from IVD-sample creation to lab reception) to improve testing traceability and quality	Selected markets[1]	✓

[1]Selected markets: 14 countries with first releases; CE=European conformity; RUO=research use only; PCR=polymerase chain reaction; IVD=in vitro diagnostic; IDH=isocitrate dehydrogenase; HEV=Hepatitis E virus; HAV=Hepatitis A virus; HBV=Hepatitis B virus; HCV=Hepatitis C virus

Diagnostics key launches 2024

	Area	Product	Description	Markets	Status
Instruments Automation	Core Lab	i601 mass spectrometry system	Launch of an unique total solution for clinical mass spectrometry testing: fully automated, integrated and IVD-compliant	CE	
		cobas c703	Introducing high-throughput clinical chemistry testing to cobas pro integrated solutions	CE	
		cobas ISE neo	Introducing high-throughput ISE testing to cobas pro integrated solutions	CE	
	Diabetes Care	Accu-Chek SmartGuide (Continuous Glucose Monitoring)	Launch of Roche's first generation Continuous Glucose Monitoring (CGM) solution	CE	
	Molecular Lab	cobas 6800/8800 v2.0	Upgraded system with increased flexibility, higher throughput and greater automation to enable broader test menu. Retrofittable with existing cobas 6800/8800 installed base	CE	
	Pathology Lab	Primary Diagnosis Claim on DP600 US	FDA 510k Primary Diagnosis clearance on DP600 scanner as a critical step to advance Digital Pathology	US	
Tests	Core Lab	cobas pro serology solution (blood screening)	FDA approval of our serology Roche Blood Safety Solution (RBSS) for the US donor screening market (largest donor screening market globally)	US	
	Point of Care	cobas Liat Respiratory Panel (SARS-CoV-2, Flu A/B & RSV)	Detection and differentiation of four respiratory targets: SARS-CoV-2, Influenza A, Influenza B & respiratory syncytial virus (RSV)	US EUA	
	Molecular Lab	cobas Respiratory flex	Using novel Temperature Assisted Generation of Signal (TAGS®) Multiplex technology & digital reflex approach, enables strategic efficiency with flexible testing for cobas x800 Systems	CE US	
		cobas Malaria (blood screening)	RT qualitative PCR test on the cobas® x800 systems detecting all five plasmodium species that occur in humans. Utilized for malaria screening of blood donors, blood products, organs, and tissues	CE US	
	Pathology Lab	VENTANA Kappa Lambda Dual ISH mRNA Probe Cocktail	Aid in diagnosis of B-cell lymphomas and plasma cell neoplasms	CE US	
Digital solutions	Diagnostics Insights	navify Analytics family	Supports lab directors/managers to track, review, identify trends/challenges and optimize operations. Has four apps tailored to Core, Pathology, Molecular Labs and Point of Care	Global	

RT=real time

Invitation to Roche Diagnostics Investor Day 2024

Innovating Diagnostics, shaping healthcare, changing lives

cobas i601 mass spectrometry system

Highlights:

- Mass spectrometry
- Continuous glucose monitoring
- Next generation sequencing
- Point of care
- Upcoming molecular diagnostics launches
- Neurology biomarkers in development

Roche Diagnostics Day on May 22

London / hybrid event

14:00 - 16:30 CEST / 13:00 – 15:30 BST
08:00 – 10:30 am EDT / 05:00 – 07:30 am PDT

Doing now what patients need next

Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

Spark

Pharma sales appendix

Diagnostics sales appendix

Foreign exchange rates information

Changes to the development pipeline

Q4 2023 update

New to phase I

6 NMEs:
RG6382 NME – SLE
RG6640 GLP-1/GIP receptor agonist (CT-388) – obesity +/- T2D
RG6652 GLP-1 receptor agonist (CT-996) – obesity +/- T2D
RG6468 NME - solid tumors
RG6457 WRN covalent inhibitor – solid tumors
CHU REVN24 – acute diseases

New to phase II

3 NMEs:
RG6631 anti-TL1A – ulcerative colitis
RG6641 GLP-1/GIP receptor agonist (CT-868) – T1D with BMI ≥ 25
CHU anti-IL-8 recycling antibody - endometriosis

2 AIs:
RG6356 Elevidys – 0 to <4 year old DMD
RG6631 anti-TL1A – Crohn's disease

New to phase III

3 AIs:
RG6168 Enspryng – TED
RG6026 Columvi – r/r Mantle cell lymphoma
RG6171 giredestrant plus CDK4/6i – 1L ET resistant ER+/HER2- BC

New to registration

2 AIs (US & EU):
RG1594 Ocrevus SC – RMS & PPMS
RG7853 Alecensa – ALK+ NSCLC adj

1 AI (US)
RG3648 Xolair – food allergy

Removed from phase I

4 NMEs:
RG6189 FAP-CD40 – solid tumors
RG6156 EGFRvIII x CD3 - glioblastoma
RG6353 HLA-G CD3 TCB – solid tumors
RG6091 rugonersen – Angelman syndrome

2 AIs:
RG6264 Phesgo OBI – HER2+ BC
RG7601 Venclexta ± azacitidine – MDS

Removed from phase II

4 NMEs:
RG7412 crenezumab – familial Alzheimer's healthy pts
RG6100 semorinemab – Alzheimer's
RG7314 balovaptan – post-traumatic stress disorder
RG1662 basmisanil – Dup15q syndrome

Removed from phase III

1 AI:
RG7446 Tecentriq – SCCHN adj

Approvals

1 AI (US):
RG7716 Vabysmo – CRVO & BRVO

1 AI (EU):
RG7446 Tecentriq SC – all approved indications

Status as of February 1, 2024

Roche Group development pipeline

Phase I (52 NMEs + 8 AIs)

RG6026	Columvi monotherapy + combos	heme tumors
RG6058	tiragolumab combos	solid tumors
RG6076	englumafusp alfa combos	heme tumors
RG6114	inavolisib	solid tumors
RG6160	cevostamab	r/r multiple myeloma
RG6171	giredestrant monotherapy + combos	solid tumors
RG6185	belvarafenib + Cotellic ± T	solid tumors
RG6194	runimotamab	breast cancer
RG6234	forimtamig monotherapy + combos	multiple myeloma
RG6279	eciskafusp alfa ± T	solid tumors
RG6286	-	colorectal cancer
RG6292	vopikitug (CD25 MAb) combos	solid tumors
RG6323	efbalropoendekin alfa (IL15/IL15Ra-Fc) ± T	heme & solid tumors
RG6330	divarasib monotherapy + combos	solid tumors
RG6333	CD19 x CD28 + Columvi	r/r NHL
RG6344	BRAF inhibitor (3)	solid tumors
RG6411	-	solid tumors
RG6433	migoprotafib (SHP2i) combos	solid tumors
RG6440	Anti-latent TGF-β1 (SOF10)	solid tumors
RG6457	WRN covalent inhibitor	solid tumors
RG6468	-	solid tumors
RG6512	FIXa x FX	Hemophilia
RG6524	DLL3 trispecific	solid tumors
RG6526[1]	camonsertib	solid tumors
RG6537	AR degrader	mCRPC
RG6538[2]	P-BCMA-ALLO1	heme tumors
RG6596[3]	HER2 TKI	HER2+ BC
RG6614[4]	USP1 inhibitor	solid tumors
RG7827	FAP-4-1BBL combos	solid tumors
RG7828	Lunsumio monotherapy + combos	heme tumors
CHU	glypican-3 x CD3	solid tumors
CHU	codrituzumab	HCC
CHU	CD137 switch antibody	solid tumors
CHU	RAS inhibitor	solid tumors
CHU	SPYK04	solid tumors
CHU	anti-CLDN6 trispecific	CLDN6+ solid tumors
CHU	ROSE12	solid tumors
RG6107	crovalimab	lupus nephritis
RG6287	-	immunology
RG6315	-	fibrosis
RG6382	-	SLE
RG6418*	selnoflast	inflammation
RG6421	TMEM16A potentiator	cystic fibrosis
RG7828	Lunsumio	SLE
CHU	anti-HLA-DQ2.5 x gluten peptides	celiac disease
CHU	RAY121	Immunology
RG6006	zosurabalpin	bacterial infections
RG6319	LepB inhibitor	complicated urinary tract infection
RG6449	HBsAg MAb	chronic hepatitis B
RG6640[5]	GLP-1/GIP RA (CT-388)	obesity +/- T2D
RG6652[5]	GLP-1 RA (CT-996)	obesity +/- T2D
RG6035	BS-CD20 MAb	multiple sclerosis
RG6163	-	psychiatric disorders
RG6182	MAGL inhibitor	multiple sclerosis
RG6289	gamma-secretase modulator	Alzheimer´s
RG6120	zifibancimig	nAMD
RG6209	-	retinal disease
RG6351	-	retinal disease
RG7921	-	RVO
CHU	REVN24	acute diseases

RG-No - Roche/Genentech; CHU - Chugai managed; [1]Repare Therapeutics managed; [2]Poseida Therapeutics managed; [3]co-development with Zion Pharma; [4]KSQ Therapeutics managed; [5]Carmot Therapeutics managed; [6]Telavant managed (TUSCANY-2 and TAHOE); [7]Alnylam Pharmaceuticals managed; [8]IONIS managed; T=Tecentriq; BS=Brainshuttle™; *also developed in neurology; **combination platform; RA=Receptor agonist

Phase II (20 NMEs + 11 AIs)

RG6058	tiragolumab + T	NSCLC
	tiragolumab + T + chemo	NSCLC periadjuvant
	tiragolumab + T	cervical cancer
	tiragolumab + T	1L PD-L1+ mSCCHN
RG6107	crovalimab	sickle cell disease
RG6139	tobemstomig monotherapy + combos	solid tumors
RG6171	giredestrant	endometrial cancer
RG6180	autogene cevumeran + pembrolizumab	1L melanoma
RG6357	dirloctogene samoparvovec	hemophilia A
RG6341	-	chronic cough
RG6536	vixarelimab	IPF/SSc-ILD
RG6631[6]	anti-TL1A	ulcerative colitis
RG6631[6]	anti-TL1A	Crohn's disease
RG7854/ RG6346/ RG6084**	ruzotolimod/xalnesiran/PDL1 LNA	HBV
RG6359	SPK-3006	Pompe disease
RG6615[7]	zilebesiran	hypertension
RG6641[5]	GLP-1/GIP RA (CT-868)	T1D with BMI ≥ 25
RG6042	tominersen	Huntington's
RG6102	trontinemab	Alzheimer's
RG6237	latent myostatin + Evrysdi	SMA
	latent myostatin	FSHD
RG6356	Elevidys	0 to <4 year old DMD
RG6416	bepranemab	Alzheimer's
RG7816	alogabat	ASD
RG7935	prasinezumab	Parkinson's
RG6179	vamikibart (anti-IL-6)	DME
RG6299[8]	ASO factor B	geographic atrophy
RG6501	OpRegen	geographic atrophy
CHU	anti-IL-8 recycling antibody	endometriosis

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology
Infectious Diseases
Cardiovascular & Metabolism
Neurology
Ophthalmology
Other

Status as of February 1, 2024

Roche Group development pipeline

Phase III (9 NMEs + 39 AIs)

RG3502	Kadcyla + T	HER-2+ eBC high-risk
RG6026	Columvi + chemo	2L+ DLBCL
	Columvi + Polivy + R-CHP	1L DLBCL
	Columvi	r/r MCL
RG6058	tiragolumab + T	1L PD-L1 high NSCLC
	tiragolumab + T + chemo	1L esophageal cancer
	tiragolumab + T	locally advanced esophageal cancer
	tiragolumab + T	stage III unresectable 1L NSCLC
	tiragolumab + T + chemo	1L non-squamous NSCLC
	tiragolumab + T + Avastin	1L HCC
RG6107	crovalimab	aHUS
RG6114	Inavolisib + palbociclib + fulvestrant	1L HR+ mBC
	Inavolisib + fulvestrant	post CDKi HR+ BC
	inavolisib + Phesgo	1L HER2+ PIK3CA-mutant mBC
RG6171	giredestrant + palbociclib	1L ER+/HER2- mBC
	giredestrant	ER+ BC adj
	giredestrant + Phesgo	1L ER+/HER2+ BC
	giredestrant + CDK4/6i	1L ET resistant ER+/HER2- BC
RG6330	divarasib	2L NSCLC
RG7446	Tecentriq + platinum chemo	NSCLC periadj
	Tecentriq + BCG	NMIBC, high-risk
	Tecentriq + capecitabine or carbo/gem	1L TNBC
	Tecentriq + Avastin	HCC adj
	Tecentriq	ctDNA+ high-risk MIBC
	Tecentriq + lurbinectedin	1L maintenance SCLC
RG7601	Venclexta + azacitidine	1L MDS
RG7828	Lunsumio + lenalidomide	2L+ FL
	Lunsumio + Polivy	2L+ DLBCL
RG6149	astegolimab	COPD
RG6299	ASO factor B	IgA nephropathy
RG7159	Gazyva	lupus nephritis
	Gazyva	membranous nephropathy
	Gazyva	systemic lupus erythematosus
	Gazyva	childhood onset idiopathic nephrotic syndrome**
RG6152	Xofluza	influenza, pediatric (0-1 year)
	Xofluza	influenza direct transmission
RG1594	Ocrevus higher dose	RMS & PPMS
RG6168	Enspryng	myasthenia gravis
	Enspryng	MOG-AD
	Enspryng	autoimmune encephalitis
RG6356	Elevidys	DMD
RG7845	fenebrutinib	RMS
	fenebrutinib	PPMS
RG6168	Enspryng	TED
RG6179	vamikibart (anti-IL-6)	UME
RG6321	Susvimo	DME
	Susvimo	DR
	Susvimo	wAMD, 36-week

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology
Infectious Diseases

Cardiovascular & Metabolism
Neurology
Ophthalmology
Other

Registration US & EU (1 NME + 6 AIs)

RG6107*	crovalimab	PNH
RG7446	Tecentriq SC[1]	all approved indications
RG7853	Alecensa	ALK+ NSCLC adj
RG3648	Xolair[2]	food allergy
RG1594	Ocrevus SC	RMS & PPMS
RG7716	Vabysmo[3]	BRVO
	Vabysmo[3]	CRVO

T=Tecentriq
*First filed in China in Q3 2022
**also known as pediatric nephrotic syndrome (PNS)
[1]Approved in EU, filed in US
[2]Filed in US
[3]Approved in US, filed in EU

Status as of February 1, 2024

Expected regulatory submissions*

New Molecular Entities: Lead and additional indications

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology
Infectious Diseases

Cardiovascular & Metabolism
Neurology
Ophthalmology
Other

*Filing timelines reflect the anticipated filing of a potential indication; projects shown are in phase II and phase III
✓ Indicates submission to health authorities has occurred
Unless stated otherwise submissions are planned to occur in US and EU
T=Tecentriq, RA=Receptor agonist
[1]First filed in China
[2]Telavant managed (TUSCANY-2 and TAHOE)
[3]IONIS managed
[4]Alnylam Pharmaceuticals managed
[5]Carmot Therapeutics managed

2023

RG6107	**crovalimab[1]** PNH (EU, US) ✓

2024

RG6114	**Inavolisib + palbociclib + fulvestrant** 1L HR+ BC
RG6356	**Elevidys** DMD (EU)
RG6321	**Susvimo** DME (US)
RG6321	**Susvimo** DR (US)

2025

RG6058	**tiragolumab + T** 1L PD-L1 high NSCLC
RG6058	**tiragolumab + T + chemo** 1L esophageal cancer (CN)
RG6058	**tiragolumab + T** Stage III unresectable 1L NSCLC
RG6107	**crovalimab** aHUS
RG6321	**Susvimo** wAMD (EU)

2026 and beyond

RG6058	**tiragolumab + T** locally adv esophageal cancer
RG6058	**tiragolumab + T + chemo** 1L non-sq NSCLC
RG6058	**tiragolumab + T** 1L PD-L1+ mSCCHN
RG6058	**tiragolumab+T+/-chemo** NSCLC periadjuvant
RG6058	**tiragolumab+T+ Avastin** 1L HCC
RG6107	**crovalimab** sickle cell disease
RG6114	**Inavolisib + fulvestrant** post CDKi HR+ BC
RG6114	**inavolisib + Phesgo** 1L HER2+ PIK3CA-mutant mBC
RG6139	**tobemstomig** solid tumors
RG6171	**giredestrant + palbociclib** 1L ER+/HER2- mBC
RG6171	**giredestrant** ER+ BC adj
RG6171	**giredestrant + Phesgo** 1L ER+/HER2+ BC
RG6171	**giredestrant** endometrial cancer
RG6171	**giredestrant + CDK4/6i** 1L ET resistant ER+/HER2- BC
RG6180	**autogene cevumeran** 1L melanoma
RG6330	**divarasib** 2L NSCLC
RG6149	**astegolimab** COPD
RG6299	**ASO factor B** IgA nephropathy
RG6341	**NME** chronic cough
RG6536	**vixarelimab** IPF & SSc-ILD
RG6631[2]	**anti-TL1A** ulcerative colitis
RG6631[2]	**anti-TL1A** Crohn's disease
RG7854/ RG6346/ RG6084	**ruzotolimod/xalnesiran/ PDL1 LNA** HBV
RG6042	**tominersen** Huntington's
RG6102	**trontinemab** Alzheimer's
RG6237	**latent myostatin + Evrysdi** SMA
RG6237	**latent myostatin** FSHD
RG6356	**Elevidys** 0 to <4 year old DMD
RG6416	**bepranemab** Alzheimer's
RG7816	**alogabat** ASD
RG7845	**fenebrutinib** RMS &PPMS
RG7935	**prasinezumab** Parkinson's
RG6179	**vamikibart (anti-IL-6)** UME & DME
RG6299[3]	**ASO factor B** geographic atrophy
RG6321	**Susvimo** DME (EU)
RG6321	**Susvimo** wAMD, 36-week refill
RG6501	**OpRegen** geographic atrophy
RG6615[4]	**zilebesiran** hypertension
RG6641[5]	**GLP-1/GIP RA (CT-868)** T1D with BMI ≥ 25

Status as of February 1, 2024

Expected regulatory submissions*

Marketed products: Additional indications

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology
Infectious Diseases

Cardiovascular & Metabolism
Neurology
Ophthalmology
Other

✓ Indicates submission to health authorities has occurred
Unless stated otherwise submissions are planned to occur in US and EU
*Filing timelines reflect the anticipated filing of a potential indication; projects shown are in phase II and phase III
**also known as pediatric nephrotic syndrome (PNS)

2023		2024				2025		2026 and beyond	
RG7853	**Alecensa** ALK+ NSCLC adj ✓	RG6026	**Columvi + chemo** 2L DLBCL	RG7159	**Gazyva** lupus nephritis	RG7828	**Lunsumio + lenalidomide** 2L FL+	RG3502	**Kadcyla + Tecentriq** HER-2+ eBC high-risk
RG1594	**Ocrevus SC** RMS & PPMS ✓	RG7446	**Tecentriq + Avastin** HCC adj	RG3625	**TNKase** stroke	RG7828	**Lunsumio + Polivy** 2L+ DLBCL (US)	RG6026	**Columvi + Polivy + R-CHP** 1L DLBCL
RG3648	**Xolair** food allergy ✓	RG7446	**Tecentriq + capecitabine or carbo/gem** TNBC	RG6168	**Enspryng** myasthenia gravis	RG7446	**Tecentriq+ lurbinectedin** 1l maintenance SCLC	RG6026	**Columvi** r/r MCL
RG7716	**Vabysmo** BRVO/CRVO ✓			RG6152	**Xofluza** direct transmission	RG7446	**Tecentriq** ctDNA+ high-risk MIBC	RG7446	**Tecentriq + BCG** High-risk NMIBC
				RG6152	**Xofluza** influenza, pediatric (0-1 year)	RG7446	**Tecentriq** NSCLC periadj	RG7159	**Gazyva** membranous nephropathy
						RG7601	**Venclexta + azacitidine** 1L MDS	RG7159	**Gazyva** systemic lupus erythematosus
						RG1594	**Ocrevus higher dose** RMS & PPMS	RG7159	**Gazyva** childhood onset idiopathic nephrotic syndrome**
						RG6168	**Enspryng** autoimmune encephalitis	RG6168	**Enspryng** MOG-AD
						RG6168	**Enspryng** TED		

Status as of February 1, 2024

Major pending approvals 2023 and 2024 YTD

US		EU		China		Japan-Chugai	
RG7446	**Tecentriq SC** all approved indications Filed Nov 2022	RG6107	**crovalimab** PNH Filed June 2023	RG6107	**crovalimab** PNH Filed Aug 2022	RG7716	**Vabysmo** BRVO/CRVO Filed April 2023
RG6107	**crovalimab** PNH Filed June 2023	RG7716	**Vabysmo** BRVO/CRVO Filed Aug 2023	RG7716	**Vabysmo** BRVO/CRVO Filed March 2023	RG6107	**crovalimab** PNH Filed June 2023
RG3648	**Xolair** Food allergy Filed Aug 2023*	RG1594	**Ocrevus SC** RMS & PPMS Filed Aug 2023	RG1594	**Ocrevus** RMS & PPMS Filed June 2023	RG7853	**Alecensa** ALK+ NSCLC adj Filed Dec 2023
RG1594	**Ocrevus SC** RMS & PPMS Filed Nov 2023	RG7853	**Alecensa** ALK+ NSCLC adj Filed Nov 2023	RG7853	**Alecensa** ALK+ NSCLC adj Filed Nov 2023		
RG7853	**Alecensa** ALK+ NSCLC adj Filed Nov 2023			RG7828	**Lunsumio** 3L+ FL Filed Dec 2023		

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology
Infectious Diseases

Cardiovascular & Metabolism
Neurology
Ophthalmology
Other

Status as of February 1, 2024

*Filing acceptance Q4 2023

Major granted approvals 2023 and 2024 YTD

US

RG7596	**Polivy** 1L DLBCL (US) April 2023
RG6026	**Columvi** 3L+ DLBCL June 2023
RG7716	**Vabysmo** BRVO/CRVO Oct 2023

EU

RG6152	**Xofluza** influenza pediatric Jan 2023
RG6013	**Hemlibra** moderate hemophilia A Jan 2023
RG6413+ RG6412	**Ronapreve** SARS-CoV-2 hospitalized May 2023
RG6026	**Columvi** 3L+ DLBCL July 2023
RG7916	**Evrysdi** SMA presymptomatic pediatric <2mo Aug 2023
RG7446	**Tecentriq SC** all approved indications Jan 2024

China

RG7596	**Polivy** 1L DLBCL Jan 2023
RG7596	**Polivy** r/r DLBCL Jan 2023
RG6152	**Xofluza** influenza pediatric 5 to <12 years March 2023
RG7916	**Evrysdi** SMA presymptomatic pediatric <2mo June 2023
RG7716	**Vabysmo** nAMD/DME Dec 2023
RG6026	**Columvi** 3L+ DLBCL Dec 2023
RG6264	**Phesgo** HER-2+ BC Dec 2023

Japan-Chugai

RG6264	**Phesgo** HER-2+ BC/CC Sept 2023
RG1569	**Actemra** Cytokine release syndrome (CRS) Sept 2023
RG105	**Rituxan** lupus nephritis Aug 2023
RG105	**Rituxan** Ab-mediated rejection in organ transplantation Dec 2023

New Molecular Entity (NME)
Additional Indication (AI)
Oncology / Hematology
Immunology
Infectious Diseases

Cardiovascular & Metabolism
Neurology
Ophthalmology
Other

Status as of February 1, 2024

Ab=Antibody

Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

Spark

Pharma sales appendix

Diagnostics sales appendix

Foreign exchange rates information

Hemlibra (emicizumab, RG6013)

Factor VIII mimetic for treatment of hemophilia A

Indication	Hemophilia A patients without inhibitors to factor VIII	Hemophilia A patients with and without inhibitors to Factor VIII, dosing every 4 weeks
Phase/study	**Phase III HAVEN 3**	**Phase III HAVEN 4**
# of patients	N=135	N=46
Design	Patients on FVIII episodic treatment prior to study entry: ▪ **ARM A:** Hemlibra prophylaxis QW ▪ **ARM B:** Hemlibra prophylaxis Q2W ▪ **ARM C:** Episodic FVIII treatment; switch to Hemlibra prophylaxis possible after 24 weeks Patients on FVIII prophylaxis prior to study entry: ▪ **ARM D:** Hemlibra prophylaxis QW	▪ **Part I:** Pharmacokinetic run-in part (N=6); Hemlibra Q4W ▪ **Part II:** Expansion part (N=40); Hemlibra Q4W
Primary endpoint	▪ Number of bleeds over 24 weeks	▪ Number of bleeds over 24 weeks
Status	▪ Study met primary and key secondary endpoints Q4 2017 ▪ FDA granted Breakthrough Therapy Designation April 2018 ▪ Data presented at WFH 2018 ▪ Filed in US (priority review) and EU in Q2 2018 ▪ Data published in *NEJM* 2018; 379: 811-822	▪ Pharmacokinetic run-in data at ASH 2017 ▪ Positive interim analysis outcome reported Q4 2017 ▪ Data presented at WFH 2018 ▪ Interim data filed in US and EU in Q2 2018 ▪ Data published in Lancet Haematology 2019 Jun;6(6):e295-e305
	▪ Approved in US Q4 2018 and EU Q1 2019	
CT Identifier	NCT02847637	NCT03020160

In collaboration with Chugai

ASH=American Society of Hematology; WFH=World Federation of Hemophilia; NEJM=New England Journal of Medicine

Hemlibra (emicizumab, RG6013)

Factor VIII mimetic for treatment of hemophilia A

Indication	Hemophilia A patients with and without inhibitors to Factor VIII	Hemophilia A mild to moderate patients without inhibitors to Factor VIII
Phase/study	**Phase III HAVEN 5**	**Phase III HAVEN 6**
# of patients	N=85	N=70
Design	Patients with Hemophilia regardless of FVIII inhibitor status on prophylactic or episodic treatment prior to study entry: ▪ **ARM A**: Hemlibra prophylaxis QW ▪ **ARM B**: Hemlibra prophylaxis Q4W ▪ **ARM C**: No prophylaxis (control arm)	Patients with mild or moderate Hemophilia A without FVIII inhibitors ▪ Hemlibra QW (1.5mg/kg), Q2W (3.0mg/kg) or Q4W (6.0mg/kg) (patients preference)
Primary endpoint	▪ Number of bleeds over 24 weeks	▪ Safety and efficacy
Status	▪ FPI Q2 2018 ▪ Recruitment completed Q1 2019 ▪ Filed in China Q2 2020 ▪ Approved in China Q2 2021	▪ FPI Q1 2020, recruitment completed Q1 2021 ▪ Interim data presented at ASH 2021 and primary data presented at ISTH 2022 ▪ Filed in EU Q4 2021 ▪ Data presented at ASH 2022 ▪ Approved in EU for moderate Hemophilia A Q1 2023
CT Identifier	NCT03315455	NCT04158648

In collaboration with Chugai

ASH=American Society of Hematology; ISTH=International Society on Thrombosis and Haemostasis

Alecensa (alectinib, RG7853)

New CNS-active inhibitor of anaplastic lymphoma kinase

Indication	Treatment-naïve ALK+ advanced NSCLC	Adjuvant ALK+ NSCLC
Phase/study	**Phase III ALEX**	**Phase III ALINA**
# of patients	N=286	N=257
Design	▪ **ARM A:** Alecensa 600mg BID ▪ **ARM B:** Crizotinib 250mg BID	▪ **ARM A:** Alecensa 600mg BID ▪ **ARM B:** Platinum-based chemotherapy
Primary endpoint	▪ Progression-free survival	▪ Disease-free survival
Status	▪ Data presented at ASCO 2017, 2018, ESMO 2017, 2018 and 2019 (final PFS and updated OS) ▪ Data published in *NEJM* 2017; 377:829-838 ▪ Approved in US Q4 2017 (priority review) and in EU Q4 2017	▪ FPI Q3 2018 ▪ Recruitment completed Q4 2021 ▪ Study met it's primary endpoint Q3 2023 ▪ Filed in US, EU, China and Japan Q4 2023 ▪ Priority Review granted by FDA Jan 2024
CT Identifier	NCT02075840	NCT03456076

In collaboration with Chugai

ALK=anaplastic lymphoma kinase; CNS= Central nervous system; NSCLC=non-small cell lung cancer; OS=Overall survival, PFS=Progression-free survival; ASCO=American Society of Clinical Oncology; NEJM=New England Journal of Medicine; ESMO=European Society for Medical Oncology

Kadcyla (trastuzumab emtansine, RG3502)

First ADC for HER2-positive breast cancer

Indication	HER2-positive early breast cancer (BC) high-risk patients	HER2-positive early breast cancer (BC) high-risk patients
Phase/study	**Phase III KATHERINE**	**Phase III ASTEFANIA**
# of patients	N=1,484	N=1,700
Design	▪ **ARM A:** Kadcyla 3.6mg/kg Q3W ▪ **ARM B:** Herceptin	▪ **ARM A:** Kadcyla plus Tecentriq ▪ **ARM B:** Kadcyla plus placebo
Primary endpoint	▪ Invasive disease-free survival	▪ Invasive disease-free survival
Status	▪ Stopped at pre-planned interim data analysis for efficacy Q4 2018 ▪ Data presented at SABCS 2018 ▪ BTD granted by FDA in Q1 2019 ▪ Filed in US (under RTOR) and EU Q1 2019 ▪ Approved in US Q2 2019 and in EU Q4 2019 ▪ Data published in *NEJM* 2019; 380:617-628 ▪ 7-year data presented at ASH 2023	▪ FPI Q2 2021
CT Identifier	NCT01772472	NCT04873362

In collaboration with ImmunoGen, Inc.

ADC=antibody drug conjugate; BTD=Breakthrough therapy designation; HER2=Human Epidermal growth factor Receptor 2; SABCS=San Antonio Breast Cancer Symposium; RTOR=Real time oncology review; NEJM=New England Journal of Medicine

Phesgo (pertuzumab/trastuzumab, RG6264)

FDC of Perjeta and Herceptin for subcutaneous administration

Indication	HER2-positive early breast cancer (BC)	
Phase/study	**Phase III** **FeDeriCa**	**Phase II** **PHranceSCa**
# of patients	N=500	N=160
Design	Phesgo in combination with chemotherapy in neoadjuvant/adjuvant setting ▪ **ARM A:** Perjeta IV plus Herceptin IV plus chemotherapy ▪ **ARM B:** Phesgo plus chemotherapy	▪ **ARM A:** Perjeta and Herceptin IV followed by Phesgo ▪ **ARM B:** Phesgo followed by IV
Primary endpoint	▪ Trough Serum Concentration (Ctrough) of Perjeta during cycle 7	▪ Percentage of patients who preferred Phesgo
Status	▪ Primary endpoint met Q3 2019 ▪ Data presented at SABCS 2019 ▪ Data published in Lancet Oncology 2021 Jan;22(1):85-97	▪ Final analysis completed, 85% patients preferred Phesgo ▪ Data presented at ESMO 2020 ▪ Data published in *Eur J Cancer* 2021 Jul;152:223-232
	▪ Filed in US Q4 2019 & in EU Q1 2020; Approved in US Q2 2020 and EU Q4 2020	
CT Identifier	NCT03493854	NCT03674112

SC with Halozyme's rHuPH20/ Halozyme's human hyaluronidase

FDC=Fixed-dose combination; Phesgo=FDC of Perjeta and Herceptin for SC administration; HER2=Human Epidermal growth factor Receptor 2, IV=intravenous; SC=Subcutaneous; SABCS=San Antonio Breast Cancer Symposium; Eur J Cancer=European Journal of Cancer; ESMO=European Society for Medical Oncology

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – lung cancer

Indication	Adjuvant NSCLC	Periadjuvant NSCLC
Phase/study	**Phase III** **IMpower010**	**Phase III** **IMpower030**
# of patients	N=1,280	N=450
Design	Following adjuvant cisplatin-based chemotherapy ▪ **ARM A:** Tecentriq ▪ **ARM B:** Best supportive care	▪ **ARM A:** Tecentriq plus platinum-based chemotherapy ▪ **ARM B:** Platinum-based chemotherapy
Primary endpoint	▪ Disease-free survival	▪ Event-free survival
Status	▪ Recruitment completed Q3 2018 ▪ Study met primary endpoint Q1 2021 ▪ Data presented at ASCO, WCLC and ESMO 2021 ▪ Filed in US (priority review) and EU Q2 2021 ▪ Approved in US Q4 2021 and EU Q2 2022	▪ FPI Q2 2018 ▪ Recruitment completed Q3 2021
CT Identifier	NCT02486718	NCT03456063

NSCLC=non-small cell lung cancer; PD-L1=Programmed cell death-ligand 1; ASCO=American Society of Clinical Oncology; ESMO=European Society for Medical Oncology; WCLC=World Conference on Lung Cancer

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – lung cancer

Indication	1L maintenance extensive-stage SCLC	Stage IV NSCLC
Phase/study	**Phase III** **IMforte**[1]	**Phase Ib/III** **IMscin001**[2]
# of patients	N=450	N=371
Design	▪ **ARM A:** Platinum-etoposide + Tecentriq followed by maintenance Tecentriq plus lurbinectedin ▪ **ARM B:** Platinum-etoposide + Tecentriq followed by maintenance Tecentriq	**Phase Ib** ▪ Dose finding, Tecentriq SC followed by Tecentriq IV **Phase III** ▪ 2L NSCLC non inferiority of Tecentriq SC vs Tecentriq IV
Primary endpoint	▪ Progression-free survival and overall survival	▪ Observed concentration of Tecentriq in serum at cycle 1
Status	▪ FPI Q4 2021 ▪ Recruitment completed Jan 2024	▪ FPI Phase Ib Q4 2018 and FPI Phase III Q4 2020 ▪ Recruitment completed Q1 2022 ▪ Study met its primary end point Q3 2022 ▪ Data presented at ESMO-IO 2022 ▪ Filed in US and EU Q4 2022 ▪ Approved in EU Jan 2024
CT Identifier	NCT05091567	NCT03735121

[1]In collaboration with Jazz Pharma, [2]SC with Halozyme's rHuPH20/ Halozyme's human hyaluronidase

NSCLC=non-small cell lung cancer; PD-L1=Programmed cell death-ligand 1; SCLC=small cell lung cancer, SC=Subcutaneous, IV=Intravenous; ESMO-IO=European Society for Medical Oncology-Immuno-Oncology

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – SCCHN

Indication	Adjuvant squamous cell carcinoma of the head and neck (SCCHN)
Phase/study	**Phase III** **IMvoke010**
# of patients	N=406
Design	▪ **ARM A:** Tecentriq 1200mg Q3W ▪ **ARM B:** Placebo
Primary endpoint	▪ Event-free survival and overall survival
Status	▪ FPI Q1 2018 ▪ Recruitment completed Q1 2020 ▪ Study did not meet it's primary endpoint Q4 2023
CT Identifier	NCT03452137

SCCHN=squamous cell carcinoma of the head and neck

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – urothelial carcinoma

Indication	High-risk non-muscle-invasive bladder cancer (NMIBC)	ctDNA+, high-risk muscle-invasive bladder cancer (MIBC)
Phase/study	**Phase III ALBAN**	**Phase III IMvigor011**
# of patients	N=516	N=495
Design	▪ **ARM A:** BCG induction and maintenance ▪ **ARM B:** Tecentriq plus BCG induction and maintenance	▪ **ARM A:** Tecentriq monotherapy ▪ **ARM B:** Placebo
Primary endpoint	▪ Recurrence-free survival	▪ Recurrence-free survival
Status	▪ FPI Q4 2018	▪ FPI Q2 2021
CT Identifier	NCT03799835	NCT04660344

BCG=Bacille Calmette-Guérin; PD-L1=Programmed cell death-ligand 1

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – hepatocellular carcinoma

Indication	Adjuvant hepatocellular carcinoma (HCC)
Phase/study	**Phase III** **IMbrave050**
# of patients	N=668
Design	▪ **ARM A:** Tecentriq plus Avastin ▪ **ARM B:** Active surveillance
Primary endpoint	▪ Recurrence-free survival
Status	▪ FPI Q4 2019 ▪ Recruitment completed Q4 2021 ▪ Study met its primary endpoint Q1 2023 ▪ Data presented at AACR 2023 and ASCO 2023 (PROs)
CT Identifier	NCT04102098

PD-L1=Programmed cell death-ligand 1; AACR=American Association for Cancer Research; PROs=Patient-reported outcomes

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – breast cancer

Indication	Previously untreated metastatic triple negative breast cancer (TNBC)	
Phase/study	**Phase III IMpassion130**	**Phase III IMpassion132**
# of patients	N=902	N=572
Design	▪ **ARM A:** Tecentriq plus nab-paclitaxel ▪ **ARM B:** Placebo plus nab-paclitaxel	▪ **ARM A:** Tecentriq plus capecitabine or carbo/gem ▪ **ARM B:** Placebo plus capecitabine or carbo/gem
Primary endpoint	▪ Progression-free survival and overall survival (co-primary endpoint)	▪ Overall survival
Status	▪ Study met co-primary endpoint of PFS in both PD-L1+ and ITT populations Q3 2018 ▪ Primary PFS and interim OS data presented at ESMO 2018 and ASCO 2019 ▪ Data published in *NEJM* 2018; 379:2108-2121 ▪ US accelerated approval Q1 2019 – US indication voluntarily withdrawn Q3 2021 ▪ Approved in EU Q3 2019 ▪ Final OS presented at ESMO Asia 2020	▪ FPI Q1 2018
CT Identifier	NCT02425891	NCT03371017

Carbo/gem=gemcitabine and carboplatin; ITT=Intention to treat; PD-L1=Programmed cell death-ligand 1; PFS=Progression-free survival; OS=Overall survival; ESMO=European Society for Medical Oncology; ASCO=American Society of Clinical Oncology; NEJM=New England Journal of Medicine

Tecentriq (atezolizumab, RG7446)

Anti-PD-L1 cancer immunotherapy – breast cancer

Indication	Neoadjuvant triple negative breast cancer (TNBC)
Phase/study	**Phase III** **IMpassion031**
# of patients	N=333
Design	▪ **ARM A:** Tecentriq plus nab-paclitaxel ▪ **ARM B:** Placebo plus nab-paclitaxel
Primary endpoint	▪ Percentage of participants with pathologic complete response
Status	▪ Study met primary endpoint Q2 2020 ▪ Data presented at ESMO 2020 ▪ Data published in Lancet 2020;396 (10257):1090-1100 ▪ Filed in EU Q4 2020 - application withdrawn Q3 2021
CT Identifier	NCT03197935

PD-L1=Programmed cell death-ligand 1; ESMO=European Society for Medical Oncology, IDMC=Independent Data Monitoring Committee

Venclexta (venetoclax, RG7601)

Novel small molecule Bcl-2 selective inhibitor – chronic lymphocytic leukemia

Indication	Untreated chronic lymphocytic leukemia (CLL) patients with coexisting medical conditions	Untreated fit chronic lymphocytic leukemia (CLL) patients
Phase/study	**Phase III** **CLL14**	**Phase III** **CristaLLo**
# of patients	N=445	N=165
Design	▪ **ARM A:** Venclexta plus Gazyva ▪ **ARM B:** Chlorambucil plus Gazyva	▪ **ARM A:** Venclexta plus Gazyva ▪ **ARM B:** Fludarabine plus cyclophosphamide plus Rituxan or bendamustine plus Rituxan
Primary endpoint	▪ Progression-free survival	▪ MRD negativity rate in peripheral blood at 15 months
Status	▪ Study met primary endpoint Q4 2018 ▪ BTD granted by FDA Q1 2019 ▪ Filed in US (under RTOR) Q1 2019 and EU Q2 2019 ▪ Data presented at ASCO 2019, ASH 2019, 2020 and EHA 2021, 2022; 6-year data presented at EHA and ICML 2023 ▪ Data published in *NEJM* 2019; 380:2225-2236 ▪ Approved US Q2 2019 and EU Q1 2020	▪ FPI Q2 2020 ▪ Recruitment completed Q1 2023
CT Identifier	NCT02242942	NCT04285567

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute

Bcl-2=B-cell lymphoma 2; BTD=Breakthrough therapy designation; MRD=Minimal Residual Disease; ASH=American Society of Hematology; ASCO=American Society of Clinical Oncology; EHA=European Hematology Association; RTOR=Real time oncology review; NEJM=New England Journal of Medicine

Venclexta (venetoclax, RG7601)

Novel small molecule Bcl-2 selective inhibitor – multiple myeloma

Indication	Relapsed or refractory multiple myeloma (MM)
Phase/study	**Phase III** **CANOVA**
# of patients	N=263
Design	▪ **ARM A:** Venclexta plus dexamethazone ▪ **ARM B:** Pomalidomide plus dexamethasone in t(11;14) positive r/r MM
Primary endpoint	▪ Progression-free survival
Status	▪ FPI Q4 2018 ▪ Recruitment completed Q3 2022 ▪ Study did not meet its primary endpoint Q3 2023 ▪ Data presented at IMS 2023
CT Identifier	NCT03539744

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute

Bcl-2=B-cell lymphoma 2; MM=multiple myeloma; r/r=Relapsed or refractory; IMS=International Myeloma Society

Venclexta (venetoclax, RG7601)

Novel small molecule Bcl-2 selective inhibitor – myelodysplastic syndromes

Indication	Newly diagnosed higher-risk myelodysplatic syndromes (MDS)
Phase/study	**Phase III VERONA**
# of patients	N=500
Design	▪ **ARM A:** Venclexta plus azacitidine ▪ **ARM B:** Placebo plus azacitidine
Primary endpoint	▪ Overall survival
Status	▪ FPI Q4 2020 ▪ Recruitment completed Q3 2022
CT Identifier	NCT04401748

Joint project with AbbVie, in collaboration with The Walter and Eliza Hall Institute
Bcl-2=B-cell lymphoma 2

Polivy (polatuzumab vedotin, RG7596)

ADC targeting CD79b to treat B cell malignancies

Indication	1L DLBCL
Phase/study	**Phase III** **POLARIX**
# of patients	N=879
Design	▪ **ARM A:** Polivy plus R-CHP ▪ **ARM B:** R-CHOP
Primary endpoint	▪ Progression-free survival
Status	▪ Data presented at ASH 2021 and 2022 ▪ Filed in EU, Japan and China Q4 2021 and in the US Q3 2022 ▪ Published in *NEJM* 2022 Jan 27;386(4):351-363 ▪ Approved in EU Q2 2022, Japan Q3 2022, China Q1 2023 and US April 2023
CT Identifier	NCT03274492

In collaboration with Seagen Inc.

DLBCL=diffuse large B cell lymphoma; R-CHP=Rituxan, cyclophosphamide, hydroxydoxorubicin, prednisone; R-CHOP=Rituxan, cyclophosphamide, doxorubicin, vincristine, and prednisone; ASH=American Society of Hematology, NEJM=New England Journal of Medicine

Gavreto (pralsetinib, RG6396)

Highly selective RET inhibitor

Indication	RET+ NSCLC, thyroid cancer and other advanced solid tumors	1L RET fusion-positive, metastatic NSCLC
Phase/study	**Phase I/II ARROW**	**Phase III AcceleRET Lung**
# of patients	N=647	N=250
Design	▪ **Part I:** Gavreto 30-600mg dose escalation ▪ **Part II:** Gavreto 400mg dose expansion	▪ **ARM A:** Gavreto 400mg ▪ **ARM B:** Platinum-based chemotherapy +/- pembrolizumab
Primary endpoint	▪ Safety and efficacy	▪ Progression-free survival
Status	▪ Filed in US and EU for RET fusion-positive NSCLC and US for RET-mutant MTC and RET fusion-positive thyroid cancer ▪ Approved in US Q3 2020 in RET fusion-positive NSCLC, in Q4 2020 in RET-mutant MTC and RET fusion-positive thyroid cancer ▪ Updated data presented at ASCO 2021 and 2022 ▪ Data published in Lancet Oncol 2021 Jul;22(7):959-969 and Lancet Diabetes & Endocrinology Aug 2021;9(8):491-501 ▪ Approved in EU for RET fusion-positive NSCLC Q4 2021 ▪ Filing withdrawn in EU Q4 2022 for RET-mutant MTC and RET fusion-positive thyroid cancer ▪ US Approval withdrawn Q2 2023 for RET-mutant medullary thyroid cancer	▪ Study initiated in Q1 2020
CT Identifier	NCT03037385	NCT04222972

In collaboration with Blueprint Medicines

NSCLC=non-small cell lung cancer; MTC=medullary thyroid cancer; RET=Rearranged during transfection; ASCO=American Society of Clinical Oncology; ESMO=European Society for Medical Oncology

Lunsumio (mosunetuzumab, CD20 x CD3, RG7828)

Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	3L+ FL, 3L+ DLBCL & other relapsed or refractory NHL	1L DLBCL	Relapsed or refractory DLBCL
Phase/study	**Phase I/II**	**Phase Ib/II**	**Phase Ib/II**
# of patients	N=746	N=160	N=262
Design	▪ Dose escalation of Lunsumio monotheraphy and in combination with Tecentriq ▪ Expansion cohorts for r/r FL, r/r DLBCL and SC in r/r NHL	▪ Lunsumio plus CHOP ▪ Lunsumio plus CHP plus Polivy ▪ Lunsumio plus CHP-Polivy vs Rituximab plus CHP-Polivy	Lunsumio plus Polivy, randomised cohorts ▪ **ARM A:** Lunsumio SC plus Polivy ▪ **ARM B:** Rituximab plus Polivy
Primary endpoint	▪ Safety, tolerability, dose/schedule, PK and response rates	▪ Safety/tolerability and response	▪ Safety/tolerability and response
Status	▪ Data in r/r NHL presented at ASH 2018, 2019, and in r/r FL at ASH 2020, 2021 and 2022 ▪ BTD granted by FDA Q2 2020 ▪ Filed in EU and rolling submission in US Q4 2021; Filed in US (priority review) Q2 2022 ▪ Approved in EU Q2 2022 and US Q4 2022 ▪ DLBCL data published in *J. Clin. Oncol.* 40(5)481-491 and *Blood Advances* 2023 Apr 17: doi:10.1182/bloodadvances.2022009260 ▪ FL data published in the *Lancet Oncology* 2022 Aug;23(8):1055-1065 ▪ 3-year data in r/r FL presented at ASH 2023	▪ FPI Q1 2019 ▪ Recruitment completed Q2 2021 ▪ Data for Lunsumio plus CHOP presented at ASH 2020	▪ FPI Q3 2018 ▪ Recruitment completed Q1 2023 ▪ Initial data presented at ASCO 2021 and ASH 2021, 2022 ▪ Data presented at ASH 2023 ▪ Data published in *Nature Medicine* Dec 2023 https://doi.org/10.1038/s41591-023-02726-5
CT Identifier	NCT02500407	NCT03677141	NCT03671018

FL=follicular lymphoma; DLBCL=diffuse large B cell lymphoma; r/r=relapsed/refractory; NHL=non-Hodgkin's lymphoma; R=Rituximab; SC=subcutaneous; CHOP=cyclophosphamide, doxorubicin, vincristine, and prednisone; CHP=cyclophosphamide, doxorubicin, and prednisone; PK=Pharmacokinetics; BTD=Breakthrough Therapy Designation; ASH=American Society of Hematology; ASCO=American Society of Clinical Oncology

Lunsumio (mosunetuzumab, CD20 x CD3, RG7828)

Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	1L DLBCL & 2L DLBCL following 1L induction	FL
Phase/study	**Phase I**	**Phase Ib**
# of patients	N=188	N=27
Design	▪ **Cohort A:** Lunsumio monotherapy (after a response to prior systemic chemotherapy) ▪ **Cohort B:** Lunsumio monotherapy (1L treatment in elderly/frail) ▪ **Cohort C:** Lunsumio SC plus Polivy in 1L elderly/unfit	▪ Lunsumio plus lenalidomide safety run-in for phase III ▪ Lunsumio SC plus lenalidomide
Primary endpoint	▪ Safety/tolerability and response	▪ Safety/tolerability and response
Status	▪ FPI Q2 2019 – Cohort B ▪ FPI Q3 2019 – Cohort A ▪ FPI Q1 2021 – Cohort C ▪ Recruitment completed Q1 2023 ▪ Initial data presented at ASH 2020 (Cohort B) and ASH 2022	▪ FPI Q3 2020 ▪ Initial data presented at ASH 2021 and 2022 ▪ Recruitment completed Q2 2023
CT Identifier	NCT03677154	NCT04246086

FL=follicular lymphoma; DLBCL=diffuse large B cell lymphoma; SC=subcutaneous; ASH=American Society of Hematology

Lunsumio (mosunetuzumab, CD20 x CD3, RG7828)

Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	2L+ FL	Relapsed or refractory CLL
Phase/study	**Phase III CELESTIMO**	**Phase Ib/II**
# of patients	N=400	N=56
Design	▪ **ARM A**: Lunsumio plus lenalidomide ▪ **ARM B:** Rituxan plus lenalidomide	▪ Lunsumio monotherapy (3L+ CLL)
Primary endpoint	▪ Progression-free survival	▪ Safety, dose-limiting toxicity and RPTD
Status	▪ FPI Q4 2021	▪ FPI Q1 2022
CT Identifier	NCT04712097	NCT05091424

FL=follicular lymphoma; r/r=relapsed/refractory; RPTD=Recommended Phase II Dose; CLL=Chronic lymphocytic leukemia

Lunsumio (mosunetuzumab, CD20 x CD3, RG7828)

Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	2L+ SCT ineligible DLBCL
Phase/study	**Phase III** **SUNMO**
# of patients	N=222
Design	▪ **ARM A:** Lunsumio plus Polivy ▪ **ARM B:** R + GemOx
Primary endpoint	▪ Progression-free survival
Status	▪ FPI Q2 2022
CT Identifier	NCT05171647

DLBCL=diffuse large B cell lymphoma; SCT=stem cell transplant; R=Rituxan/MabThera; GemOx=Gemcitabin und Oxaliplatin

Columvi (glofitamab, CD20-TCB, RG6026)

Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	Relapsed or refractory Non-Hodgkin's lymphoma (NHL)		
Phase/study	**Phase I**	**Phase Ib**	**Phase I**
# of patients	N=700	N=140	N=18-36
Design	**Cohort 1:** Single-agent dose escalation study ▪ Initial dose escalation ▪ Expansion cohort in r/r DLBCL ▪ Expansion cohort in r/r FL ▪ All patients will receive pretreatment with a single dose of Gazyva (1000mg) **Cohort 2:** Columvi plus Gazyva (i.e. continuous treatment with Gazyva)	Dose escalation and expansion ▪ **ARM A:** Columvi plus Tecentriq ▪ **ARM B:** Columvi plus Polivy	Columvi SC ▪ Part 1 dose escalation
Primary endpoint	▪ Efficacy, safety, tolerability and PK	▪ Safety	▪ Safety
Status	▪ Data presented at ASH 2018, 2020, 2021, 2022, ICML 2019, 2021, EHA 2020, 2021, 2022 and ASCO 2021, 2022 and 2023 ▪ Data published in *J Clin Oncology* 2021; 39:18:1959-1970 and *NEJM* 2022; 387:2220-2231 ▪ Filed in EU Q2 2022 and US Q4 2022 ▪ Approved in Canada Q1, US Q2 and EU Q3 2023 ▪ Follow up data in r/r DLBCL presented at ASH 2023	▪ **ARM A:** FPI Q2 2018 ▪ **ARM B:** FPI Q4 2020 ▪ Recruitment completed Q2 2022 ▪ Data presented at ASH 2019, 2021	▪ FPI Q3 2021
CT Identifier	NCT03075696	NCT03533283	ISRCTN17975931

DLBCL=diffuse large B cell lymphoma; FL=Follicular lymphoma; r/r=Relapsed or refractory; SC=subcutenous; PK=Pharmacokinetics; ASCO=American Society of Clinical Oncology; ASH=American Society of Hematology; EHA=European Hematology Association; ICML=International Conference on Malignant Lymphoma; NEJM=New England Journal of Medicine

Columvi (glofitamab, CD20-TCB, RG6026)

Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	Non-Hodgkin's lymphoma (NHL)	2L+ SCT-ineligible DLBCL	1L ctDNA high risk DLBCL
Phase/study	**Phase Ib**	**Phase III STARGLO**	**Phase II**
# of patients	Part I: 15-60 Part II: ~66-104	N=270	N=40
Design	▪ **Part I:** Dose-finding for the combination of Columvi plus G/R-CHOP in r/r indolent NHL ▪ **Part II:** Dose expansion Columvi plus G/R-CHOP or R-CHOP in 1L DLBCL ▪ **Part III:** Columvi plus R-CHP plus Polivy	▪ **ARM A:** Columvi plus gemcitabine and oxaliplatin, followed by up to 4 cycles of Columvi monotherapy ▪ **ARM B:** Rituxan in combination with gemcitabine and oxaliplatin A single dose of Gazyva will be administered 7 days prior to the first dose of Columvi	▪ Columvi plus R-CHOP (Columvi is introduced as a consolidation to R-CHOP at cycle 3-8 in patients ctDNA+ at cycle 2)
Primary endpoint	▪ Safety	▪ Overall survival	▪ EOT PET-CR
Status	▪ Part I: FPI Q1 2018 ▪ Part II: FPI Q1 2021 ▪ Recruitment completed Q1 2023 ▪ Data presented at ASH 2021, 2022, 2023 and ASCO 2023	▪ FPI Q1 2021 ▪ Recruitment completed Q1 2023	▪ FPI Q1 2022
CT Identifier	NCT03467373	NCT04408638	NCT04980222

DLBCL=diffuse large B cell lymphoma; SCT=stem cell transplant; CHOP=cyclophosphamide, doxorubicin, vincristine and prednisone; R=Rituxan/MabThera; G=Gazyva; NHL=Non-Hodgkin's lymphoma; ctDNA=circulating tumor DNA; ASH=American Society of Hematology; EOT PET-CR=End of treatment PET-complete response rate

Columvi (glofitamab, CD20-TCB, RG6026)

Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	2L+ SCT-eligible DLBCL	2L+ SCT-ineligible DLBCL	1L DLBCL fit (IPI 2-5)
Phase/study	**Phase Ib**	**Phase Ib**	**Phase III SKYGLO**
# of patients	N=40	N=112	N=1130
Design	▪ Columvi plus R-ICE (single-arm study)	▪ **ARM A:** Columvi IV plus CELMoD (CC-220 and CC-99282) ▪ **ARM B:** Lunsumio SC plus CELMoD (CC-220 and CC-99282)	▪ **ARM A:** Columvi plus Polivy plus R-CHP ▪ **ARM B:** Polivy plus R-CHP
Primary endpoint	▪ Objective response rate within 3 cycles	▪ Safety, DLT, RPTD	▪ Progression-free survival
Status	▪ FPI Q4 2022	▪ FPI Q4 2022	▪ FPI Q4 2023
CT Identifier	NCT05364424	NCT05169515	NCT06047080

DLBCL=diffuse large B cell lymphoma; DLT=Dose-limiting toxicity, RPTD=Recommended Phase II Dose; R-ICE= Rituxan plus ifosfamide, carboplatin, and etoposide; IV=Intravenous; SC=Subcutaneous; ; R-CHP=Rituxan, cyclophosphamide, hydroxydoxorubicin, prednisone; IPI=International prognostic index

Columvi (glofitamab, CD20-TCB, RG6026)

Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	Relapsed or refractory mantle cell lymphoma (MCL)
Phase/study	**Phase III** **GloBryte**
# of patients	N=182
Design	▪ **ARM A:** Columvi monotherapy ▪ **ARM B**: bendamustine + rituximab or rituximab + lenalidomide
Primary endpoint	▪ Progression-free survival by IRC
Status	▪ FPI Q4 2023
CT Identifier	NCT06084936

IRC=Independent review committee

Ocrevus (ocrelizumab, RG1594)

Humanized monoclonal antibody selectively targeting CD20+ B cells

Indication	Primary progressive multiple sclerosis (PPMS)
Phase/study	**Phase IIIb** **ORATORIO-HAND**
# of patients	N ~ 1,000
Design	120-week treatment period: ▪ **ARM A:** Ocrevus 600mg IV Q24W ▪ **ARM B:** Placebo
Primary endpoint	▪ Time to upper limb disability progression confirmed for at least 12 weeks
Status	▪ FPI Q3 2019
CT Identifier	NCT04035005

IV=intravenous

Ocrevus (ocrelizumab, RG1594)

Humanized monoclonal antibody selectively targeting CD20+ B cells

Indication	Primary progressive multiple sclerosis (PPMS)	Relapsing multiple sclerosis (RMS)	PPMS & RMS
Phase/study	**Phase IIIb GAVOTTE**	**Phase IIIb MUSETTE**	**Phase III Ocarina II[1]**
# of patients	N ~ 699	N ~ 786	N ~ 232
Design	120-week treatment period: ▪ **ARM A:** Ocrevus 600mg IV Q24W ▪ **ARM B:** Ocrevus 1200mg if BW <75kg or 1800mg if BW ≥75kg Q24W	120-week treatment period: ▪ **ARM A:** Ocrevus 600mg IV Q24W ▪ **ARM B:** Ocrevus 1200mg if BW <75kg or 1800mg if BW ≥75kg Q24W	▪ **ARM A:** Ocrevus IV ▪ **ARM B:** Ocrevus SC
Primary endpoint	▪ Superiority of Ocrevus higher dose versus approved dose on cCDP	▪ Superiority of Ocrevus higher dose versus approved dose on cCDP	▪ Serum Ocrevus area under the concentration-time curve (AUCW1-12) at week 12
Status	▪ FPI Q4 2020 ▪ Recruitment completed Q2 2023	▪ FPI Q4 2020 ▪ Recruitment completed Q4 2021	▪ FPI Q2 2022 ▪ Recruitment completed Q4 2022 ▪ Study met it's primary endpoint July 2023 ▪ Data presented at ECTRIMS 2023 ▪ Filed in EU Q3 2023 and US Q4 2023
CT Identifier	NCT04548999	NCT04544436	NCT05232825

[1]SC with Halozyme's rHuPH20/ Halozyme's human hyaluronidase
cCDP=composite confirmed disability progression; IV=intravenous; SC=Subcutaneous

Evrysdi (risdiplam, RG7916)

Oral SMN2 splicing modifier

Indication	Spinal muscular atrophy (SMA)		
Phase/study	**Phase II/III FIREFISH**	**Phase II/III SUNFISH**	**Phase II JEWELFISH**
# of patients	N=21 (Part 1), 41 (Part 2)	N=51 (Part 1), 180 (Part 2)	N=174
Design	Infants with type 1 SMA ▪ **Part I (dose-finding):** ≥4 weeks ▪ **Part II (confirmatory):** 24 months	Adult & pediatric patients with type 2 or 3 SMA: ▪ **Part I (dose-finding):** At least 12 weeks ▪ **Part II (confirmatory):** 24 months	▪ Adult and pediatric patients with previously treated SMA type 1, 2 and 3
Primary endpoint	▪ Safety, tolerability, PK/PD and efficacy	▪ Safety, tolerability, PK/PD and efficacy	▪ Safety, tolerability, PK/PD
Status	▪ Part I 12-month data presented at AAN, CureSMA and EAN 2019; 16-month data presented at WMS 2019 ▪ Part II 1-year data presented at AAN 2020, Part I 2-year data at WMS 2020 ▪ Part I data published in *NEJM* 2021;384:915-923 ▪ Part II 2-year data presented at AAN 2021 ▪ Part II 1-year data published in *NEJM* 2021;385:427-435 ▪ 3-year data presented at EPNS 2022 and 4-year data presented at Cure SMA and EAN 2023	▪ Part I 12-month data presented at AAN, CureSMA and EAN 2019; 16-month data presented at WMS 2019 ▪ Part II 1-year data presented at SMA Europe 2020, 2-year data at MDA 2021, 3-year data at MDA 2022 and 4-year data at MDA and EAN 2023 ▪ Part II 1-year data published in Lancet Neurology, 2022; 21 (1) 42-52	▪ Data presented at WMS 2017, AAN 2018, WMS 2018, CureSMA 2019, WMS 2019, CureSMA 2020 and 2021 ▪ 2-year data presented at WMS 2022
	▪ ODD granted by FDA Q1 2017 and EU Q1 2019, PRIME designation in Q4 2018 ▪ Approved in US Q3 2020 and EU Q1 2021		
CT Identifier	NCT02913482	NCT02908685	NCT03032172

In collaboration with PTC Therapeutics and SMA Foundation

SMA=Spinal muscular atrophy; SMN=survival motor neuron; PK/PD=Pharmacokinetics/Pharmacodynamics; PRIME=priority medicines; AAN=American Academy of Neurology; WMS=World Muscle Society; EAN=European Academy of Neurology; NEJM=New England Journal of Medicine; MDA=Muscular Dystrophy Association; CureSMA=Annual SMA Conference; EPNS=European Paediatric Neurology Society; ODD=Orphan drug designation

Evrysdi (risdiplam, RG7916)

Oral SMN2 splicing modifier

Indication	Spinal muscular atrophy (SMA)
Phase/study	**Phase II** **RAINBOWFISH**
# of patients	N=25
Design	▪ Infants aged from birth to 6 weeks who have been genetically diagnosed with SMA but are not yet presenting with symptoms
Primary endpoint	▪ Proportion of participants with two copies of the SMN2 gene and baseline CMAP>=1.5 millivolt who are sitting without support
Status	▪ FPI Q3 2019 ▪ Recruitment completed Q1 2022 ▪ Initial data presented at CureSMA , WMS 2021, MDA and WMS 2022 ▪ Primary data presented at WMS 2023 ▪ Filed in US and EU Q4 2021 ▪ Approved in US Q2 2022 and EU Q3 2023
CT Identifier	NCT03779334

In collaboration with PTC Therapeutics and SMA Foundation

SMN=survival motor neuron; CMAP=compound muscle action potential; WMS=World Muscle Society; CureSMA=Annual SMA Conference; MDA=Muscular Dystrophy Association

Enspryng (satralizumab, RG6168, SA237)

Anti-IL-6 receptor humanized monoclonal antibody

Indication	Neuromyelitis optica spectrum disorder (NMOSD)	
Phase/study	**Phase III** **SAkuraStar**	**Phase III** **SAkuraSky**
# of patients	N=95	N=83
Design	Enspryng monotherapy: ▪ **ARM A:** Enspryng 120mg SC monthly ▪ **ARM B:** Placebo SC monthly	Add-on therapy of Enspryng: ▪ **ARM A:** Enspryng 120mg SC monthly ▪ **ARM B:** Placebo SC monthly ▪ Both arms on top of baseline therapies: azathioprine, mycophenolate mofetil or oral corticosteroids
Primary endpoint	▪ Efficacy (time to first relapse), safety and PK/PD	▪ Efficacy (time to first relapse), safety and PK/PD
Status	▪ Primary endpoint met Q4 2018 ▪ Data presented at ECTRIMS 2019 ▪ Published in Lancet Neurology 2020; 19(5): 402-412	▪ Primary endpoint met Q3 2018 ▪ Data presented at ECTRIMS 2018 and AAN 2019 ▪ Published in *NEJM* 2019; 381:2114-2124
	▪ BTD granted by FDA Q4 2018 ▪ Filed in EU Q3 2019; US acceptance of filing Q4 2019 ▪ Approved in US Q3 2020 and EU Q2 2021	
CT Identifier	NCT02073279	NCT02028884

Trials managed by Chugai (Roche opted-in)

BTD=Breakthrough therapy designation; PK/PD=Pharmacokinetics/Pharmacodynamics; SC=Subcutaneous; ECTRIMS=European Committee for Treatment and Research in Multiple Sclerosis; AAN=American Academy of Neurology; NEJM=New England Journal of Medicine

Enspryng (satralizumab, RG6168, SA237)

Anti-IL-6 receptor humanized monoclonal antibody

Indication	Generalised myasthenia gravis (MG)	Myelin oligodendrocyte glycoprotein antibody disease (MOG-AD)	Autoimmune encephalitis (AIE)
Phase/study	**Phase III Luminesce**	**Phase III METEOROID**	**Phase III CIELO**
# of patients	N=186	N=152	N=152
Design	▪ **ARM A:** Enspryng plus standard of care ▪ **ARM B:** Placebo plus standard of care	▪ **ARM A**: Enspryng at weeks 0, 2, 4 (loading doses) and maintenance doses Q4W ▪ **ARM B:** Placebo	▪ **ARM A**: Enspryng at weeks 0, 2, 4 (loading doses) and maintenance doses Q4W ▪ **ARM B**: Placebo
Primary endpoint	▪ Mean change from baseline in total MG-ADL score at week 24 in AChR+ population	▪ Time from randomization to the first occurrence of a MOG-AD relapse	▪ Efficacy (proportion of participants with mRS score improvement ≥ 1 from baseline and no use of rescue therapy at week 24) and safety
Status	▪ ODD granted in US Q1 2021 ▪ FPI Q4 2021 ▪ Recruitment completed Q3 2023	▪ FPI Q3 2022 ▪ ODD granted by FDA in Q4 2021	▪ FPI Q3 2022 ▪ ODD granted for NMDAR AIE in US Q3 22
CT Identifier	NCT04963270	NCT05271409	NCT05503264

In collaboration with Chugai

MG-ADL= Myasthenia Gravis Activities of Daily Living; AChR=Acetylcholine receptor; MOG-AD=Myelin Oligodendrocyte Glycoprotein Antibody Disease, mRS=Modified Rankin Scale; AIE=Autoimmune encephalitis; NMDAR AIE= Anti-N-Methyl-D-Aspartic Acid Receptor Autoimmune Encephalitis; ODD=Orphan drug designation

Gazyva (obinutuzumab, RG7159)

Immunology development program

Indication	Lupus nephritis		Membranous nephropathy
Phase/study	**Phase II NOBILITY**	**Phase III REGENCY**	**Phase III MAJESTY**
# of patients	N=126	N=252	N=140
Design	▪ **ARM A:** Gazyva 1000mg IV plus MMF / mycophenolic acid ▪ **ARM B:** Placebo IV plus MMF/ mycophenolic acid	▪ **ARM A:** Gazyva 1000mg IV (6 doses through Week 52) plus MFF ▪ **ARM B:** Gazyva1000 mg IV (5 doses through Week 52) plus MFF ▪ **ARM C:** Placebo IV plus MFF	▪ **ARM A:** Gazyva 1000mg IV on top of renin-angiotensin inhibitors ▪ **ARM B:** Tacrolimus treatment for 12 months
Primary endpoint	▪ Percentage of participants who achieve complete renal response (CRR)	▪ Percentage of participants who achieve complete renal response (CRR)	▪ Percentage of patients who achieve complete remission at week 104
Status	▪ Primary endpoint met Q2 2019 ▪ BTD granted by the FDA Q3 2019 ▪ Data presented at ASN and ACR 2019 ▪ Published in *Ann Rheum Dis* 2022 Jan;81(1):100-107	▪ FPI Q3 2020 ▪ Recruitment completed Q1 2023	▪ FPI Q2 2021 ▪ Recruitmet completed Q4 2023
CT Identifier	NCT02550652	NCT04221477	NCT04629248

In collaboration with Biogen

BTD=Breakthrough therapy designation; IV=Intravenous; ASN=American Society of Nephrology; ACR=American College of Rheumatology; MMF=mycophenolate mofetil

Gazyva (obinutuzumab, RG7159)

Immunology development program

Indication	Systemic lupus erythematosus (SLE)	Childhood onset idiopathic nephrotic syndrome*
Phase/study	**Phase III** **ALLEGORY**	**Phase III** **INShore**
# of patients	N=300	N=80
Design	▪ **ARM A:** Gazyva 1000mg IV on Day 1 and Weeks 2, 24 and 26. ▪ **ARM B:** Placebo IV	▪ **ARM A:** Gazyva plus oral steroids ▪ **ARM B:** Mycophenolate mofetil (MMF) plus oral steroids
Primary endpoint	▪ Percentage of participants who achieve Systemic Lupus Erythematosus Responder Index (SRI) at week 52	▪ Percentage of participants with sustained complete remission at 1 year
Status	▪ FPI Q4 2021	▪ FPI Q1 2023
CT Identifier	NCT04963296	NCT05627557

In collaboration with Biogen
*also known as pediatric nephrotic syndrome (PNS); IV=Intravenous

Lunsumio (mosunetuzumab, CD20 x CD3, RG7828)

Bispecific anti-CD20/CD3 antibody engaging T and B cells simultaneously

Indication	Systemic lupus erythematosus (SLE)
Phase/study	**Phase I**
# of patients	N=50
Design	▪ **ARM A:** Mosunetuzumab SC on either Day 1 or on Days 1 and 8 ▪ **ARM B:** Fractionated (divided) dose of mosunetuzumab SC on Days 1 and 8
Primary endpoint	▪ Safety
Status	▪ FPI Q1 2022
CT Identifier	NCT05155345

In collaboration with Biogen
SC=subcutaneous

Xolair (omalizumab, RG3648)

Humanized monoclonal antibody that selectively binds to IgE

Indication	Food allergy
Phase/study	**Phase III** **OUtMATCH**[1]
# of patients	N=180
Design	▪ Xolair by SC injection either Q2W or Q4W for 16 to 20 weeks
Primary endpoint	▪ Number of participants who successfully consume ≥600mg of peanut protein without dose-limiting symptoms
Status	▪ FPI Q3 2019 ▪ Study met primary endpoint Q3 2023 ▪ Filed in US Q3 2023* ▪ Priority review granted by FDA Q4 2023
CT Identifier	NCT03881696

In collaboration with Novartis; 1 Sponsor of the study is the National Institute of Allergy and Infectious Diseases (NIAID)
*Filing acceptance Q4 2023; IgE=Immunoglobulin E; SC=Subcutaneous

Susvimo (PDS, RG6321)

First eye implant to achieve sustained delivery of a biologic medicine

Indication	Wet age-related macular degeneration (wAMD)		
Phase/study	**Phase III Archway**	**Phase II+III extension Portal**	**Phase IIIb Velodrome**
# of patients	N=418	N=1,000	N=442
Design	▪ **ARM A:** PDS Q24W ▪ **ARM B:** Intravitreal ranibizumab Q4W	▪ Patients from LADDER or Archway receive refills of ranibizumab Q24W (patients without the PDS will receive the PDS and subsequent refills) ▪ Patients from Velodrome, who don't meet the criteria for randomization to receive refills Q36W at week 24, receive refills of ranibizumab q24w ▪ Patients who complete or withdraw from Velodrome, receive refills of ranibizumab q24w	▪ **ARM A:** PDS Q36W ▪ **ARM B:** PDS Q24W
Primary endpoint	▪ Change in BCVA from baseline at the average of week 36 and week 40	▪ Safety and long term efficacy	▪ Change in BCVA from baseline averaged over weeks 68 and 72
Status	▪ Study met primary endpoint Q2 2020 ▪ Data presented at ASRS 2020, 44/48 week data at Angiogenesis 2021 and 2-year data at Angiogenesis 2022 ▪ Filed in US (PRIME) and EU Q2 2021 ▪ Approved in US Q4 2021	▪ FPI Q3 2018	▪ FPI Q3 2021
CT Identifier	NCT03677934	NCT03683251	NCT04657289

BCVA=best corrected visual acuity; wAMD=wet age-related macular degeneration; ASRS=American Society of Retinal Specialists; PDS=Port Delivery System with ranibizumab; PRIME=Priority review

Susvimo (PDS, RG6321)

First eye implant to achieve sustained delivery of a biologic medicine

Indication	Diabetic macular edema (DME)	Diabetic retinopathy (DR) without center-involved diabetic macular edema (DME)
Phase/study	**Phase III Pagoda**	**Phase III Pavilion**
# of patients	N=634	N=174
Design	▪ **ARM A:** PDS Q24W ▪ **ARM B:** Intravitreal ranibizumab Q4W	▪ **ARM A:** Intravitreal ranibizumab (X2) followed by PDS implant (refill Q36W) ▪ **ARM B:** Q4W comprehensive clinical monitoring until participants receive PDS (refill Q36W)
Primary endpoint	▪ Change in BCVA from baseline at the average of week 60 and week 64	▪ Percentage of participants with a ≥2-step improvement from baseline on the ETDRS-DRSS at Week 52
Status	▪ FPI Q3 2019 ▪ Recruitment completed Q2 2021 ▪ Study met its primary endpoint Q4 2022 ▪ Data presented at Angiogenesis 2023	▪ FPI Q3 2020 ▪ Recruitment completed Q3 2021 ▪ Study met its primary endpoint Q4 2022 ▪ Data presented at Angiogenesis 2023
CT Identifier	NCT04108156	NCT04503551

BCVA=best corrected visual acuity; ETDRS=Early Treatment Diabetic Retinopathy Study; DRSS=Diabetic Retinopathy Severity Scale; PDS=Port Delivery System with ranibizumab

Vabysmo (faricimab, RG7716)

Bispecific antibody for the eye which targets and inhibits two signalling pathways (Ang-2 and VEGF-A)

Indication	Center-involving diabetic macular edema (CI-DME)	
Phase/study	**Phase III YOSEMITE**	**Phase III RHINE**
# of patients	N=940	N=951
Design	▪ **ARM A:** Faricimab Q8W ▪ **ARM B:** Faricimab PTI up to Q16W ▪ **ARM C:** Aflibercept, Q8W	▪ **ARM A:** Faricimab Q8W ▪ **ARM B:** Faricimab PTI up to Q16W ▪ **ARM C:** Aflibercept, Q8W
Primary endpoint	▪ Change from baseline in BCVA at 1 year	▪ Change from baseline in BCVA at 1 year
Status	▪ Study met primary endpoint Q4 2020 ▪ Data presented at Angiogenesis 2021	▪ Study met primary endpoint Q4 2020 ▪ Data presented at Angiogenesis 2021
	▪ Filed in US and EU Q2 2021 ▪ Published in the Lancet 2022 Feb 19;399(10326):741-755. ▪ 2-year data presented at Angiogenesis 2022 ▪ Approved in US Q1 2022 and EU Q3 2022 ▪ Post-hoc data indicating fast retinal drying presented at ARVO 2023	
CT Identifier	NCT03622580	NCT03622593

Ang-2=Angiopoietin-2; VEGF=Vascular endothelial growth factor; PTI=Personalized Treatment Interval; BCVA=best corrected visual acuity, ARVO=Association for Research in Vision and Ophthalmology

Vabysmo (faricimab, RG7716)

Bispecific antibody for the eye which targets and inhibits two signalling pathways (Ang-2 and VEGF-A)

Indication	Wet age related macular degeneration (wAMD)	
Phase/study	**Phase III TENAYA**	**Phase III LUCERNE**
# of patients	N=671	N=658
Design	▪ **ARM A:** Faricimab 6.0mg Q16W flexible after 4 IDs ▪ **ARM B:** Aflibercept 2.0mg Q8W after 3 IDs	▪ **ARM A:** Faricimab 6.0mg Q16W flexible after 4 IDs ▪ **ARM B:** Aflibercept 2.0mg Q8W after 3 IDs
Primary endpoint	▪ Change from baseline in BCVA week 40, 44 & 48	▪ Change from baseline in BCVA week 40, 44 & 48
Status	▪ Study met primary endpoint Q1 2021 ▪ Data presented at Angiogenesis 2021	▪ Study met primary endpoint Q1 2021 ▪ Data presented at Angiogenesis 2021
	▪ Filed in US and EU Q2 2021 ▪ Published in Lancet 2022 Feb 19;399(10326):729-740 ▪ Approved in US Q1 2022 and EU Q3 2022 ▪ 2-year data presented at ASRS 2022 ▪ Post-hoc data indicating fast retinal drying presented at ARVO 2023	
CT Identifier	NCT03823287	NCT03823300

BCVA=best corrected visual acuity; Ang-2=Angiopoietin-2; VEGF=Vascular endothelial growth factor; IDs=initiating doses; ASRS=American Society of Retina Specialists, ARVO=Association for Research in Vision and Ophthalmology

Vabysmo (faricimab, RG7716)

Bispecific antibody for the eye which targets and inhibits two signalling pathways (Ang-2 and VEGF-A)

Indication	Macular edema (ME) secondary to branch retinal vein occlusion (RVO)	Macular edema (ME) secondary to central retinal vein occlusion (RVO)
Phase/study	**Phase III** **BALATON**	**Phase III** **COMINO**
# of patients	N=570	N=750
Design	▪ **ARM A:** Faricimab, Q4W/PTI ▪ **ARM B:** Aflibercept, Q4W	▪ **ARM A:** Faricimab, Q4W/PTI ▪ **ARM B:** Aflibercept, Q4W
Primary endpoint	▪ Change from baseline in BCVA at week 24	▪ Change from baseline in BCVA at week 24
Status	▪ FPI Q1 2021 ▪ Recruitment completed Q1 2022 ▪ Study met its primary endpoint Q4 2022 ▪ Data presented at Angiogenesis 2023 ▪ Filed in US Q2 2023 and EU Q3 2023 ▪ Approved in US Q4 2023	▪ FPI Q1 2021 ▪ Recruitment completed Q1 2022 ▪ Study met its primary endpoint Q4 2022 ▪ Data presented at Angiogenesis 2023 ▪ Filed in US Q2 2023 and EU Q3 2023 ▪ Approved in US Q4 2023
CT Identifier	NCT04740905	NCT04740931

PTI=Personalized Treatment Interval; BCVA=best corrected visual acuity; Ang-2=Angiopoietin-2; VEGF=Vascular endothelial growth factor

Enspryng (satralizumab, RG6168, SA237)

Anti-IL-6 receptor humanized monoclonal antibody

Indication	Thyroid eye disease	
Phase/study	**Phase III** **SatraGo-1**	**Phase III** **SatraGo-2**
# of patients	N=120	N=120
Design	▪ **ARM A:** Satralizumab at weeks 0, 2, 4 (loading doses) and maintenance doses Q4W ▪ **ARM B:** Placebo	▪ **ARM A:** Satralizumab at weeks 0, 2, 4 (loading doses) and maintenance doses Q4W ▪ **ARM B:** Placebo
Primary endpoint	▪ Proportion of participants with active disease achieving ≥ 2 mm reduction in proptosis from baseline (Day 1) at week 24 in the study eye, provided there is no deterioration of proptosis (≥ 2mm increase) in the fellow eye.	Proportion of participants with active disease achieving ≥ 2 mm reduction in proptosis from baseline (Day 1) at week 24 in the study eye, provided there is no deterioration of proptosis (≥ 2mm increase) in the fellow eye.
Status	▪ FPI Q4 2023	FPI Q4 2023
CT Identifier	NCT05987423	NCT06106828

In collaboration with Chugai

Xofluza (baloxavir marboxil, RG6152, S-033188)

Small molecule, novel CAP-dependent endonuclease inhibitor

Indication	Influenza		
Phase/study	**Phase III** **miniSTONE 1 (0-1 year old)**	**Phase III** **miniSTONE 2 (1- <12 years old)**	**Phase IIIb** **CENTERSTONE**
# of patients	N=30	N=176	N=3,160
Design	Healthy pediatric patients from birth to <1 year with influenza-like symptoms receive Xofluza on Day 1	Healthy pediatric patients 1 to <12 years of age with influenza-like symptoms ▪ **ARM A:** Xofluza ▪ **ARM B:** Tamiflu	Reduction of direct transmission of influenza from otherwise healthy patients to household contacts ▪ **ARM A:** Xofluza ▪ **ARM B:** Placebo
Primary endpoint	▪ Safety	▪ Safety	▪ Percentage of household contacts who are PCR-positive for influenza by day 5 post randomization of index patients
Status	▪ FPI Q1 2019 ▪ Recruitment completed Q3 2023	▪ Primary endpoint met Q2 2019 ▪ Data presented at OPTIONS X 2019 ▪ Filed in US Q1 2020 and EU Q4 2021 ▪ Data published in *Pediatric Infectious Disease* 2020 Aug;39(8):700-705 ▪ Approved in the US (age 5 years and older) Q3 2022 , EU Jan 2023 and China (age 5 years and older) Q1 2023	▪ FPI Q4 2019
CT Identifier	NCT03653364	NCT03629184	NCT03969212

In collaboration with Shionogi & Co., Ltd.
CAP=Catabolite Activating Protein

Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

Spark

Pharma sales appendix

Diagnostics sales appendix

Foreign exchange rates information

Tiragolumab (anti-TIGIT, RG6058, MTIG7192A)

Monoclonal antibody targeting the immune checkpoint inhibitor TIGIT

Indication	1L NSCLC PD-L1 TPS>50%	Stage III unresectable 1L NSCLC
Phase/study	**Phase III** **SKYSCRAPER-01**	**Phase III** **SKYSCRAPER-03**
# of patients	N=500-560	N=800
Design	▪ **ARM A:** Tiragolumab plus Tecentriq ▪ **ARM B:** Placebo plus Tecentriq	▪ **ARM A:** Tiragolumab plus Tecentriq for up to 12 months ▪ **ARM B:** Durvalumab for up to 12 months
Primary endpoint	▪ Overall survival and progression-free survival	▪ Progression-free survival
Status	▪ FPI Q1 2020 ▪ Recruitment completed Q3 2021 ▪ Study did not meet one of its primary endpoints, PFS, Q2 2022	▪ FPI Q3 2020 ▪ Recruitment completed Q2 2023
CT Identifier	NCT04294810	NCT04513925

NSCLC=Non-small cell lung cancer; PD-L1=Programmed cell death-ligand 1; TPS=Tumor Proportion Score; PFS=Progression-free survival

Tiragolumab (anti-TIGIT, RG6058, MTIG7192A)

Monoclonal antibody targeting the immune checkpoint inhibitor TIGIT

Indication	Metastatic and/or recurrent PD-L1+ cervical cancer (CC)	Neoadjuvant and adjuvant NSCLC	1L non-squamous NSCLC
Phase/study	**Phase II SKYSCRAPER-04**	**Phase II SKYSCRAPER-05**	**Phase III SKYSCRAPER-06**
# of patients	N=172	N=82	N=540
Design	▪ **ARM A:** Tiragolumab plus Tecentriq ▪ **ARM B:** Tecentriq	▪ **ARM A:** (PD-L1 high) neoadjuvant tiragolumab plus Tecentriq followed by adjuvant tiragolumab plus Tecentriq or adjuvant chemotherapy ▪ **ARM B:** (PD-L1 all-comers) neoadjuvant tiragolumab plus Tecentriq plus chemo followed by adjuvant tiragolumab plus Tecentriq	▪ **ARM A:** Tiragolumab plus Tecentriq plus pemetrexed plus chemotherapy followed by maintenance tiragolumab plus Tecentriq plus pemetrexed ▪ **ARM B:** Placebo plus pembrolizumab plus pemetrexed plus chemotherapy followed by maintenance placebo plus pembrolizumab plus pemetrexed
Primary endpoint	▪ Objective response rate	▪ Pathologic complete response, major pathological response and safety	▪ Objective response rate, progression-free survival and overall survival
Status	▪ FPI Q2 2020	▪ FPI Q2 2021	▪ FPI Q4 2020
CT Identifier	NCT04300647	NCT04832854	NCT04619797

NSCLC=Non-small cell lung cancer; PD-L1=Programmed cell death-ligand 1

Tiragolumab (anti-TIGIT, RG6058, MTIG7192A)

Monoclonal antibody targeting the immune checkpoint inhibitor TIGIT

Indication	Locally advanced esophageal cancer (EC)	1L esophageal cancer (EC)	1L recurrent/metastatic PD-L1 positive squamous cell head and neck carcinoma (SCCHN)
Phase/study	**Phase III SKYSCRAPER-07**	**Phase III SKYSCRAPER-08**	**Phase II SKYSCRAPER-09**
# of patients	N=750	N=500	N=120
Design	▪ **ARM A:** Tiragolumab plus Tecentriq ▪ **ARM B:** Tecentriq plus placebo ▪ **ARM C:** Placebo plus placebo	▪ **ARM A:** Tiragolumab plus Tecentriq plus cisplatin and paclitaxel ▪ **ARM B:** Placebo plus placebo plus cisplatin and paclitaxel	▪ **ARM A:** Tiragolumab plus Tecentriq ▪ **ARM B:** Tecentriq plus placebo
Primary endpoint	▪ Progression-free survival (A vs C) ▪ Overall survival (A vs C, hierarchical, B vs C hierarchical)	▪ Overall survival and progression-free survival	▪ Objective response rate
Status	▪ FPI Q3 2020 ▪ Recruitment completed Q3 2023	▪ FPI Q4 2020 ▪ Recruitment completed Q4 2021	▪ FPI Q1 2021 ▪ Recruitment completed Q2 2022
CT Identifier	NCT04543617	NCT04540211	NCT04665843

Tiragolumab (anti-TIGIT, RG6058, MTIG7192A)

Monoclonal antibody targeting the immune checkpoint inhibitor TIGIT

Indication	Locally advanced, recurrent or metastatic solid tumors	1L HCC
Phase/study	**Phase II** **SKYSCRAPER-11**	**Phase III** **SKYSCRAPER-14**
# of patients	N=60	N=650
Design	▪ Tiragolumab plus Tecentriq IV FDC	▪ **ARM A:** Tecentriq plus Avastin plus tiragolumab ▪ **ARM B:** Tecentriq plus Avastin plus placebo
Primary endpoint	▪ Safety	▪ Progression-free survival (INV=Investigator-assessed); Overall survival
Status	▪ FPI Q2 2023	▪ FPI Q3 2023
CT Identifier	NCT05661578	NCT05904886

FDC=Fixed-dose combination; IV=Intravenous; HCC=Hepatocellular cancer; INV=Investigator-assessed

Tiragolumab (anti-TIGIT, RG6058, MTIG7192A)

Monoclonal antibody targeting the immune checkpoint inhibitor TIGIT

Indication	Solid tumors	NSCLC
Phase/study	**Phase I**	**Phase II CITYSCAPE**
# of patients	N=540	N=135
Design	▪ **Phase Ia:** Dose escalation and expansion of tiragolumab ▪ **Phase Ib:** Dose escalation and expansion of tiragolumab in combination with Tecentriq and/or other anti-cancer therapies	▪ **ARM A:** Tecentriq plus tiragolumab ▪ **ARM B:** Tecentriq monotherapy
Primary endpoint	▪ Safety, tolerability, PK variability and preliminary efficacy	▪ Overall response rate and progression-free survival
Status	▪ Data presented at AACR 2020	▪ Data presented at ASCO 2020 and WCLC and ESMO IO 2021 ▪ BTD granted by FDA Q4 2020 ▪ Data published in *Lancet Oncol* 2022 Jun;23(6):781-792
CT Identifier	NCT02794571	NCT03563716

BTD=Breakthrough therapy designation; PK=Pharmacokinetics; ASCO=American Society of Clinical Oncology; AACR=American Association for Cancer Research; WCLC=World Conference on Lung Cancer; ESMO IO=European Society for Medical Oncology - Immuno-Oncology

Inavolisib (RG6114, GDC-0077)

A potent, orally available, and selective PI3Kα inhibitor

Indication	PIK3CA-mutant HR-positive metastatic breast cancer (mBC)	post CDKi HR-positive breast cancer	PIK3CA mutant solid tumors and metastatic ER+ HER2-negative breast cancer
Phase/study	**Phase III INAVO120**	**Phase III INAVO121**	**Phase I**
# of patients	N=400	N=400	N=256
Design	▪ **ARM A:** Inavolisib plus palbociclib plus fulvestrant ▪ **ARM B:** Placebo plus palbociclib plus fulvestrant	▪ **ARM A:** Inavolisib plus fulvestrant ▪ **ARM B:** alpelisib plus fulvestrant	Monotherapy and in combination with standard of care (letrozole; letrozole plus palbociclib; fulvestrant) ▪ **Stage 1:** Dose escalation ▪ **Stage 2:** Dose expansion
Primary endpoint	▪ Progression-free survival	▪ Progression-free survival	▪ Safety, tolerability and pharmacokinetics
Status	▪ FPI Q1 2020 ▪ Recruitment completed Q3 2023 ▪ Study met its primary endpoint of PFS Q4 2023 ▪ Data presented at SABCS 2023	▪ FPI Q2 2023	▪ FPI Q4 2016 ▪ Preclinical/molecule discovery data presented at AACR 2017 ▪ Data presented at SABCS 2019, 2020 and 2021
CT Identifier	NCT04191499	NCT05646862	NCT03006172

ER=Estrogen receptor; HR=Hormone receptor; HER2=Human Epidermal growth factor Receptor 2; PI3K=Phosphoinositide 3-Kinase; AACR=American Association for Cancer Research; SABCS=San Antonio Breast Cancer Symposium; CDKi= Cyclin-dependent kinase inhibitor

Inavolisib (RG6114, GDC-0077)

A potent, orally available, and selective PI3Kα inhibitor

Indication	1L HER2-positive PIK3CA mutant metastatic breast cancer (mBC)
Phase/study	**Phase III** **INAVO122**
# of patients	N=230
Design	▪ **ARM A:** Inavolisib plus Phesgo after induction therapy with Phesgo + taxane ▪ **ARM B:** Placebo plus Phesgo after induction therapy with Phesgo + taxane
Primary endpoint	▪ Progression-free survival
Status	▪ FPI Q3 2023
CT Identifier	NCT05894239

HER2=Human Epidermal growth factor Receptor 2; PI3K=Phosphoinositide 3-Kinase

Giredestrant (SERD (3),RG6171, GDC-9545)

A selective estrogen receptor degrader or downregulator

Indication	ER+ HER2-negative metastatic breast cancer (mBC)	ER+ HER2-negative Stage I-III operable breast cancer (BC)	Neoadjuvant ER-positive breast cancer (BC)
Phase/study	**Phase I**	**Phase I**	**Phase II coopERA Breast Cancer**
# of patients	N=181	N=75	N=221
Design	▪ Dose escalation and expansion at RPTD ▪ Giredestrant monotherapy and in combination with palbociclib and/or LHRH agonist	▪ Open-label, pre-operative administration ▪ Dose escalation	▪ **ARM A:** Giredestrant followed by giredestrant plus palbociclib ▪ **ARM B:** Anastrazole followed by anastrazole plus palbociclib
Primary endpoint	▪ Safety	▪ Safety, tolerability and PK/PD	▪ Safety, tolerability and PK/PD
Status	▪ FPI Q4 2017 ▪ Data presented at SABCS 2019, 2021 and ASCO 2020, 2021	▪ FPI Q3 2019 ▪ Data presented at ASCO 2021	▪ FPI Q3 2020 ▪ Data presented at ESMO and SABCS 2021; ASCO 2022 ▪ Data (biomarker subgroup analysis) presented at ESMO 2022 ▪ Data published in Lancet Oncology 2023 Sept; 24: 1029–41
CT Identifier	NCT03332797	NCT03916744	NCT04436744

ER=Estrogen receptor; HER2=Human Epidermal growth factor Receptor; RPTD=Recommended phase II dose; LHRH=Luteinizing hormone–releasing hormone; PK/PD=Pharmacokinetics/Pharmacodynamics; SABCS=San Antonio Breast Cancer Symposium; ASCO=American Society of Clinical Oncology

Giredestrant (SERD (3),RG6171, GDC-9545)

A selective estrogen receptor degrader or downregulator

Indication	1L ER-positive metastatic breast cancer (mBC)	Adjuvant ER-positive breast cancer (BC)
Phase/study	**Phase III** **persevERA Breast Cancer**	**Phase III** **lidERA Breast Cancer**
# of patients	N=978	N=4,100
Design	▪ **ARM A:** Giredestrant plus palbociclib ▪ **ARM B:** Letrozole plus palbociclib	▪ **ARM A:** Giredestrant monotherapy ▪ **ARM B:** Tamoxifen or aromatase inhibitor
Primary endpoint	▪ Progression-free survival	▪ Invasive disease-free survival
Status	▪ FPI Q4 2020 ▪ Recruitment completed Q1 2023	▪ FPI Q3 2021
CT Identifier	NCT04546009	NCT04961996

ER=Estrogen receptor

Giredestrant (SERD (3),RG6171, GDC-9545)

A selective estrogen receptor degrader or downregulator

Indication	1L ER-positive/HER2-positive breast cancer (BC)	Grade 1 endometrial cancer	ET resistant ER+/HER2-negative breast cancer (BC)
Phase/study	**Phase III heredERA**	**Phase II endomERA**	**Phase III pionERA**
# of patients	N=812	N=45	N=1050
Design	Induction Phesgo plus taxane followed by maintenance with either: ▪ **ARM A:** Giredestrant plus Phesgo ▪ **ARM B:** Phesgo	▪ Giredestrant once a day (QD) on days 1 to 28 of each 28-day cycle for 6 cycles	▪ **ARM A**: Giredestrant plus CDK4/6i ▪ **ARM B**: Fulvestrant plus CDK4/6i
Primary endpoint	▪ Progression-free survival	▪ Percentage of participants who have regression by 6 months	▪ Progression-free survival in ESR1m and ITT
Status	▪ FPI Q2 2022	▪ FPI Q2 2023	▪ FPI Q4 2023
CT Identifier	NCT05296798	NCT05634499	NCT06065748

ER=Estrogen receptor; HER2=Human Epidermal growth factor Receptor; Phesgo=FDC of Perjeta and Herceptin for SC administration ; ITT=Intention to treat

Divarasib (KRAS G12C inhibitor, RG6330, GDC-6036)

A potent, orally available, and selective inhibitor of the KRAS G12C mutant protein

Indication	Advanced or metastatic solid tumors with a KRAS G12C mutation	2L NSCLC	2L, 1L metastatic colorectal cancer (mCRC)
Phase/study	**Phase I**	**Phase II/III B-FAST***	**Phase Ib INTRINSIC**
# of patients	N=438	Modular design	Modular design
Design	Monotherapy and combinations of divarasib with other anti-cancer therapies	**Cohort G (KRAS G12C)** ▪ **ARM A:** divarasib ▪ **ARM B:** Docetaxel	Single arm studies: ▪ **Cohort E** (1L+ CRC): divarasib + cetuximab + FOLFOX ▪ **Cohort F** (2L+ CRC): divarasib + cetuximab ▪ **Cohort G** (1L+ CRC): divarasib + cetuximab + FOLFIRI
Primary endpoint	▪ Safety	▪ Progression-free survival	▪ Safety
Status	▪ FPI Q3 2020 ▪ Data presented at WCLC 2022, ESMO 2022 ▪ Data published in *N Engl J Med* 2023 Aug 24;389(8):710-721	▪ BTD granted by FDA Q3 2022 ▪ FPI Q4 2022	▪ FPI Q1 2023
CT Identifier	NCT04449874	NCT03178552	NCT04929223

*Only cohorts with active recruitment shown; NSCLC=Non-small cell lung cancer; WCLC=World Conference on Lung Cancer; ESMO=European Society for Medical Oncology; BTD=Breakthrough therapy designation, CRC=Colorectal cancer

Divarasib (KRAS G12C inhibitor, RG6330, GDC-6036)

A potent, orally available, and selective inhibitor of the KRAS G12C mutant protein

Indication	1L NSCLC
Phase/study	**Phase Ib** **KRASCENDO 170**
# of patients	N=60
Design	▪ **Cohort A**: Combination of divarasib plus pembrolizumab (PD-L1+ NSCLC) ▪ **Cohort B:** Combination of divarasib plus pembrolizumab plus carboplatin/cisplatin plus pemetrexed
Primary endpoint	▪ Safety, tolerability
Status	▪ **Cohort A**: FPI Q2 2023 ▪ **Cohort B**: FPI expected Q1 2024
CT Identifier	NCT05789082

NSCLC=Non-small cell lung cancer; PD-L1=Programmed cell death-ligand

Crovalimab (RG6107, SKY59)

A humanized monoclonal antibody against complement C5

Indication	Paroxysmal nocturnal hemoglobinuria (PNH)	Paroxysmal nocturnal hemoglobinuria (PNH) patients switching from a C5 inhibitor
Phase/study	**Phase I/II COMPOSER**	**Phase III COMMODORE 1**
# of patients	N=59	N=89 (ARMs A/B)
Design	Healthy volunteers and treatment naïve and pretreated patients with PNH: ▪ **Part I:** Single ascending dose study in healthy subjects ▪ **Part II:** Intra-patient single ascending dose study in PNH patients ▪ **Part III:** Multiple-dose study in PNH patients ▪ **Part IV:** Dose confirmation in PNH patients	▪ **ARM A:** Crovalimab ▪ **ARM B:** Eculizumab ▪ **ARM C:** Patients switching to crovalimab from ravulizumab, higher than labeled doses of eculizumab & C5 SNP patients (descriptive-arm)
Primary endpoint	▪ Safety, PK, PD	▪ Safety
Status	▪ Nonclinical data published in Scientific Reports 2017 Apr; 7(1):1080 ▪ Data presented for Part 2 and 3 at ASH 2018 and 2019	▪ FPI Q3 2020 ▪ Study results in Q1 2023 supported the favorable benefit-risk profile of crovalimab, as seen in the pivotal COMMODORE 2 study ▪ Data presented at EHA 2023 ▪ Filed in US and EU Q2 2023
CT Identifier	NCT03157635	NCT04432584

In collaboration with Chugai

ASH=American Society of Hematology; PNH=Paroxysmal nocturnal hemoglobinuria; PK/PD=Pharmacokinetics/Pharmacodynamics

Crovalimab (RG6107, SKY59)

A humanized monoclonal antibody against complement C5

Indication	Paroxysmal nocturnal hemoglobinuria (PNH) C5 inhibitor naive patients	Paroxysmal nocturnal hemoglobinuria (PNH) C5 inhibitor naive patients (China only)
Phase/study	**Phase III** **COMMODORE 2**	**Phase III** **COMMODORE 3**
# of patients	N=204	N=51
Design	▪ **ARM A:** Crovalimab ▪ **ARM B:** Eculizumab	▪ Crovalimab loading dose IV on Day 1, followed by weekly crovalimab SC doses for 4 weeks
Primary endpoint	▪ Non-inferiority of crovalimab compared to eculizumab: ▪ % patients with transfusion avoidance from baseline through week 25 ▪ % patients with haemolysis control, as measured by LDH <=1.5ULN from week 5-25	▪ Percentage of patients with transfusion avoidance from baseline through week 25 ▪ Mean percentage of participants with hemolysis control (week 5 through week 25)
Status	▪ FPI Q4 2020 ▪ Recruitment completed Q2 2022 ▪ Study met its primary endpoint Q1 2023 ▪ Data presented at EHA 2023 ▪ Filed in US and EU Q2 2023	▪ FPI Q1 2021; Recruitment completed Q3 2021 ▪ Study met its co-primary endpoints Q1 2022 ▪ Filed in China (priority review) Q3 2022 ▪ Data presented at ASH 2022
CT Identifier	NCT04434092	NCT04654468

In collaboration with Chugai

LDH=Lactate Dehydrogenase; ULN=Upper Limit of Normal; IV=Intravenous; SC=Subcutaneous, ASH=American Society of Hematology

Crovalimab (RG6107, SKY59)

A humanized monoclonal antibody against complement C5

Indication	Atypical hemolytic uremic syndrome (aHUS) study 1 - adults	Atypical hemolytic uremic syndrome (aHUS) study 2 - paediatrics
Phase/study	**Phase III COMMUTE-a**	**Phase III COMMUTE-p**
# of patients	N=90	N=35
Design	Single-arm study of aHUS patients ▪ **Cohort 1**: not previously treated with C5i ▪ **Cohort 2:** switching from C5i ▪ **Cohort 3:** known C5 polymorphism	Single-arm study of aHUS patients ▪ **Cohort 1:** not previously treated with C5i ▪ **Cohort 2:** switching from C5i ≤18y/o ▪ **Cohort 3:** previously treated with C5i (includes participants with known C5 polymorphism)
Primary endpoint	▪ Cohort 1+3: proportion of patients with complete TMA response anytime between baseline and week 25 ▪ Cohort 2: proportion of patients with maintained TMA control from baseline through week 25	▪ Cohort 1: proportion of patients with complete TMA response anytime between baseline and week 25 ▪ Cohort 2: proportion of patients with maintained TMA control from baseline through week 25
Status	▪ FPI Q4 2021	▪ FPI Q4 2021
CT Identifier	NCT04861259	NCT04958265

In collaboration with Chugai

aHUS=Atypical Hemolytic Uremic Syndrome; C5i=C5 inhibitor; TMA=thrombotic microangiopathy

Crovalimab (RG6107, SKY59)

A humanized monoclonal antibody against complement C5

Indication	Sickle cell disease (SCD) acute treatment	Sickle cell disease (SCD) chronic VOC prevention
Phase/study	**Phase Ib CROSSWALK-a**	**Phase IIa CROSSWALK-c**
# of patients	N=30	N=90
Design	▪ **ARM A:** Crovalimab ▪ **ARM B:** Placebo	▪ **ARM A:** Crovalimab ▪ **ARM B:** Placebo
Primary endpoint	▪ Safety	▪ VOC rate, up to 48 weeks
Status	▪ FPI Q1 2022	▪ FPI Q1 2022
CT Identifier	NCT04912869	NCT05075824

VOC=Vaso-occlusive crises

Crovalimab (RG6107, SKY59)

A humanized monoclonal antibody against complement C5

Indication	Lupus nephritis (LN)
Phase/study	**Phase I**
# of patients	N=15
Design	▪ Single-arm study of patients with active class III, IV, or V lupus nephritis and urine protein-to-creatinine ratio >=1.5 g/g ▪ All patients to receive crovalimab IV loading dose and subsequent crovalimab SC q1w (Day 1, Week 1,2 and 3) followed by corvalimab SC Q4W
Primary endpoint	▪ PK, safety
Status	▪ FPI Q1 2023
CT Identifier	ISRCTN12809537

In collaboration with Chugai
IV=Intravenous, SC=Subcutaneous, PK=Pharmacokinetics

Astegolimab (RG6149, Anti-ST2)

A monoclonal antibody that selective binds to ST2

Indication	Chronic obstructive pulmonary disease (COPD)		
Phase/study	**Phase II** **COPD-ST2OP**	**Phase IIb** **ALIENTO**	**Phase III** **ARNASA**
# of patients	N=81	N=1,290	N=1,290
Design	▪ Astegolimab SC 490mg Q4W for 48 weeks	▪ **ARM A:** SC astegolimab Q2W ▪ **ARM B:** SC astegolimab Q4W ▪ **ARM C:** SC placebo Q2W	▪ **ARM A:** SC astegolimab Q2W ▪ **ARM B:** SC astegolimab Q4W ▪ **ARM C:** SC placebo Q2W
Primary endpoint	▪ Number of moderate to severe exacerbation	▪ Annualized rate of moderate and severe COPD exacerbations over the 52-week treatment period	▪ Annualized rate of moderate and severe COPD exacerbations over the 52-week treatment period
Status	▪ Published in Lancet Respir Med 2022;10(5):469-477. doi: 10.1016/S2213-2600(21)00556-7	▪ FPI Q4 2021	▪ FPI Q1 2023
CT Identifier	NCT03615040	NCT05037929	NCT05595642

In collaboration with Amgen
COPD=Chronic obstructive pulmonary disease, SC=Subcutaneous

ASO factor B (RG6299)

Antisense oligonucleotide that targets factor B

Indication	IgA nephropathy (igAN)		Geographic atrophy (GA)
Phase/study	**Phase II***	**Phase III IMAGINATION**	**Phase II* GOLDEN STUDY**
# of patients	N=25	N=428	N=330

Design	▪ ASO factor B SC at week 1 following Q4W dosing through week 25
	▪ Optional 48-week extension (Q4W)
		▪ **ARM A:** ASO factor B SC at week 1, 3, 5 following Q4W dosing for 104 weeks
		▪ **ARM B:** Placebo
			▪ **ARM A:**
			  ▪ Stage 1: ASO factor B SC at 1 of 3 dose levels Q4W up to week 45
			  ▪ Stage 2: dose cohort expansion
			▪ **ARM B:** Placebo

Primary endpoint	▪ % reduction in 24-hour urine protein excretion at week 29	▪ Change in UPCR at week 37 from baseline	▪ Absolute change from baseline in the GA area at week 49
Status	▪ FPI Q2 2020	▪ FPI Q3 2023	▪ FPI Q2 2019
CT Identifier	NCT04014335	NCT05797610	NCT03815825

In collaboration with IONIS

*Study run by IONIS, GA=Geographic atrophy; UPCR=Urine protein-to-creatinine ratio; SC=Subcutaneous; ASO=Antisense oligonucleotide

Vamikibart (anti-IL-6, RG6179)

A monoclonal antibody that potently binds interleukin-6 (IL-6) cytokine

Indication	Diabetic macular edema (DME) and Uveitic macular edema (UME)	Diabetic macular edema (DME)	
Phase/study	**Phase I** **DOVETAIL**	**Phase II** **BARDENAS**	**Phase II** **ALLUVIUM**
# of patients	N=90	N=210-230	N=360-400
Design	▪ Part I: Multiple ascending dose study of intravitreal monotherapy ▪ Part II: monotherapy and in combination with anti-VEGF	▪ **ARM A:** Anti-IL-6 plus ranibizumab ▪ **ARM B:** Ranibizumab plus sham control	▪ **Arm A:** 0.25 mg anti-IL-6 Q8W ▪ **Arm B:** 1.0 mg anti-IL-6 Q8W ▪ **Arm C:** 1.0 mg anti-IL-6 Q4W ▪ **Arm D**: 0.5 mg ranibizumab Q4W
Primary endpoint	▪ Safety, tolerability, PK	▪ Mean change from baseline in BCVA averaged over week 44 and week 48	▪ Mean change from baseline in BCVA averaged over week 44 and week 48
Status	▪ FPI Q3 2019 ▪ Data presentation at ARVO 2023	▪ FPI Q4 2021 ▪ Recruitment completed Q2 2023	▪ FPI Q4 2021 ▪ Recruitment completed Q4 2023
CT Identifier		NCT05151744	NCT05151731

PK=Pharmacokinetics; BCVA=Best corrected visual acuity, ARVO=Association for Research in Vision & Ophthalmology

Vamikibart (anti-IL-6, RG6179)

A monoclonal antibody that potently binds interleukin-6 (IL-6) cytokine

Indication	Uveitic macular edema (UME)	
Phase/study	**Phase III MEERKAT**	**Phase III SANDCAT**
# of patients	N=225	N=225
Design	▪ **ARM A:** Anti-IL-6 low-dose Q4W to week 12, followed by PRN ▪ **ARM B:** Anti-IL-6 high-dose Q4W to week 12, followed by PRN ▪ **ARM C:** Sham control Q4W to week 12,followed by PRN	▪ **ARM A:** Anti-IL-6 low-dose Q4W to week 12, followed by PRN ▪ **ARM B:** Anti-IL-6 high-dose Q4W to week 12, followed by PRN ▪ **ARM C:** Sham control Q4W to week 12,followed by PRN
Primary endpoint	▪ Proportion of participants with ≥ 15 letter improvement from baseline in BCVA at week 16	▪ Proportion of participants with ≥ 15 letter improvement from baseline in BCVA at week 16
Status	▪ FPI Q1 2023	▪ FPI Q1 2023
CT Identifier	NCT05642312	NCT05642325

BCVA=Best corrected visual acuity; PRN= Pro re nata

Elevidys (delandistrogene moxeparvovec, SRP-9001, RG6356)

rAAVrh74.MHCK7.Micro-dystrophin gene therapy

Indication	Duchenne muscular dystrophy (DMD)
Phase/study	**Phase II** **ENVOL**
# of patients	N=21
Design	Open label single arm study in 0 to <4 year old DMD boys who will receive a single intravenous (IV) infusion of Elevidys on Day 1, separated into 4 cohorts: ▪ **Cohort A**: ~ 10 participants who are 3 years of age ▪ **Cohort B:** ~ 4 participants who are 2 years of age ▪ **Cohort C:** ~ 4 participants who are > 6 months to < 2 years of age ▪ **Cohort D:** ~ 3 participants who are <= 6 months of age
Primary endpoint	▪ Safety
Status	▪ FPI Q4 2023
CT Identifier	

In collaboration with Sarepta
DMD=Duchenne muscular dystrophy

Tominersen (RG6042, HTT ASO)

Antisense oligonucleotide (ASO) targeting human HTT mRNA

Indication	Huntington's disease
Phase/study	**Phase II** **GENERATION HD2**
# of patients	N=360
Design	Patients aged 25 to 50 years with prodromal (very early subtle signs of HD) or early manifest HD ▪ **ARM A:** Tominersen 60mg Q16W via a lumbar puncture ▪ **ARM B:** Tominersen 100mg Q16W via a lumbar puncture ▪ **ARM C:** Placebo Q16W via a lumbar puncture
Primary endpoint	▪ Safety, biomarkers and efficacy
Status	▪ FPI Q1 2023
CT Identifier	NCT05686551

In collaboration with IONIS
HD=Huntington's Disease; HTT=Huntingtin

Fenebrutinib (RG7845, GCD-0853)

Highly selective and reversible (noncovalent) bruton tyrosine kinase

Indication	Primary progressive multiple sclerosis (PPMS)	Relapsing multiple sclerosis (RMS)	
Phase/study	**Phase III FENtrepid**	**Phase III FENhance 1**	**Phase III FENhance 2**
# of patients	N=946	N=736	N=736
Design	▪ **ARM A:** Fenebrutinib twice daily oral ▪ **ARM B:** Ocrevus 2x300mg IV Q24W	▪ **ARM A:** Fenebrutinib twice daily oral ▪ **ARM B:** Teriflunomide once daily oral	▪ **ARM A:** Fenebrutinib twice daily oral ▪ **ARM B:** Teriflunomide once daily oral
Primary endpoint	▪ Time to onset of cCDP12	▪ Time to onset of cCDP12 and annualized relapse rate	▪ Time to onset of cCDP12 and annualized relapse rate
Status	▪ FPI Q4 2020 ▪ Recruitment completed Q3 2023	▪ FPI Q1 2021	▪ FPI Q1 2021
CT Identifier	NCT04544449	NCT04586023	NCT04586010

IV=Intravenous; cCDP12=Composite 12-week confirmed disability progression

Fenebrutinib (RG7845, GCD-0853)

Highly selective and reversible (noncovalent) bruton tyrosine kinase

Indication	Relapsing multiple sclerosis (RMS)
Phase/study	**Phase II (Biomarker study)** **FENopta**
# of patients	N=109
Design	▪ **ARM A:** Fenebrutinib ▪ **ARM B:** Placebo
Primary endpoint	▪ Total number of new gadolinium-enhancing T1 lesions observed on MRI scans of the brain at 12 weeks
Status	▪ Data presented at EAN and ECTRIMS 2023
CT Identifier	NCT05119569

MRI=Magnetic resonance imaging; EAN=European Academy of Neurology

Latent myostatin (RG6237, GYM329)

Recycling and antigen-sweeping monoclonal anti-latent myostatin antibody

Indication	Facioscapulohumeral Muscular Dystrophy (FSHD)	Spinal muscular atrophy (SMA)	Obesity
Phase/study	**Phase II** **MANOEUVRE**	**Phase II/III** **MANATEE**[1]	**Phase Ib**
# of patients	N=48	N=180	N=30-36
Design	▪ **ARM A:** 4-week pre-treatment to collect baseline movement data with a wearable device, followed by latent myostatin ▪ **ARM B:** Placebo	**ARM A:** ▪ **Part I**: GYM329 plus Evrysdi for 24 weeks, followed by GYM329 plus Evrysdi for 72 weeks ▪ **Part II:** GYM329 plus Evrysdi for 72 weeks **ARM B:** ▪ Placebo plus Evrysdi	▪ **Cohort A** (n=15-18): Single dose 50mg SC ▪ **Cohort B** (n=15-18): Multiple dosing 100mg SC Q4W week plus loading dose for first 3 doses
Primary endpoint	▪ Percent change in contractile muscle volume of quadriceps femoris muscles by MRI at week 52 and safety	▪ Change from baseline in RHS score after week 72 of treatment ▪ Safety, PK/PD and muscle biomarkers	▪ PK/PD, tolerability, safety
Status	▪ FPI Q1 2023	▪ ODD granted by FDA in Q4 2021 for GYM329 ▪ FPI Part I ambulatory cohort Q2 2022; non-ambulatory cohort July 2023	▪ FPI expected Q2 2024
CT Identifier	NCT05548556	NCT05115110	

[1] In collaboration with PTC Therapeutics and SMA Foundation

PK/PD=Pharmacokinetics/Pharmacodynamics; ODD=Orphan drug designation; RHS=Revised hammersmith scale ; MRI=Magnetic Resonance Imaging, SC=Subcutaneous

Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

Spark

Pharma sales appendix

Diagnostics sales appendix

Foreign exchange rates information

pRED oncology development programs -1

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Oncology					
FAP-4-1BBL (RG7827)	3L+ MSS mCRC	Ib	80	FPI Q3 2021 Combination study with cibisatamab	NCT04826003
tobemstomig PD1-LAG3 (RG6139)	Solid tumors	I	320	FPI Q4 2019 Data presented at ESMO 2022 Recruitment completed Q4 2022	NCT04140500
	advanced or metastatic esophageal squamous cell cancer	II	210	FPI Q2 2021 Randomized trial, compared with nivolumab Recruitment completed Q3 2023	NCT04785820 TALIOS
	Untreated unresectable or metastatic melanoma	II	80	FPI Q3 2022 Recruitment completed Q3 2023	NCT05419388
	Non-small cell lung cancer	II	180	FPI Q1 2023	NCT05775289
	advanced and metastatic urothelial cancer	II	240	FPI Q2 2023	NCT05645692
	Metastatic renal cell carcinoma	II	210	FPI Q2 2023	NCT05805501
	Triple-negative breast cancer	II	160	FPI Q3 2023	NCT05852691
englumafusp alfa (CD19-4-1BBL, RG6076)	R/R B cell non-Hodgkin's lymphoma	I	362	Part I: FPI Q3 2019 Part II: FPI Q3 2020 Combination study with Columvi Data presented at ASH 2022 and ICML 2023	NCT04077723

pRED oncology development programs -2

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Oncology					
eciskafusp alfa (PD1-IL2v, RG6279)	Solid tumors	Ib	256	Part I: FPI Q2 2020; recruitment completed Q4 2021 Part II: FPI Q1 2022 Part III: FPI Q1 2023	NCT04303858
vopikitug (Anti-CD25, RG6292)	Advanced and metastatic solid tumors	I	160	FPI Q4 2020 PK/PD data presented at AACR 2023	NCT04642365
forimtamig (Anti-GPRC5D, RG6234)	Multiple myeloma	I	400	FPI Q4 2020 Data presented at EHA 2022 and ASH 2022	NCT04557150
BRAFi (3) (RG6344)	Solid tumors	I	292	FPI Q1 2022	ISRCTN13713551
CD19xCD28 (RG6333)	R/R B cell non-Hodgkin's lymphoma	I	~200	FPI Q1 2022 Combination study with Columvi	NCT05219513
DLL3 trispecific (RG6524)	Solid tumors	I	168	FPI Q1 2023	NCT05619744
WRN covalent inhibitor[1] (RG6457)	Solid tumors	I	220	FPI Jan 2024	NCT06004245

Partner: [1]Vividion Therapeutics

pRED neurology development programs -1

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Neurology					
trontinemab (BS-anti-Aβ mAb, RG6102)	Alzheimer's disease	IIa	~210	FPI Q1 2021	NCT04639050
Brainshuttle™-CD20 (BS-CD20, RG6035)	Multiple sclerosis	I	30-63	FPI Q3 2021	ISRCTN16295177 NCT05704361
Gamma-secretase modulator (RG6289)	Alzheimer's disease	I	138	FPI Q4 2021	
prasinezumab[1] (anti-αSynuclein, RG7935, PRX002)	Parkinson's disease	II	316	The study did not meet its primary endpoint, but showed a reduced clinical decline of core motor signs (MDS UPDRS partIII). Data presented at MDS & ADPD 2020-22. The Open Label Extension is ongoing. Data presented at MDS 2023	NCT03100149 (PASADENA)
		IIb	575	FPI Q2 2021 Recruitment completed Q1 2023	NCT04777331 (PADOVA)
alogabat (GABA-Aa5 PAM, RG7816)	Autism spectrum disorder	II	105	FPI Q1 2021	NCT04299464 (Aurora)

Partner: [1]Prothena
BS=Brainshuttle™; mAb=monoclonal antibody

pRED neurology development programs -2

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Neurology					
MAGL inhibitor (RG6182)	Multiple sclerosis	I	Up to 36	FPI Q3 2023	
NME (RG6163)	Psychiatric disorders	I	84	FPI Q1 2022	
selnoflast* (NLRP3i, RG6418)	Parkinson's disease	Ib	48	FPI Q3 2022	

*molecule also in gRED development: Phase Ic in coronary artery disease with FPI Q4 2022

pRED immunology and ophthalmology development programs

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Immunology					
selnoflast* (NLRP3i, RG6418)	Asthma	Ib	60	FPI expected Q1 2024	
NME (RG6382)	SLE	I	70	FPI Q4 2023	NCT05835986
Ophthalmology					
zifibancimig (VEGF-Ang2 DutaFab, RG6120)	nAMD	I	251	FPI Q4 2020	NCT04567303 (BURGUNDY)
NME (RG6209)	retinal disease	I	~70 (Part I)	FPI Q4 2022	

*molecule also in gRED development: Phase Ic in coronary artery disease with FPI Q4 2022

pRED infectious diseases development programs

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Infectious Diseases					
ruzotolimod (TLR7 agonist (3) RG7854)	Chronic hepatitis B	I	150	FPI Q4 2016 Data presented at APASL 2019	NCT02956850
ruzotolimod/ xalnesiran[1]/ PDL1 LNA (RG7854/RG6346/RG6084)	Chronic hepatitis B	II	275	FPI Q3 2020	NCT04225715 (PIRANGA)
PDL1 LNA (RG6084)	Chronic hepatitis B	I	35	FPI Q1 2019 Part Ia: completed Part Ib: initiated	
zosurabalpin (Abx MCP, RG6006)	A. baumannii infections	I	204	FPI Q4 2020	NCT04605718
HBsAg MAb (RG6449)	Chronic hepatitis B	I	110	Part I: FPI Q2 2023 Part II: FPI Q4 2023	NCT05763576

Partner: [1]Dicerna Pharmaceuticals Inc./Novo Nordisk
Abx MCP=antibiotic macrocyclic peptide

Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

Spark

Pharma sales appendix

Diagnostics sales appendix

Foreign exchange rates information

gRED oncology development programs -1

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Oncology					
cevostamab (anti-FcRH5 x CD3; RG6160)	R/R multiple myeloma	I	300	FPI Q3 2017 Data presented at ASH 2020, 2021 & 2022	NCT03275103
	R/R multiple myeloma	I	120	FPI Q2 2021	NCT04910568
	BCMA-experienced R/R MM	I/II	140	FPI Q4 2022	NCT05535244
	R/R multiple myeloma	Ib	~110	FPI Q3 2023 In combination with elranatamab	NCT05927571
	Multiple myeloma platform study	I/II	50	FPI Q4 2023 Multiple molecules and combinations	NCT05583617
efbalropoendekin alfa (IL15/IL15Ra-Fc, RG6323)[1]	Solid tumors	Ia/Ib	250	FPI Q1 2020	NCT04250155
	R/R multiple myeloma	I	60	FPI Q2 2022	NCT05243342
	R/R multiple myeloma	I	90	FPI Q1 2023 Combination study with cevostamab	NCT05646836
autogene cevumeran (Individualized Neoantigen-Specific Therapy (iNeST); RG6180)[2]	Solid tumors	Ia/Ib	272	FPI Q4 2017 Data presented at AACR 2020 Recruitment completed Q1 2022	NCT03289962
	1L advanced melanoma	II	131	FPI Q1 2019	NCT03815058 (IMcode001)
	Adjuvant PDAC	II	260	FPI Q4 2023	NCT05968326 (IMcode003)

Partner: [1]Xencor, [2]BioNTech

gRED oncology development programs -2

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Oncology					
runimotamab (HER2 x CD3, RG6194)	Metastatic HER2-expressing cancers	I	440	FPI Q2 2018	NCT03448042
NME (RG6286)	Locally advanced or metastatic colorectal cancer	I	67	FPI Q3 2020	NCT04468607
migoprotafib (SHP2i, RG6433)[1]	Solid tumors	Ib	~125	FPI Q3 2022	NCT05487235
	KRAS-G12C mutant solid tumors	Ib	~500	FPI Q4 2021 Arm F of a combination study investigating divarasib monotheraphy and combinations	NCT04449874
belvarafenib (RG6185)[2]	nRASmt CPI-experienced melanoma	Ib	83	FPI Q2 2021 Data presented at ESMO 2021	NCT04835805
NME (RG6411)	Solid tumors	I	110	FPI Q4 2022	NCT05581004
AR degrader (RG6537)[3]	mCRPC	I	~160	FPI Q2 2023	NCT05800665
anti-latent TGFβ1 (SOF10; RG6440)	Solid tumors	Ib	120	FPI Q3 2023	NCT05867121
NME (RG6468)	Solid tumors	I	110	FPI Q4 2023	NCT06031441

Partner: [1]Relay, [2]Hanmi, [3]Jemincare

gRED immunology and ophthalmology development programs

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Immunology					
NME (RG6287, GDC-8264)	Acute graft versus host disease	Ib	40	FPI Q2 2023 Study closed Q4 2023	NCT05673876
NME (RG6315, MTBT1466A)	Systemic sclerosis	Ib	100	FPI Q1 2023	NCT05462522
NME (RG6341, GDC-6599)	Asthma	Ia/Ib	84	FPI Q4 2021	
	Chronic cough	IIa	80	FPI Q1 2023	NCT05660850
TMEM16A potentiator (RG6421, GDC-6988)	Cystic fibrosis	Ib	30	FPI Q3 2022 Recruitment completed Q2 2023	ISRCTN15406513
Vixarelimab (RG6536)[1]	Idiopathic pulmonary fibrosis / Systemic sclerosis-sssociated interstitial lung disease	II	~290	FPI Q2 2023	NCT05785624
Ophthalmology					
NME (RG6351)	DME	I	~90	FPI Q2 2022	ISRCTN14152148
OpRegen (RG6501)[2]	Geographic atrophy	II	60	FPI Q1 2023	NCT05626114

Partner: [1]Kiniksa Pharmaceuticals, [2]Lineage Cell Therapeutics

gRED infectious diseases development program

Molecule	Indication	Phase	# of patients	Status	CT Identifier
Infectious Diseases					
LepB inhibitor (RG6319)	Complicated urinary tract infection	I	33	FPI Q1 2023	

Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

Spark

Pharma sales appendix

Diagnostics sales appendix

Foreign exchange rates information

Hemophilia A

Unique gene therapy platform

Molecule	Dirloctogene Samoparvovec (SPK-8011) (RG6357)	
Indication	**Hemophilia A**	
Phase/study	**Phase I**	**Phase I/II**
# of patients	N=100	N=30
Design	▪ Long term follow up study of patients who have received SPK-8011 in any prior Spark-sponsored SPK-8011 study	▪ Gene transfer, dose-finding safety, tolerability, and efficacy study of SPK-8011
Primary endpoint	▪ Safety	▪ Safety and changes from baseline in FVIII activity levels at week 52
Status	▪ Ongoing	▪ Updated data presented at ISTH 2020 and 2021 ▪ Recruitment completed Q1 2021 ▪ Data published in *NEJM* 2021;385:1961-1973 ▪ 5-year data published at ASH 2022
CT Identifier	NCT03432520	NCT03003533

ISTH=International Society on Thrombosis and Haemostasis; NEJM=New England Journal of Medicine

Pompe disease

Unique gene therapy platform

Molecule	**SPK-3006 (RG6359)**
Indication	**Pompe disease**
Phase/study	**Phase I/II RESOLUTE**
# of patients	N=20
Design	▪ Gene transfer study for late-onset Pompe disease
Primary endpoint	▪ Safety
Status	▪ FPI Q4 2020 ▪ Recruitment completed Q2 2022
CT Identifier	NCT04093349

Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

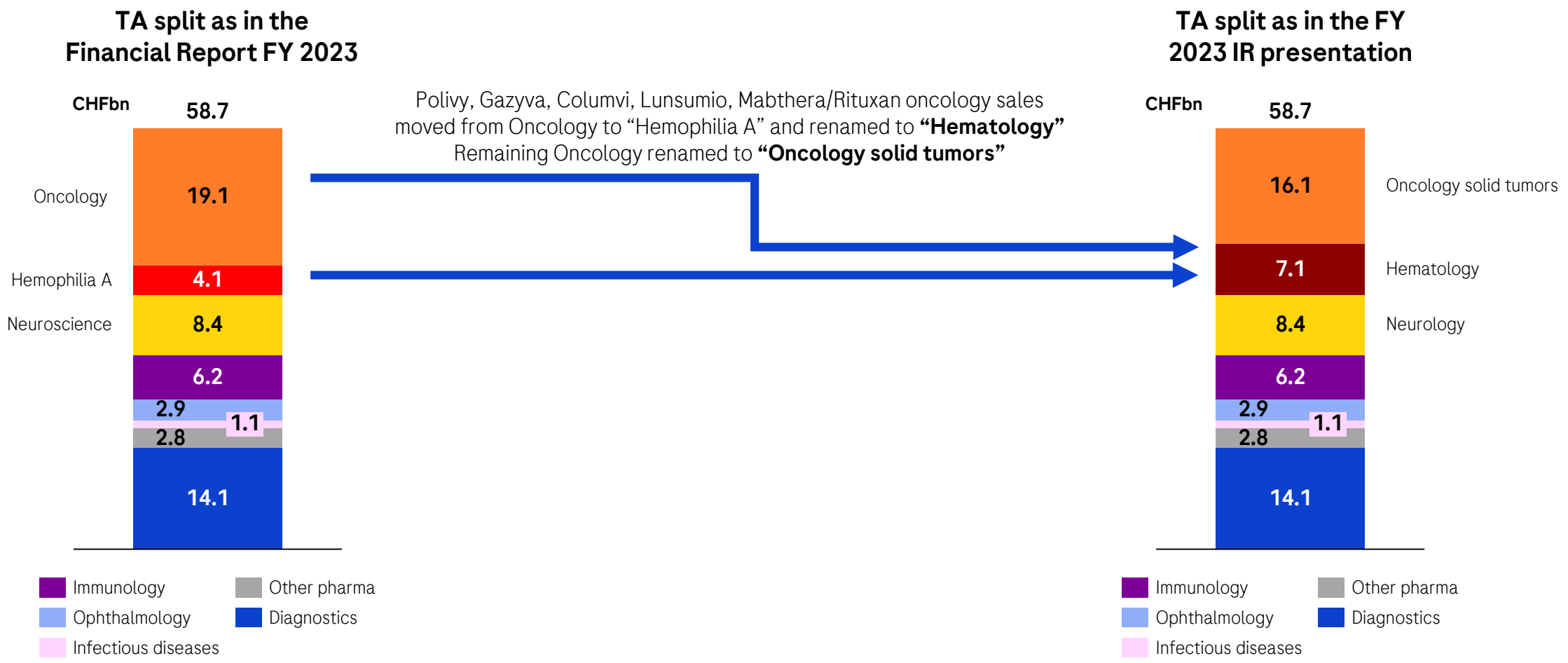
Spark

Pharma sales appendix

Diagnostics sales appendix

Foreign exchange rates information

Updated Pharma TA definitions



Oncology as defined in the Financial Report 2023 generated FY 2023 sales of CHF 19.1 bn, CER growth +4%; TA=therapeutic area

Geographical sales split by Divisions and Group*

CHFm	FY 2022	FY 2023	% change CER
Pharmaceuticals Division	**45,551**	**44,612**	**+6**
United States	23,322	23,606	+8
Europe	8,143	8,306	+6
Japan	4,949	3,745	-14
International	9,137	8,955	+13
Diagnostics Division	**17,730**	**14,104**	**-13**
United States	4,518	3,424	-19
Europe	4,807	3,732	-18
Japan	915	785	-3
International	7,490	6,163	-7
Group	**63,281**	**58,716**	**+1**
United States	27,840	27,030	+3
Europe	12,950	12,038	-3
Japan	5,864	4,530	-12
International	16,627	15,118	+4

CER=Constant Exchange Rates; * Geographical sales split shown here does not represent operational organization

Pharma Division sales FY 2023

Top 20 products

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Ocrevus	6,381	13	4,684	11	1,166	12	-	-	531	31
Hemlibra	4,147	16	2,493	14	845	18	373	12	436	29
Perjeta	3,768	1	1,336	-7	776	-8	215	4	1,441	16
Tecentriq	3,766	9	1,941	4	845	10	419	8	561	29
Actemra / RoActemra	2,630	5	1,223	9	775	0	311	3	321	4
Vabysmo	2,357	324	1,914	293	276	*	98	138	69	*
Xolair	2,176	5	2,176	5	-	-	-	-	-	-
Kadcyla	1,966	4	757	-2	577	-11	102	-12	530	43
MabThera	1,630	-15	987	-20	180	-9	24	-13	439	-6
Herceptin	1,626	-16	331	-26	353	-14	30	-33	912	-13
Avastin	1,573	-19	484	-19	98	-47	318	-26	673	-7
Alecensa	1,502	8	467	9	292	4	212	5	531	11
Evrysdi	1,419	39	505	14	509	49	93	26	312	80
TNKase / Activase	1,173	6	1,112	6	-	-	-	-	61	5
Phesgo	1,120	64	423	48	534	52	4	-	159	189
Polivy	837	108	340	119	173	36	227	129	97	317
Gazyva	811	19	395	22	229	24	38	-14	149	18
Ronapreve	525	-65	-	-	5	-95	519	-60	1	-99
Lucentis	460	-52	460	-52	-	-	-	-	-	-
Pulmozyme	452	-10	303	-13	76	-18	1	8	72	9
Pharma Division	**44,612**	**6**	**23,606**	**8**	**8,306**	**6**	**3,745**	**-14**	**8,955**	**13**

CER=Constant Exchange Rates; *over 500%

Pharma Division sales FY 2023

Products launched since 2015

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Cotellic	50	14	22	61	11	-22	-	-	17	7
Alecensa	1,502	8	467	9	292	4	212	5	531	11
Tecentriq	3,766	9	1,941	4	845	10	419	8	561	29
Ocrevus	6,381	13	4,684	11	1,166	12	-	-	531	31
Hemlibra	4,147	16	2,493	14	845	18	373	12	436	29
Luxturna	44	4	44	4	-	-	-	-	-	-
Xofluza	90	49	12	-75	-	-	-	-	78	494
Polivy	837	108	340	119	173	36	227	129	97	317
Rozlytrek	86	25	45	2	16	36	8	27	17	147
Phesgo	1,120	64	423	48	534	52	4	-	159	189
Enspryng	256	49	69	37	18	111	153	43	16	180
Evrysdi	1,419	39	505	14	509	49	93	26	312	80
Gavreto	55	120	25	21	6	58	-	-	24	*
Ronapreve	525	-65	-	-	5	-95	519	-60	1	-99
Susvimo	3	54	3	54	-	-	-	-	-	-
Vabysmo	2,357	324	1,914	293	276	*	98	138	69	*
Lunsumio	58	*	50	-	8	188	-	-	-	-
Columvi	28	-	20	-	8	-	-	-	-	-
Total	**22,724**	**22**	**13,057**	**27**	**4,712**	**25**	**2,106**	**-17**	**2,849**	**40**

CER=Constant Exchange Rates; *over 500%

Pharma Division sales FY 2023

Product sales Pharmaceuticals Division

	Global		US		Europe		Japan		International	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Ocrevus	6,381	13	4,684	11	1,166	12	-	-	531	31
Hemlibra	4,147	16	2,493	14	845	18	373	12	436	29
Perjeta	3,768	1	1,336	-7	776	-8	215	4	1,441	16
Tecentriq	3,766	9	1,941	4	845	10	419	8	561	29
Actemra / RoActemra	2,630	5	1,223	9	775	0	311	3	321	4
Vabysmo	2,357	324	1,914	293	276	*	98	138	69	*
Xolair	2,176	5	2,176	5	-	-	-	-	-	-
Kadcyla	1,966	4	757	-2	577	-11	102	-12	530	43
MabThera	1,630	-15	987	-20	180	-9	24	-13	439	-6
Herceptin	1,626	-16	331	-26	353	-14	30	-33	912	-13
Avastin	1,573	-19	484	-19	98	-47	318	-26	673	-7
Alecensa	1,502	8	467	9	292	4	212	5	531	11
Evrysdi	1,419	39	505	14	509	49	93	26	312	80
TNKase / Activase	1,173	6	1,112	6	-	-	-	-	61	5
Phesgo	1,120	64	423	48	534	52	4	-	159	189
Polivy	837	108	340	119	173	36	227	129	97	317
Gazyva	811	19	395	22	229	24	38	-14	149	18
Ronapreve	525	-65	-	-	5	-95	519	-60	1	-99
Lucentis	460	-52	460	-52	-	-	-	-	-	-
Pulmozyme	452	-10	303	-13	76	-18	1	8	72	9
Enspryng	256	49	69	37	18	111	153	43	16	180
Xofluza	90	49	12	-75	-	-	-	-	78	494
Rozlytrek	86	25	45	2	16	36	8	27	17	147
Lunsumio	58	*	50	-	8	188	-	-	-	-
Gavreto	55	120	25	21	6	58	-	-	24	*
Cotellic	50	14	22	61	11	-22	-	-	17	7
Luxturna	44	4	44	4	-	-	-	-	-	-
Columvi	28	-	20	-	8	-	-	-	-	-
Susvimo	3	54	3	54	-	-	-	-	-	-
Other Products	3,623	-13	985	-24	530	-29	600	-5	1,508	0
Pharma Division	**44,612**	**6**	**23,606**	**8**	**8,306**	**6**	**3,745**	**-14**	**8,955**	**13**

CER=Constant Exchange Rates; *over 500%

Pharma Division CER sales growth[1] in %

Global top 20 products

	Q1/22	Q2/22	Q3/22	Q4/22	Q1/23	Q2/23	Q3/23	Q4/23
Ocrevus	18	17	16	18	14	15	12	9
Hemlibra	30	31	23	24	24	17	17	9
Perjeta	1	9	5	4	11	6	0	-11
Tecentriq	8	13	9	24	15	8	10	5
Actemra / RoActemra	3	-23	-42	-22	-12	2	21	13
Vabysmo	-	-	-	-	*	*	309	160
Xolair	9	13	8	6	5	4	3	7
Kadcyla	9	18	6	-3	5	-5	5	13
MabThera	-21	-20	-19	-20	-17	-17	-13	-15
Herceptin	-19	-11	-23	-22	-17	-22	-13	-14
Avastin	-32	-27	-28	-25	-24	-17	-18	-15
Alecensa	23	16	11	10	9	11	7	7
Evrysdi	189	65	93	59	62	36	41	22
TNKase / Activase	-20	1	-5	-27	23	9	-4	-1
Phesgo	410	168	76	73	72	67	61	58
Polivy	89	93	63	97	96	129	144	74
Gazyva	7	9	9	9	24	20	22	12
Ronapreve	272	-91	-92	118	9	-98	-100	-100
Lucentis	-26	-9	-39	-40	-35	-55	-53	-66
Pulmozyme	-3	2	-3	-15	-5	-15	-15	-6

CER=Constant Exchange Rates; *over 500%; [1] Q1-Q4/22 vs Q1-Q4/21 at CER avg. full year 2021; Q1-Q4/23 vs Q1-Q4/22 at CER avg. full year 2022

Pharma Division CER sales growth[1] in %

Top 20 products by region

	US				Europe				Japan				International			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Ocrevus	13	14	10	8	11	16	10	11	-	-	-	-	32	23	50	22
Hemlibra	21	14	15	8	27	18	22	8	24	19	5	5	38	31	39	14
Perjeta	8	6	-6	-35	1	-12	0	-21	2	5	6	3	22	18	4	21
Tecentriq	14	5	4	-4	11	7	22	2	12	11	5	3	34	23	18	39
Actemra / RoActemra	-22	6	33	33	-8	0	11	-1	0	5	4	3	10	-9	20	-3
Vabysmo	*	458	276	142	-	*	*	406	-	299	77	42	-	*	*	*
Xolair	5	4	3	7	-	-	-	-	-	-	-	-	-	-	-	-
Kadcyla	-3	-5	-2	3	-6	-15	-6	-17	-8	-17	-15	-6	42	11	41	91
MabThera	-21	-19	-19	-22	0	-9	-11	-15	-13	-15	-11	-15	-12	-14	4	2
Herceptin	-37	-23	-21	-20	-17	-18	-9	-10	-30	-34	-35	-31	-7	-22	-11	-12
Avastin	-25	-20	-19	-9	-45	-51	-50	-43	-21	-25	-28	-31	-19	1	-5	-4
Alecensa	7	14	4	13	3	5	5	1	5	7	5	5	14	13	10	5
Evrysdi	13	19	14	11	74	61	35	39	47	25	21	19	189	39	134	18
TNKase / Activase	23	9	-5	-1	-	-	-	-	-	-	-	-	17	8	-1	-1
Phesgo	62	53	54	27	59	55	47	49	-	-	-	-	232	206	151	196
Polivy	35	91	161	173	93	76	53	-21	169	194	178	55	340	339	422	214
Gazyva	32	18	24	14	25	22	29	18	-35	1	-18	-4	27	29	18	2
Ronapreve	-	-	-	-	-100	-100	-100	*	33	-	-	-100	-100	-97	-100	-
Lucentis	-35	-55	-53	-66	-	-	-	-	-	-	-	-	-	-	-	-
Pulmozyme	-5	-16	-19	-9	-16	-20	-18	-15	18	-4	34	-4	10	-5	14	18

CER=Constant Exchange Rates; *over 500%; [1] Q1-Q4/23 vs Q1-Q4/22 at CER avg. full year 2022

CER sales growth (%)

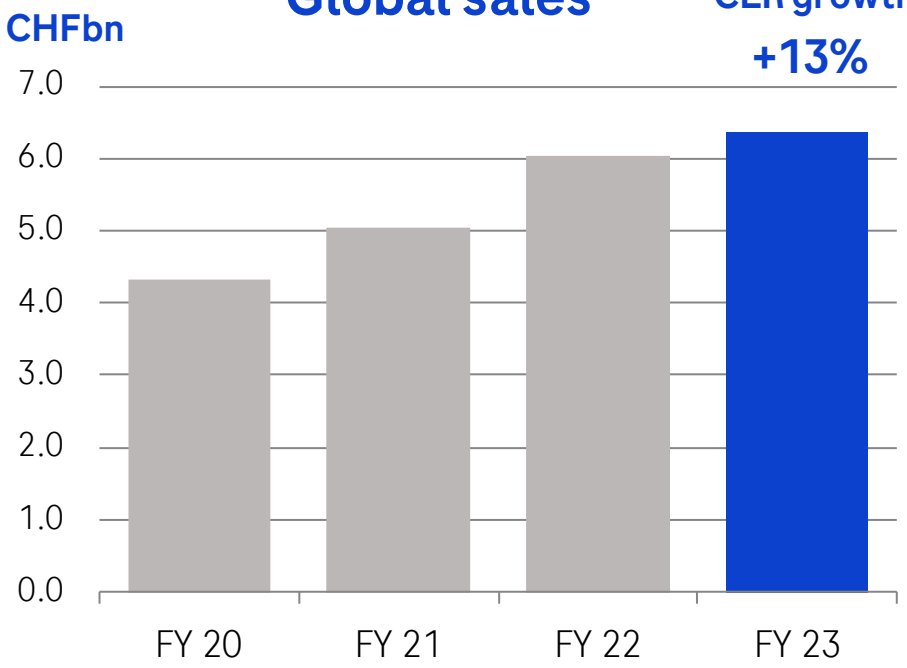
Quarterly development

	2022 vs. 2021				2023 vs. 2022			
	Q1	Q2	Q3	Q4	Q1	Q2	Q3	Q4
Pharmaceuticals Division	**6**	**0**	**-6**	**9**	**9**	**7**	**11**	**-2**
United States	2	1	-6	1	6	7	11	5
Europe	-1	-6	4	-3	5	5	9	3
Japan	69	3	-27	69	18	8	1	-50
International	0	4	-3	4	13	6	17	16
Diagnostics Division	**24**	**0**	**-4**	**-9**	**-28**	**-17**	**-5**	**4**
Roche Group	**11**	**0**	**-6**	**4**	**-3**	**0**	**7**	**0**

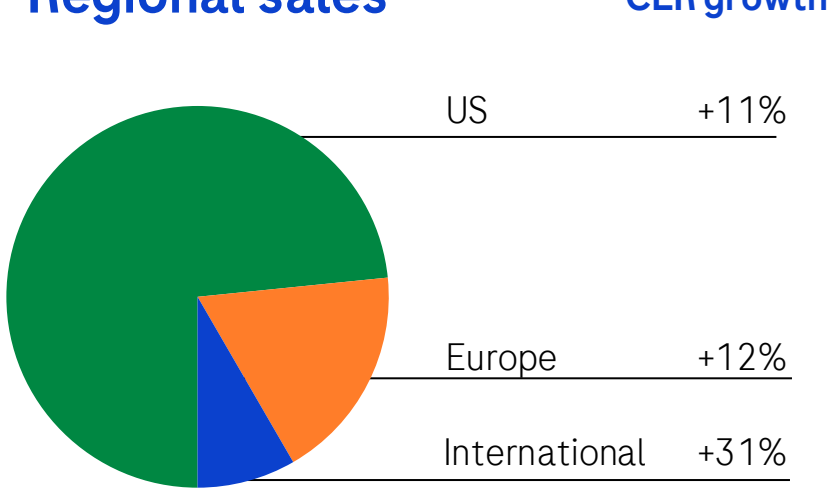
CER=Constant Exchange Rates of the respective year

Ocrevus

Global sales



Regional sales



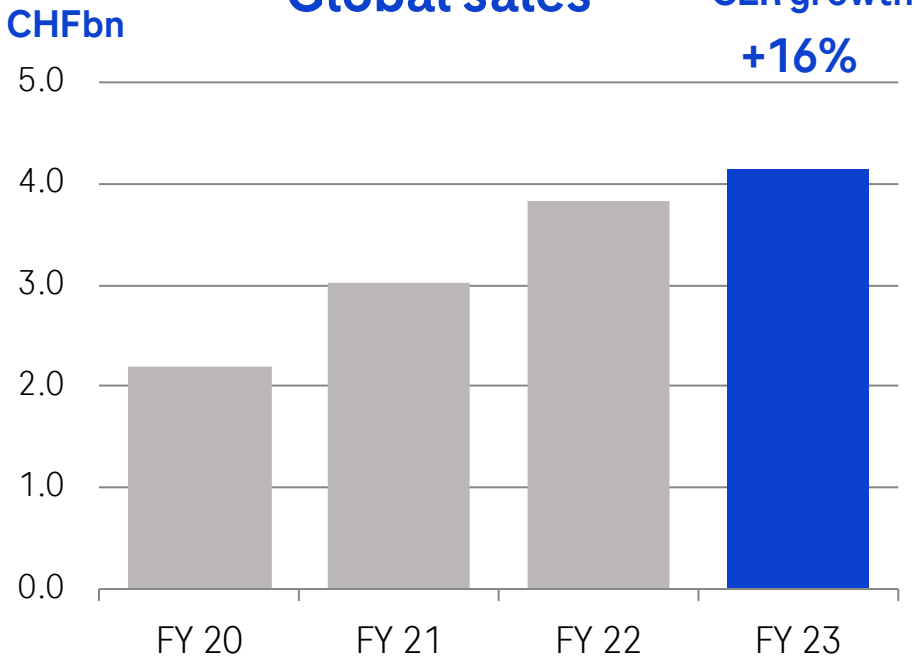
FY 2023 sales of CHF 6,381m

- US: Moving into earlier lines displacing orals; #1 in US for both dynamic and total share
- EU: Moving into earlier lines displacing orals; #1 in EU5 for both dynamic and total share

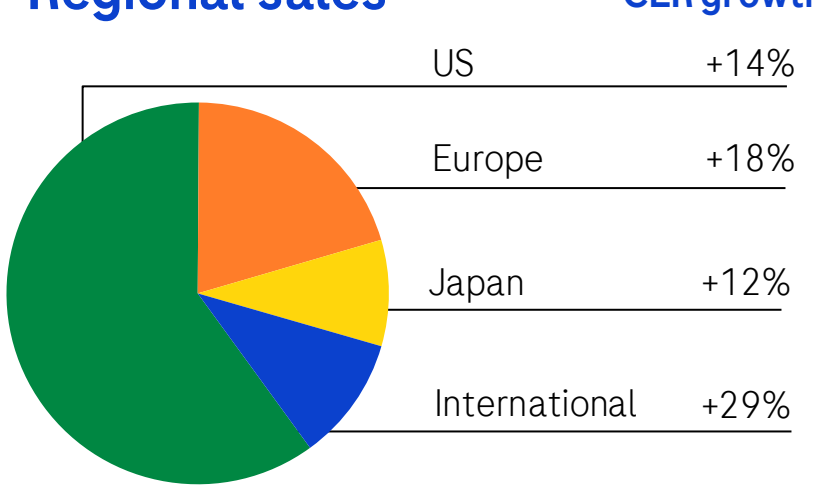
CER=Constant Exchange Rates

Hemlibra

Global sales



Regional sales

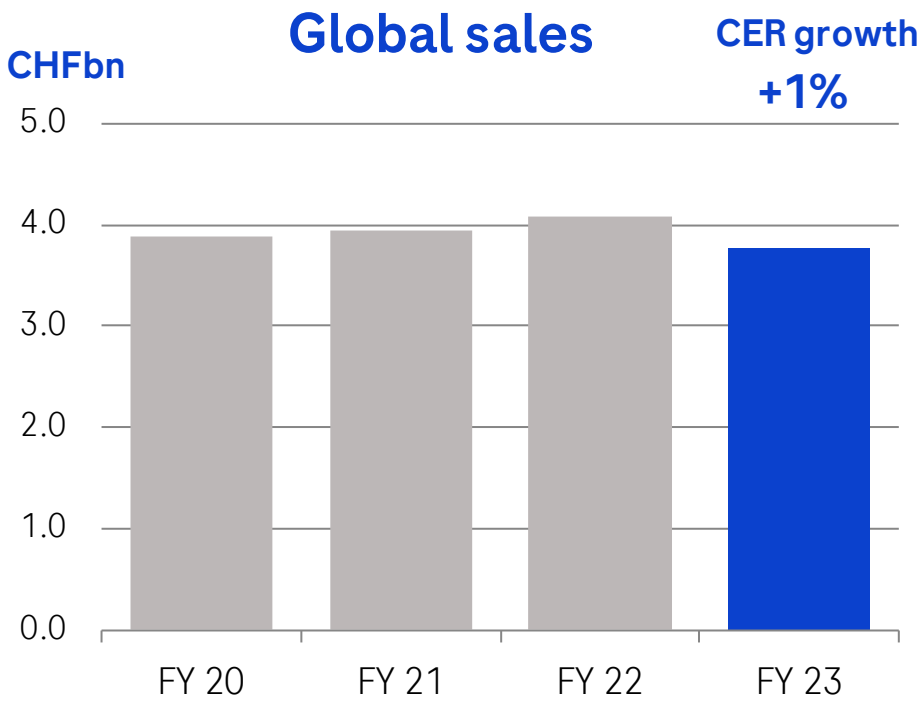


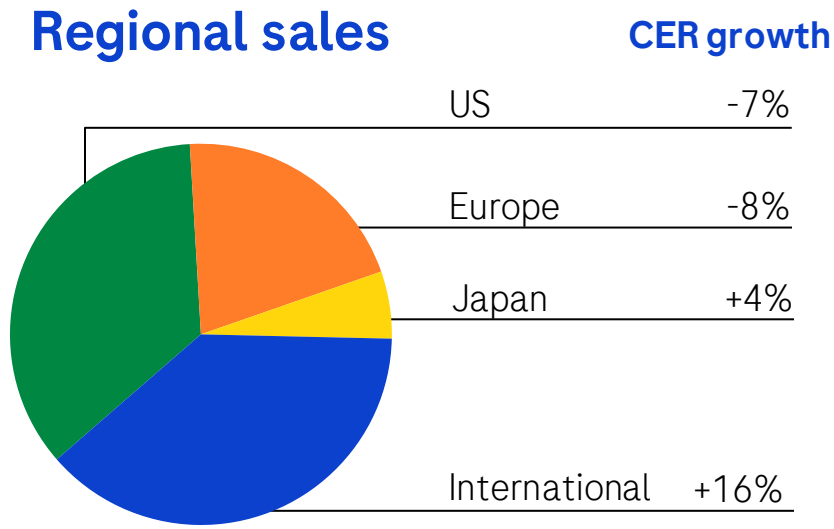
FY 2023 sales of CHF 4,147m

- US: Continued share gains in non-inhibitor patients
- EU: Continued share gains in non-inhibitor severe patients, label extension including moderate patients granted in Q1
- Japan: Strong uptake in non-inhibitor patients
- International: Accelerating momentum in all regions (LATAM, APAC, EEMEA)

CER=Constant Exchange Rates

Perjeta





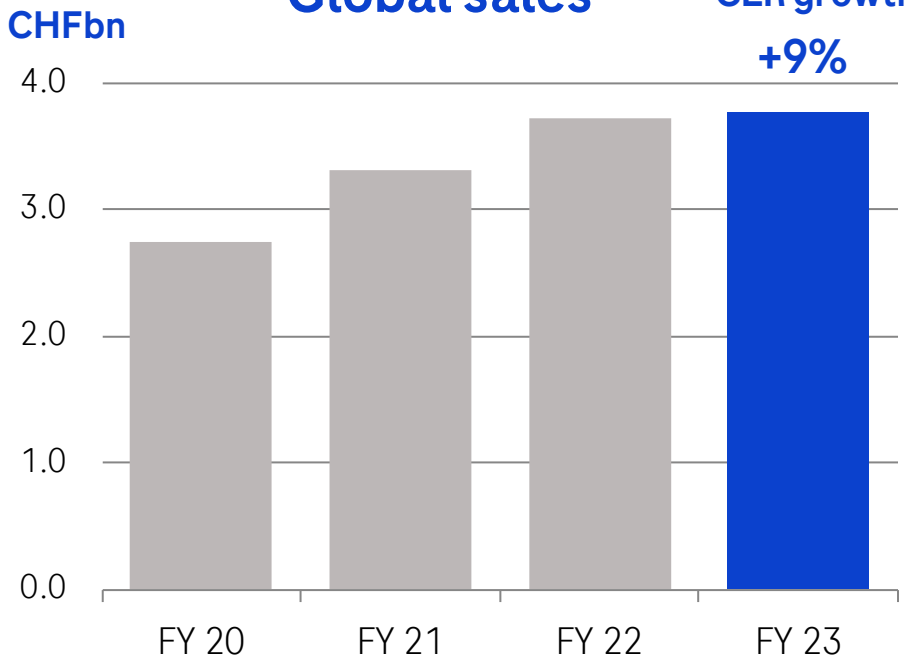
FY 2023 sales of CHF 3,768m

- US: Increasing conversion to Phesgo; Q4 impacted by adjustment in reserves related to government programs
- EU: Conversion to Phesgo
- International: Strong growth in all regions (LATAM, APAC, EEMEA)

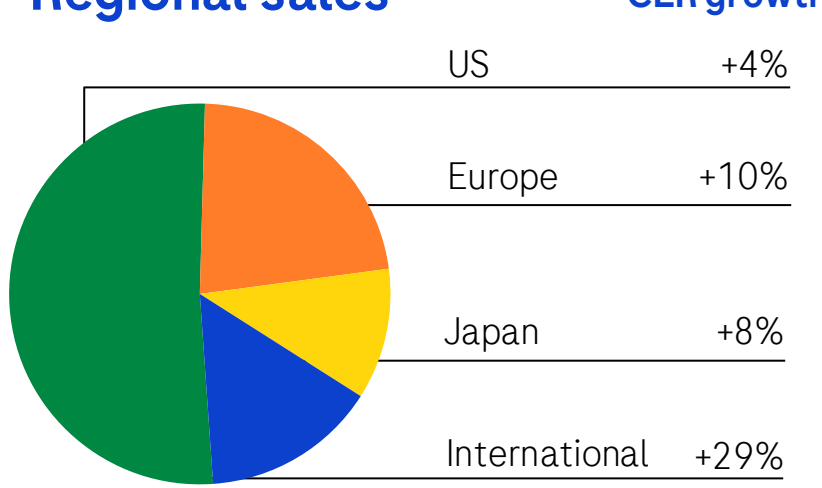
CER=Constant Exchange Rates

Tecentriq

Global sales



Regional sales



FY 2023 sales of CHF 3,766m

- US: Growth driven by adj NSCLC; 1L HCC nearing peak penetration; competitive pressure intensifying
- EU: Growth drive by adj NSCLC and 1L HCC
- Japan: Growing share in adj NSCLC

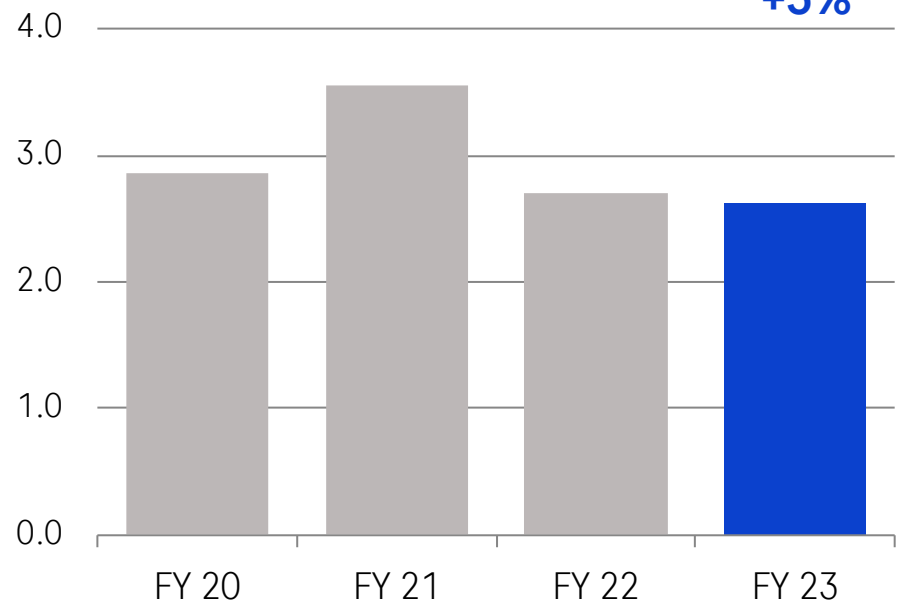
CER=Constant Exchange Rates

Actemra / RoActemra

Global sales

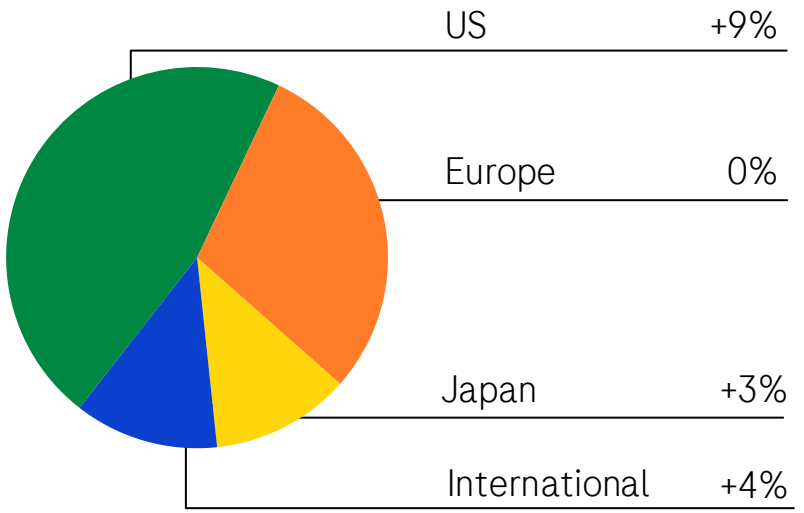
CHFbn

CER growth +5%



Regional sales

CER growth



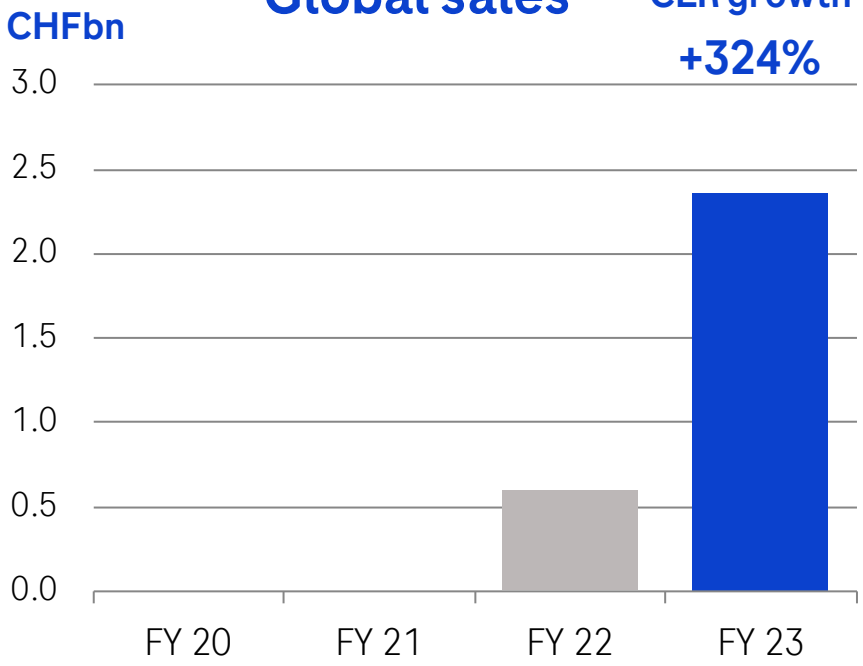
FY 2023 sales of CHF 2,630m

- US: Ongoing patient shift from Actemra IV to SC in RA; rebounding and growth
- EU: Stable share of Actemra SC in RA; COVID 19 sales completely washed out as of Q2

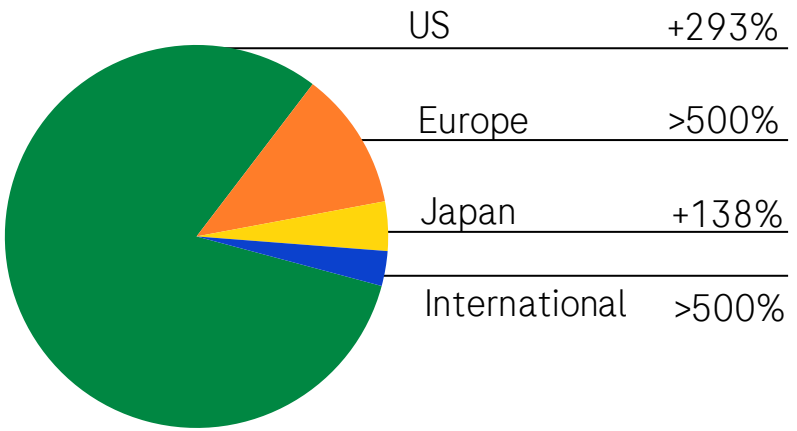
CER=Constant Exchange Rates

Vabysmo

Global sales



Regional sales

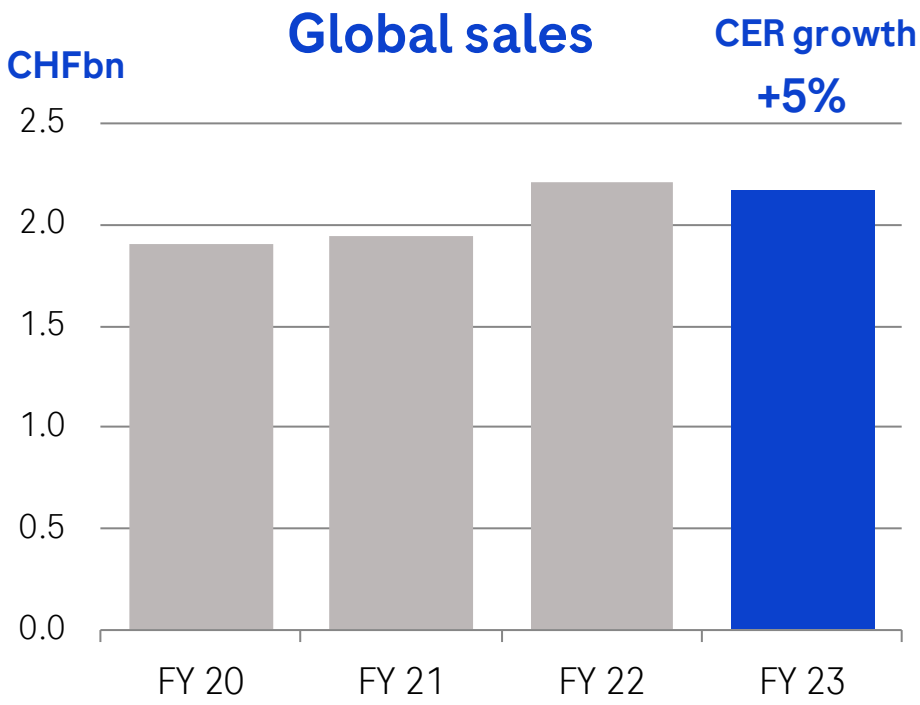


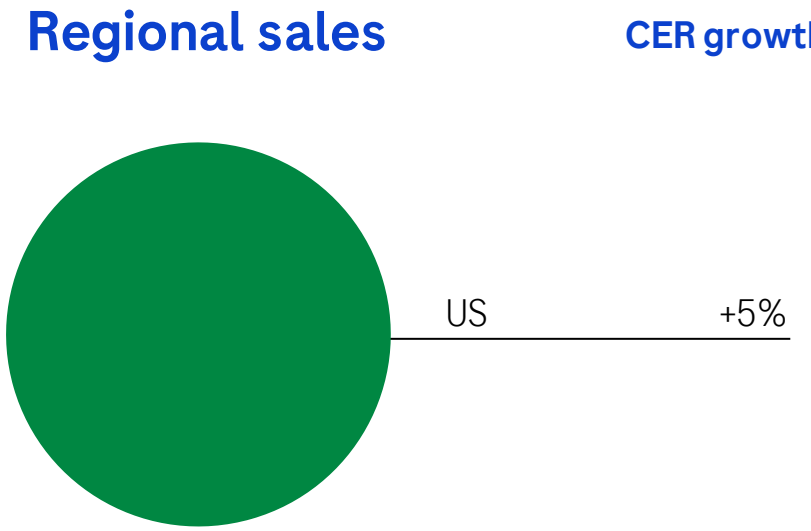
FY 2023 sales of CHF 2,357m

- US: Strong uptake with 42% naïve patients, 58% switches (mostly from aflibercept)
- EU: Similar uptake dynamics in first launch countries as seen in the US
- Japan: Double-digit market share

CER=Constant Exchange Rates

Xolair





FY 2023 sales of CHF 2,176m

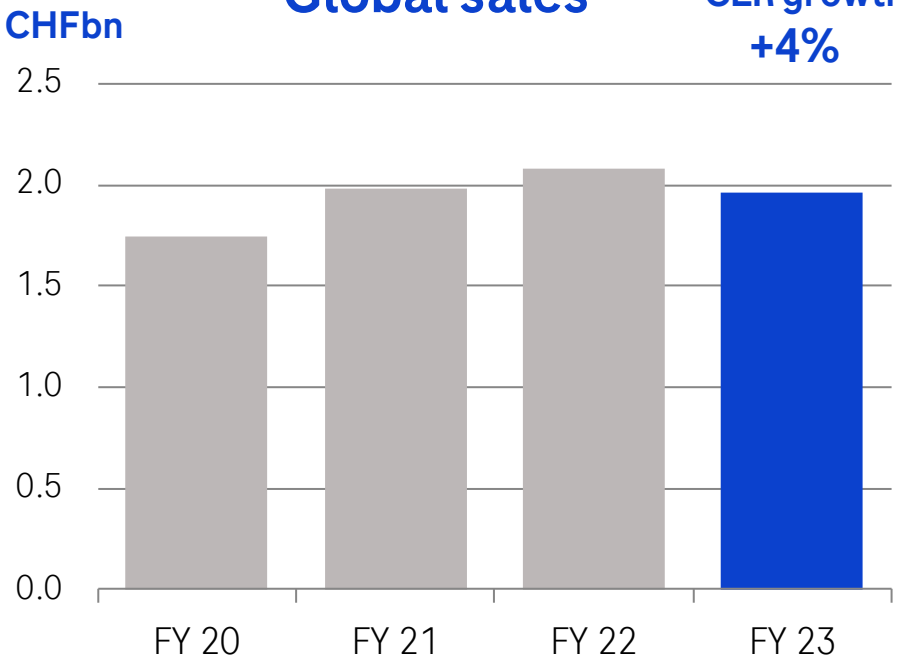
- US: Growth driven by uptake in CSU

CER=Constant Exchange Rates

Kadcyla

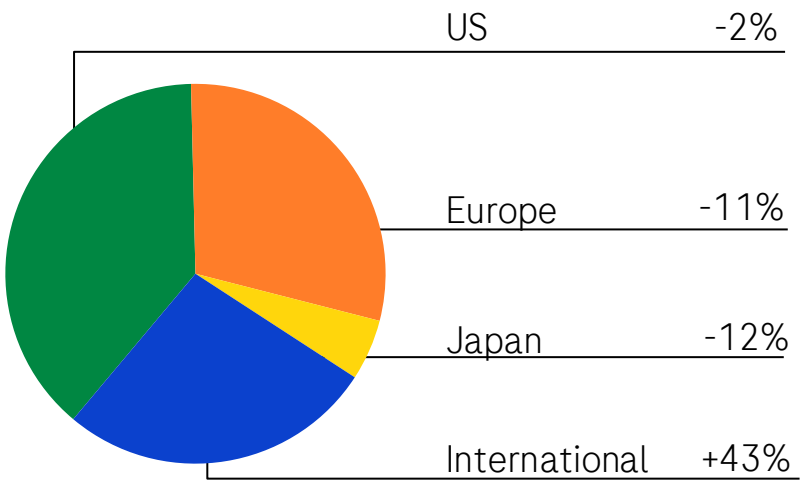
Global sales

CER growth +4%



Regional sales

CER growth



FY 2023 sales of CHF 1,966m

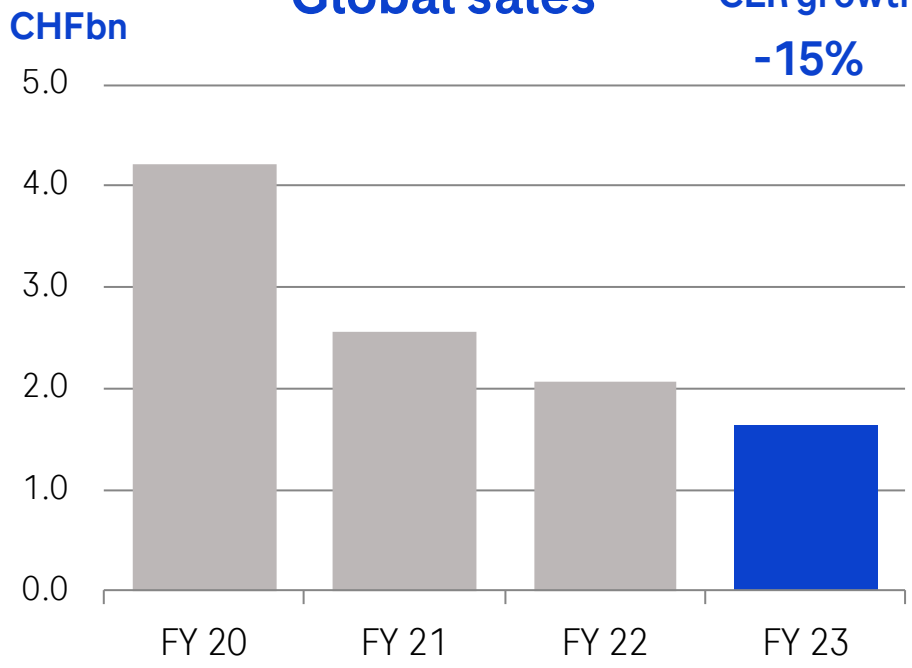
- US: Share decline in metastatic BC due to competition
- EU: Share decline in metastatic BC due to competition
- Japan: Share decline in metastatic BC due to competition
- International: Growth driven by uptake in eBC all regions (LATAM, EEMEA, APAC)

CER=Constant Exchange Rates

Rituxan / Mabthera

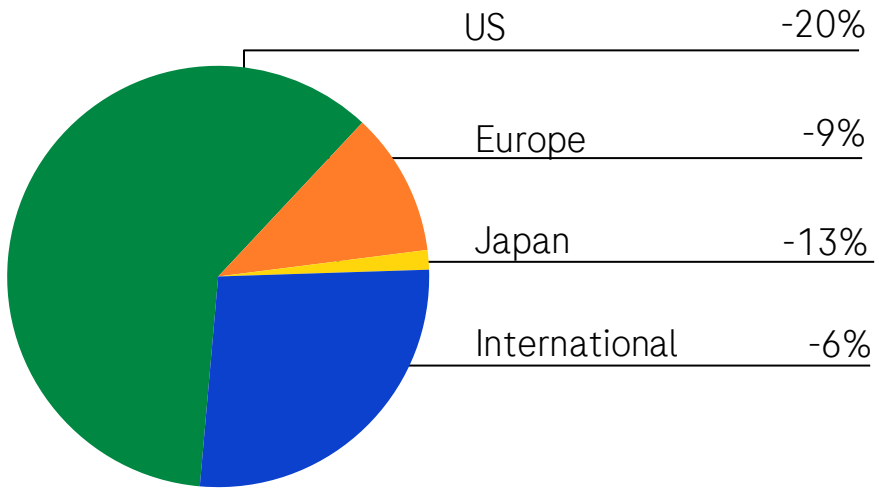
Global sales

CER growth
-15%



Regional sales

CER growth



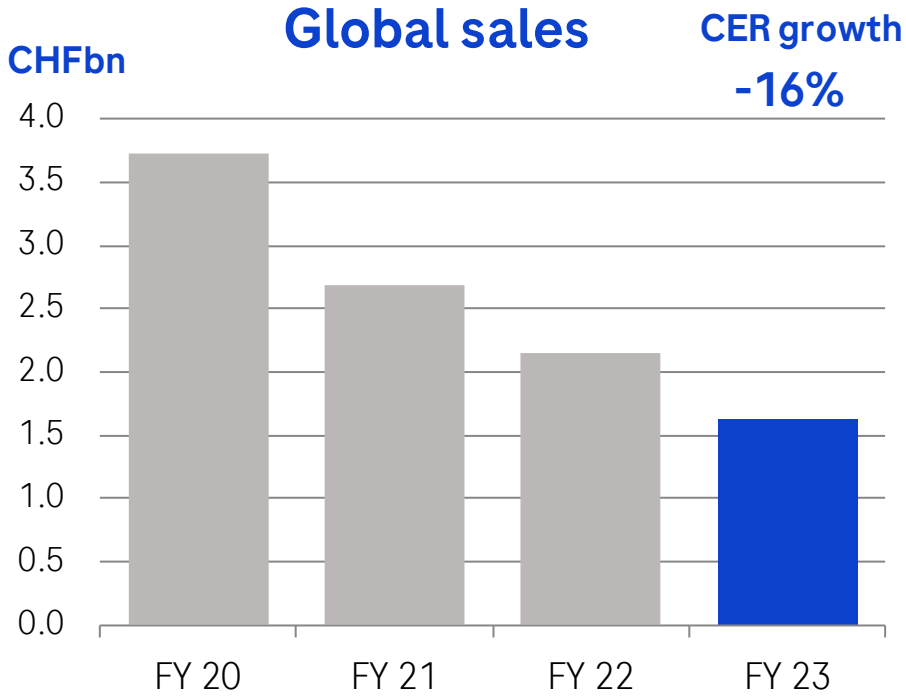
FY 2023 sales of CHF 1,630m

- US: Biosimilar erosion slowing
- EU: Biosimilar erosion bottoms out
- Japan: Biosimilar erosion slowing
- International: Biosimilar erosion slowing

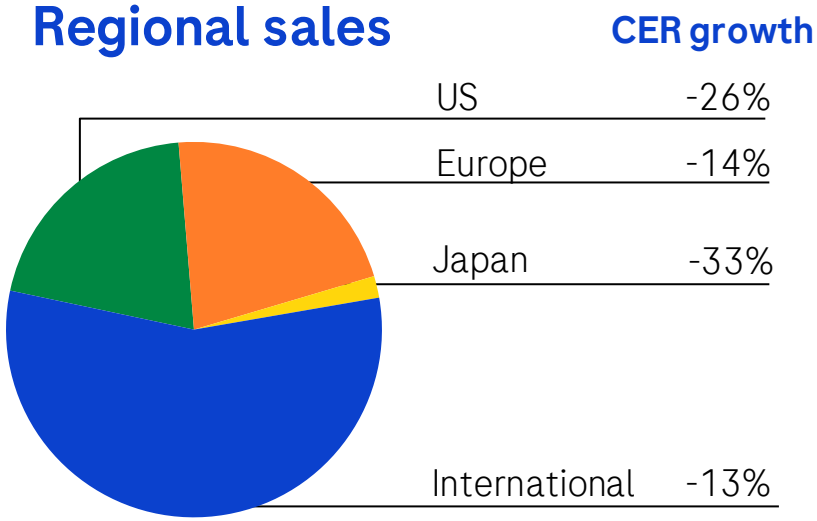
CER=Constant Exchange Rates

Herceptin

Global sales



Regional sales



FY 2023 sales of CHF 1,626m

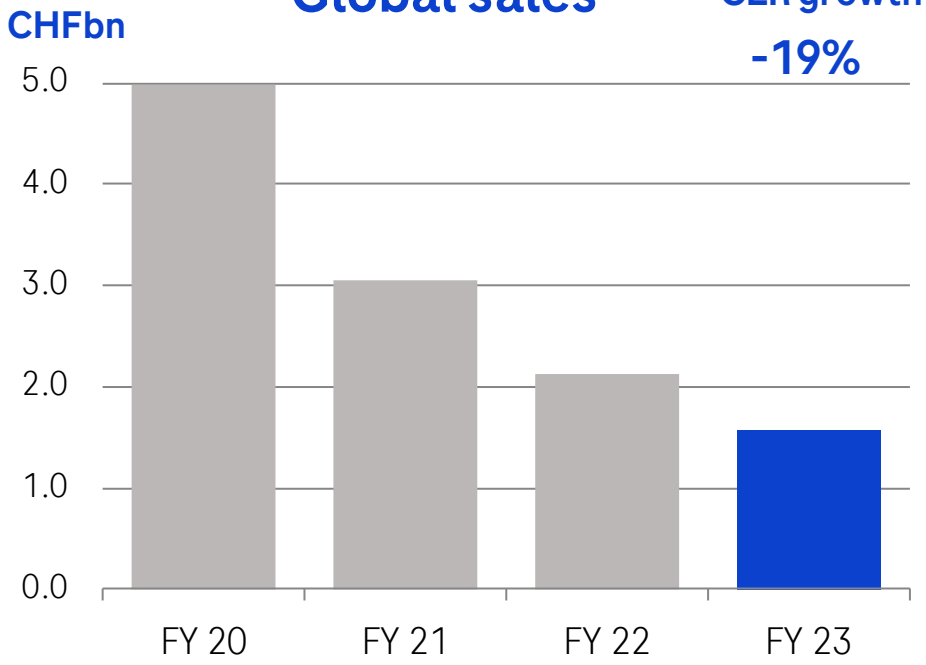
- US: Biosimilar erosion slowing; Switching of patients with residual disease to Kadcyla; Conversion to Phesgo
- EU: Biosimilar erosion slowing; Switching of patients with residual disease to Kadcyla; Conversion to Phesgo
- Japan: Decline due to biosimilars
- International: Decline due to biosimilars; Conversion to Phesgo

CER=Constant Exchange Rates

Avastin

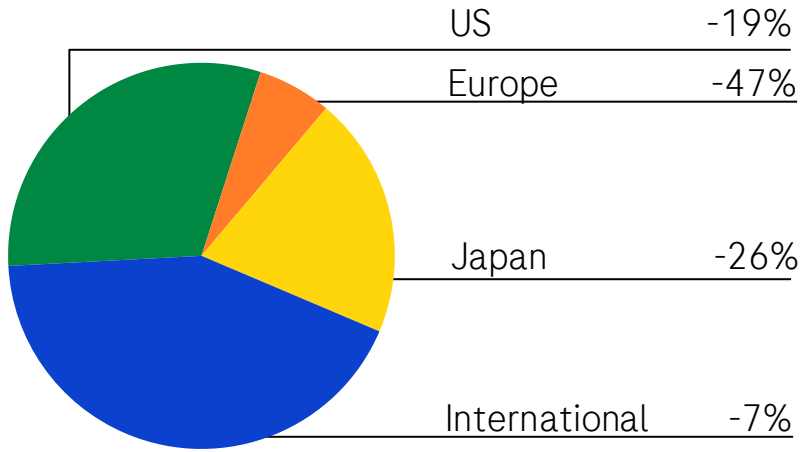
Global sales

CER growth
-19%



Regional sales

CER growth



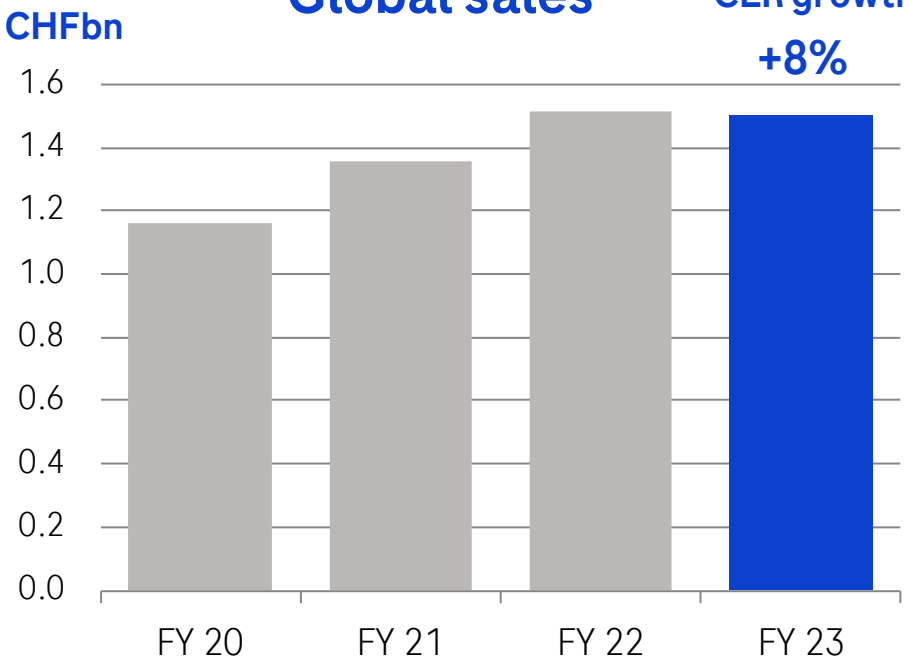
FY 2023 sales of CHF 1,573m

- US: Biosimilar erosion slowing
- EU: Ongoing biosimilar erosion
- Japan: Ongoing biosimilar erosion
- International: Biosimilar erosion slowing

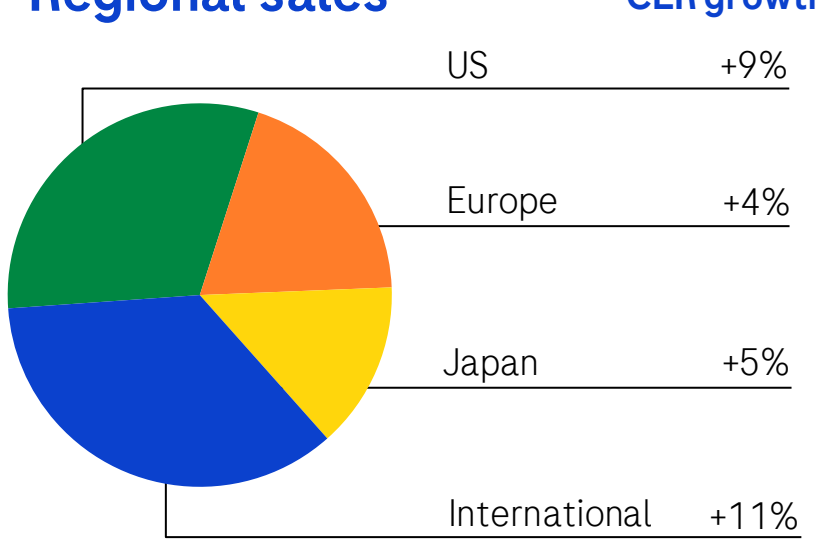
CER=Constant Exchange Rates

Alecensa

Global sales



Regional sales



FY 2023 sales of CHF 1,502m

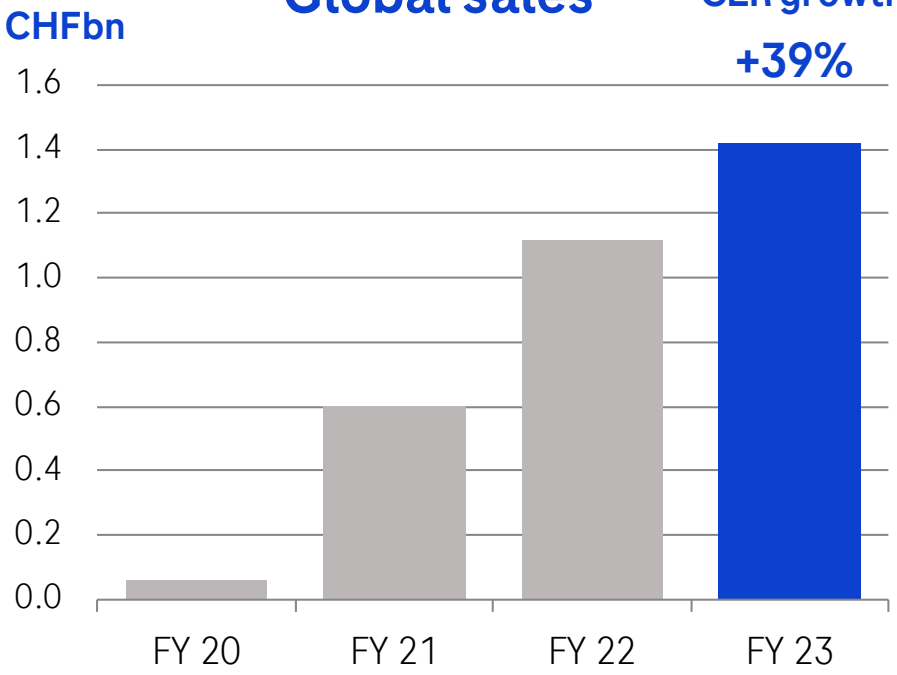
- US: Market leadership in 1L ALK+ NSCLC is maintained
- EU: Market leadership in 1L ALK+ NSCLC is maintained
- Japan: Market leadership in 1L ALK+ NSCLC is maintained
- International: Strong growth driven by all regions

CER=Constant Exchange Rates

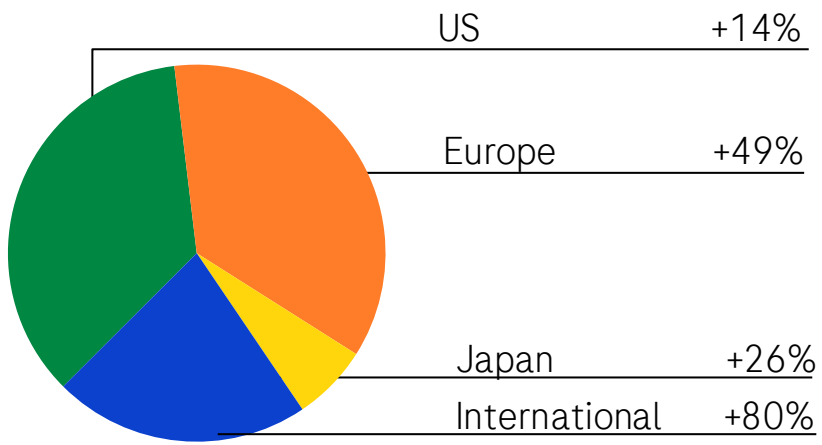
Evrysdi

Global sales

CER growth +39%



Regional sales



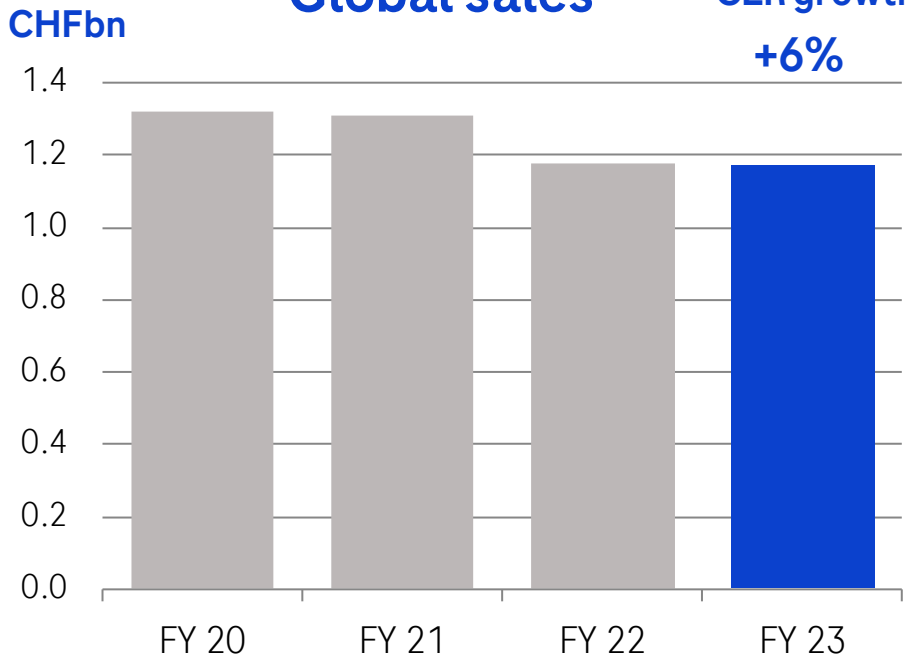
FY 2023 sales of CHF 1,419m

- US: Strong uptake across all patient segments; including treatment-naïve patients; leading market share with >25%
- EU: Continued strong growth and share gains, especially in Germany, UK and Italy
- Japan: Market leading position with >50%
- International: Strong growth in all regions

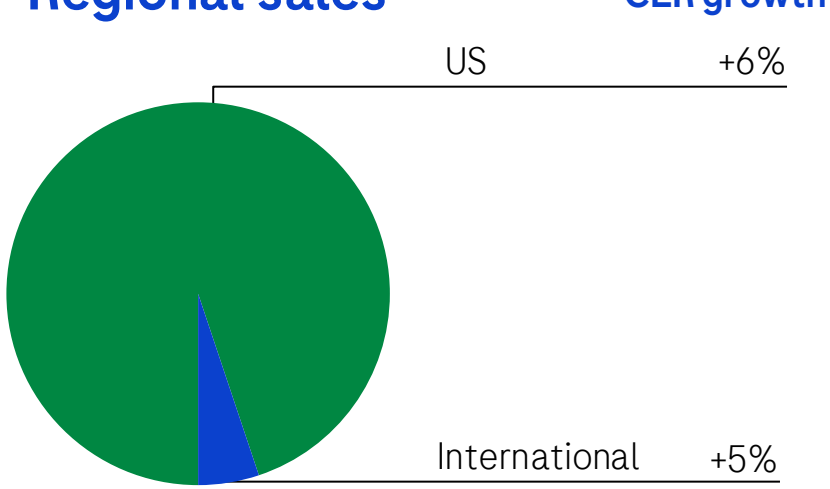
CER=Constant Exchange Rates

TNKase / Activase

Global sales



Regional sales

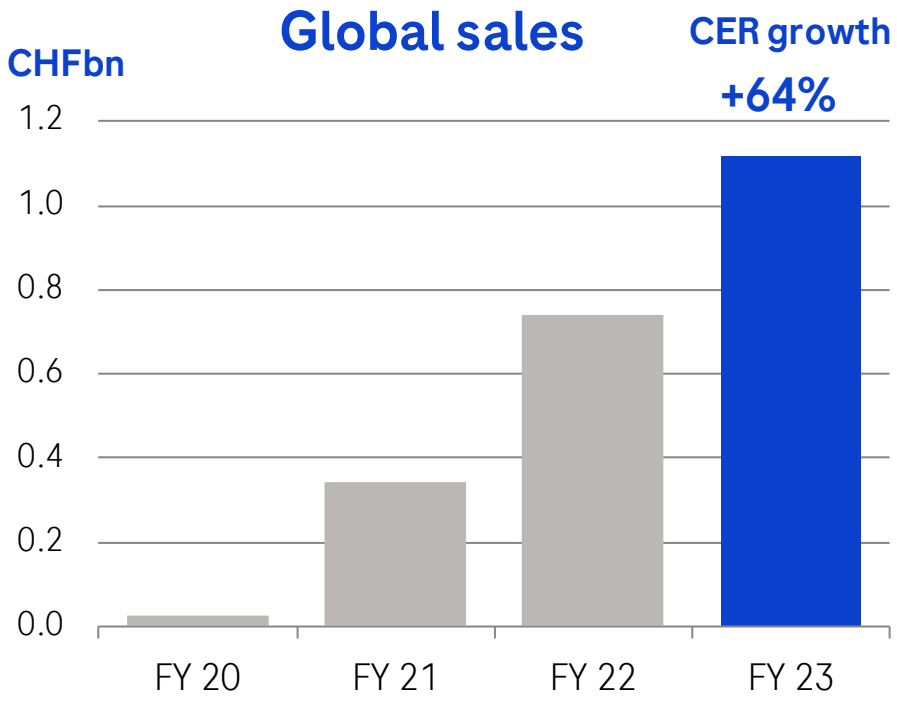


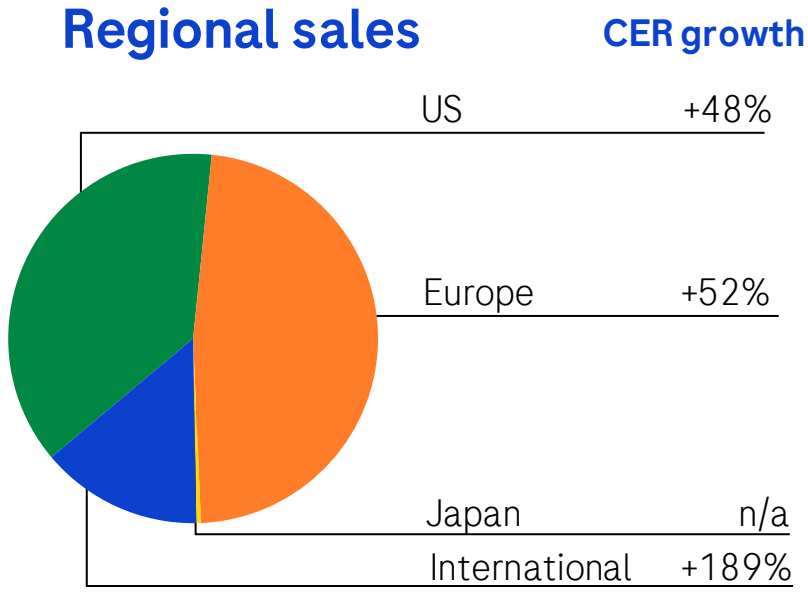
FY 2023 sales of CHF 1,173m

- Spontaneous TNKase use in AIS early time window

CER=Constant Exchange Rates

Phesgo





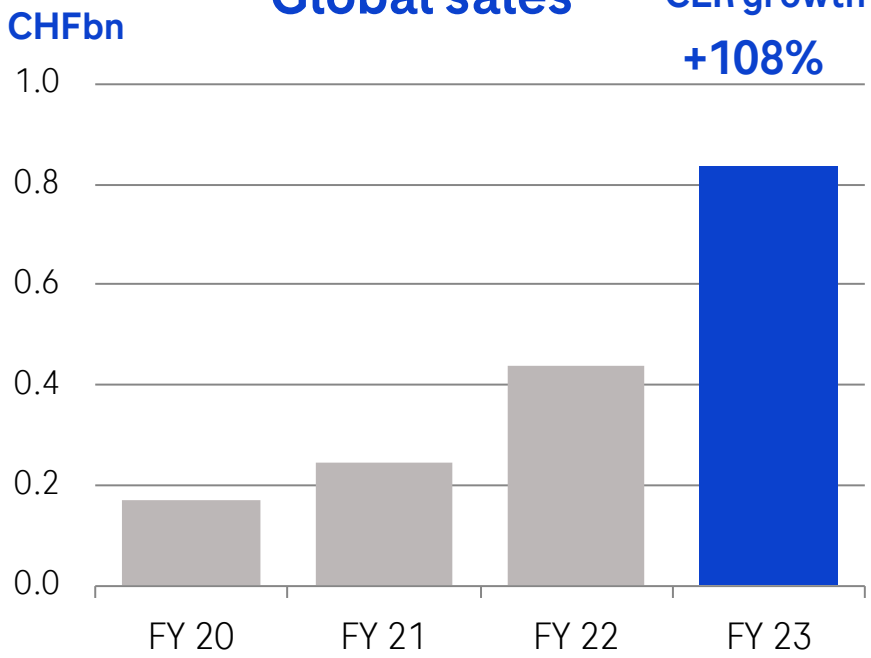
FY 2023 sales of CHF 1,120m

- US: Strong growth driven by eBC, switching of patients from Perjeta+Herceptin to Phesgo
- EU: Strong growth in all regions, mainly UK, France, Germany and Italy
- International: Strong uptake in all regions

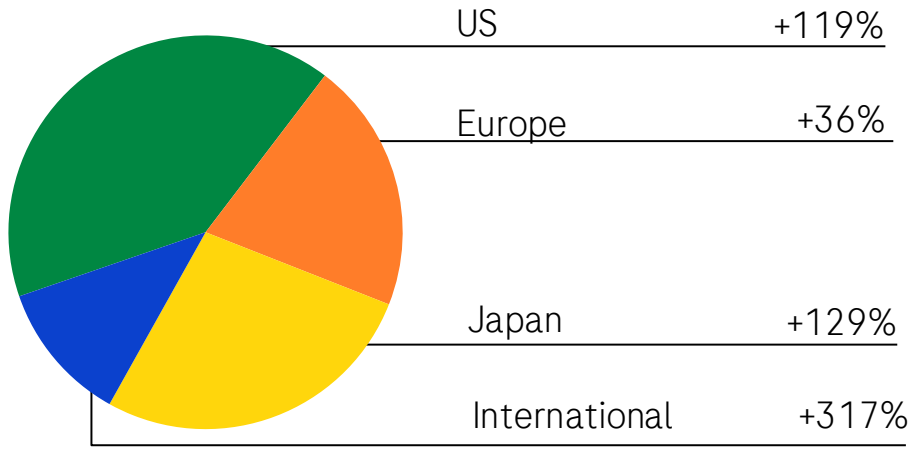
CER=Constant Exchange Rates

Polivy

Global sales



Regional sales

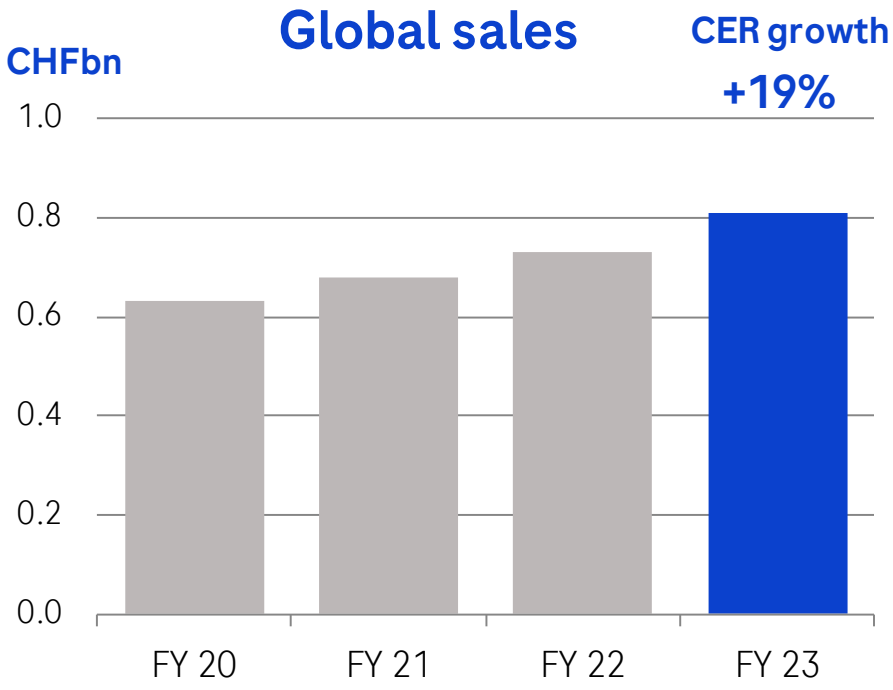


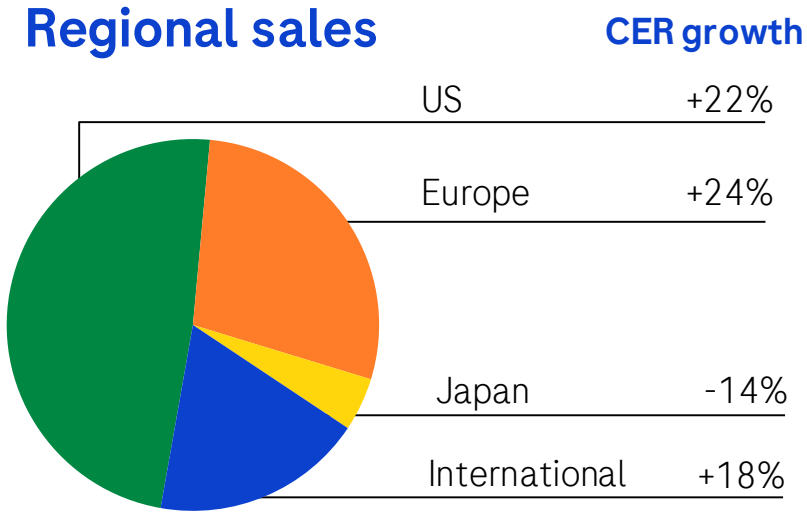
FY 2023 sales of CHF 837m

- US: Strong growth following approval in 1L DLBCL and inclusion to the NCCN guidelines as Category I
- EU: Strong growth following approval in 1L DLBCL
- JP: Strong growth following approval in 1L DLBCL
- International: Strong growth following approval in 1L DLBCL

CER=Constant Exchange Rates

Gazyva





FY 2023 sales of CHF 811m

- US: Strong growth driven by combination therapies in 1L CLL
- EU: Strong growth driven by combination therapies in 1L CLL
- International: Continued growth in all key markets

CER=Constant Exchange Rates

Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

Spark

Pharma sales appendix

Diagnostics sales appendix

Foreign exchange rates information

2023: Diagnostics Division CER growth

By Region and Customer Area (vs. 2022)

	Global		EMEA[1]		North America		Asia-Pacific		Latin America	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Core Lab[2]	7,750	9	2,681	9	1,374	2	3,068	10	627	20
Molecular Lab	2,220	-30	712	-36	993	-21	424	-40	91	-2
Pathology Lab	1,388	14	342	15	751	12	263	15	32	46
Point of Care	1,379	-58	339	-59	506	-62	487	-55	47	-45
Diabetes Care	1,367	-4	694	-12	202	-12	254	2	217	29
Diagnostics Division	**14,104**	**-13**	**4,768**	**-13**	**3,826**	**-21**	**4,496**	**-11**	**1,014**	**14**

CER=Constant Exchange Rates; [1] Europe, Middle East and Africa; [2] incl. Roche Information Solutions

Diagnostics Division quarterly sales and CER growth[1]

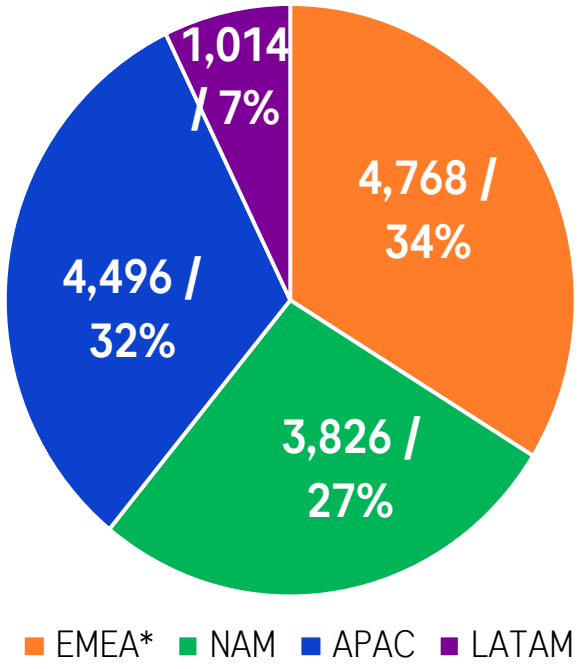
	Q1 22		Q2 22		Q3 22		Q4 22		Q1 23		Q2 23		Q3 23		Q4 23	
	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER	CHFm	% CER
Core Lab[2]	1,896	8	1,979	1	1,958	7	1,942	9	1,928	7	2,007	12	1,901	8	1,914	9
Molecular Lab	1,189	21	791	-20	755	-24	715	-35	593	-48	525	-27	529	-24	573	-13
Pathology Lab	318	14	334	7	323	10	343	12	329	7	358	17	359	22	342	10
Point of Care	1,466	84	1,143	15	477	-16	503	-26	397	-72	238	-77	230	-48	514	10
Diabetes Care	417	-7	415	-3	387	2	379	1	376	-5	347	-6	314	-7	330	3
Diagnostics Division	**5,286**	**24**	**4,662**	**0**	**3,900**	**-4**	**3,882**	**-9**	**3,623**	**-28**	**3,475**	**-17**	**3,333**	**-5**	**3,673**	**4**

CER=Constant Exchange Rates of the respective year; [1] versus same period of prior year; [2] incl. Roche Information Solutions

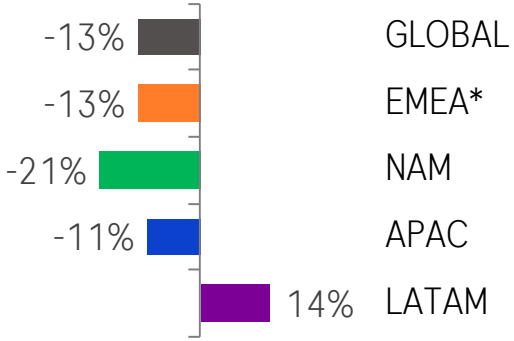
2023: Diagnostics Division regional sales

Decline in NAM, EMEA and APAC

Sales YTD CHFm & % of total sales
Total YTD Sales = 14,104

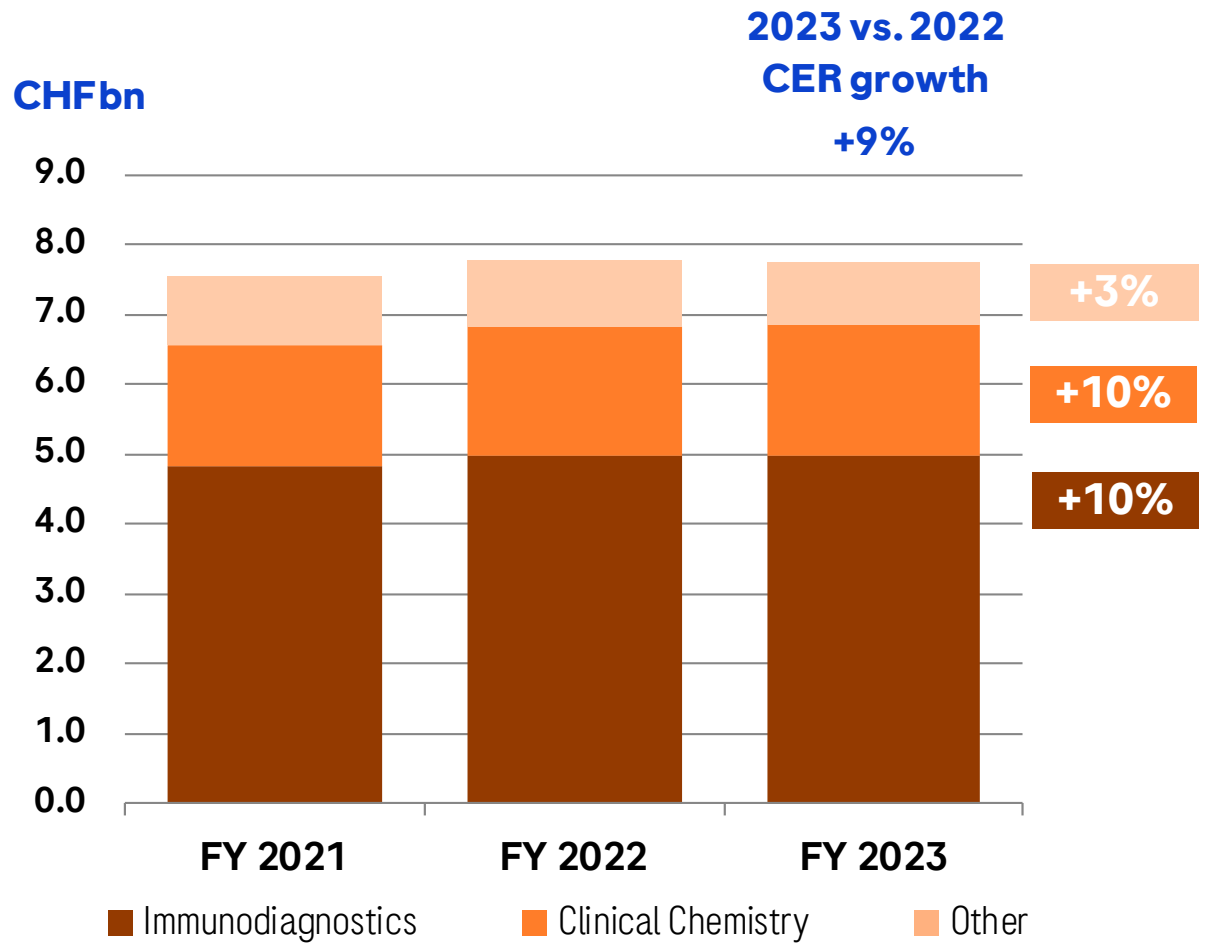


Sales growth at CER
Diagnostics Division



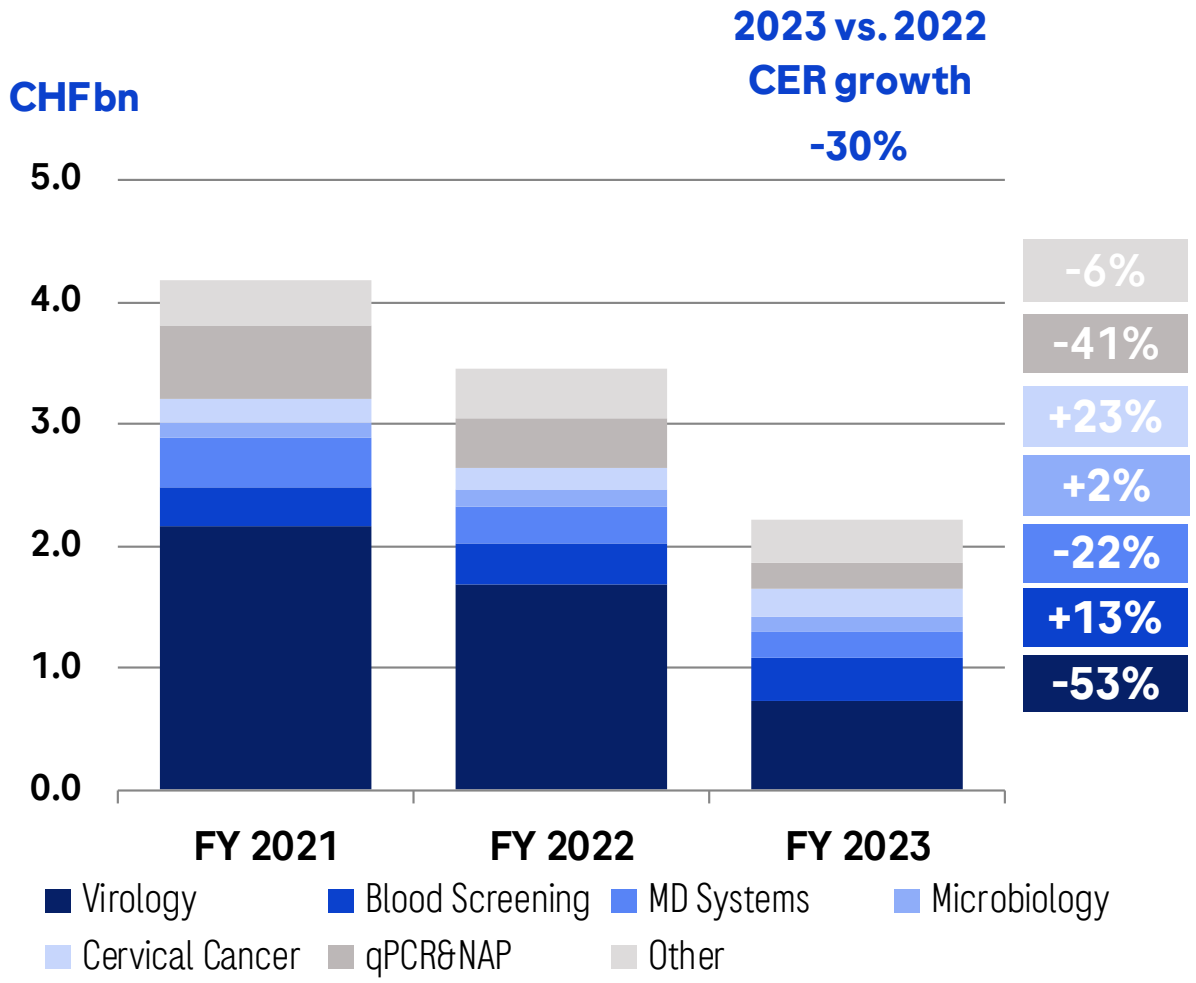
CER=Constant Exchange Rates; * Europe, Middle East and Africa

Core Lab[1]



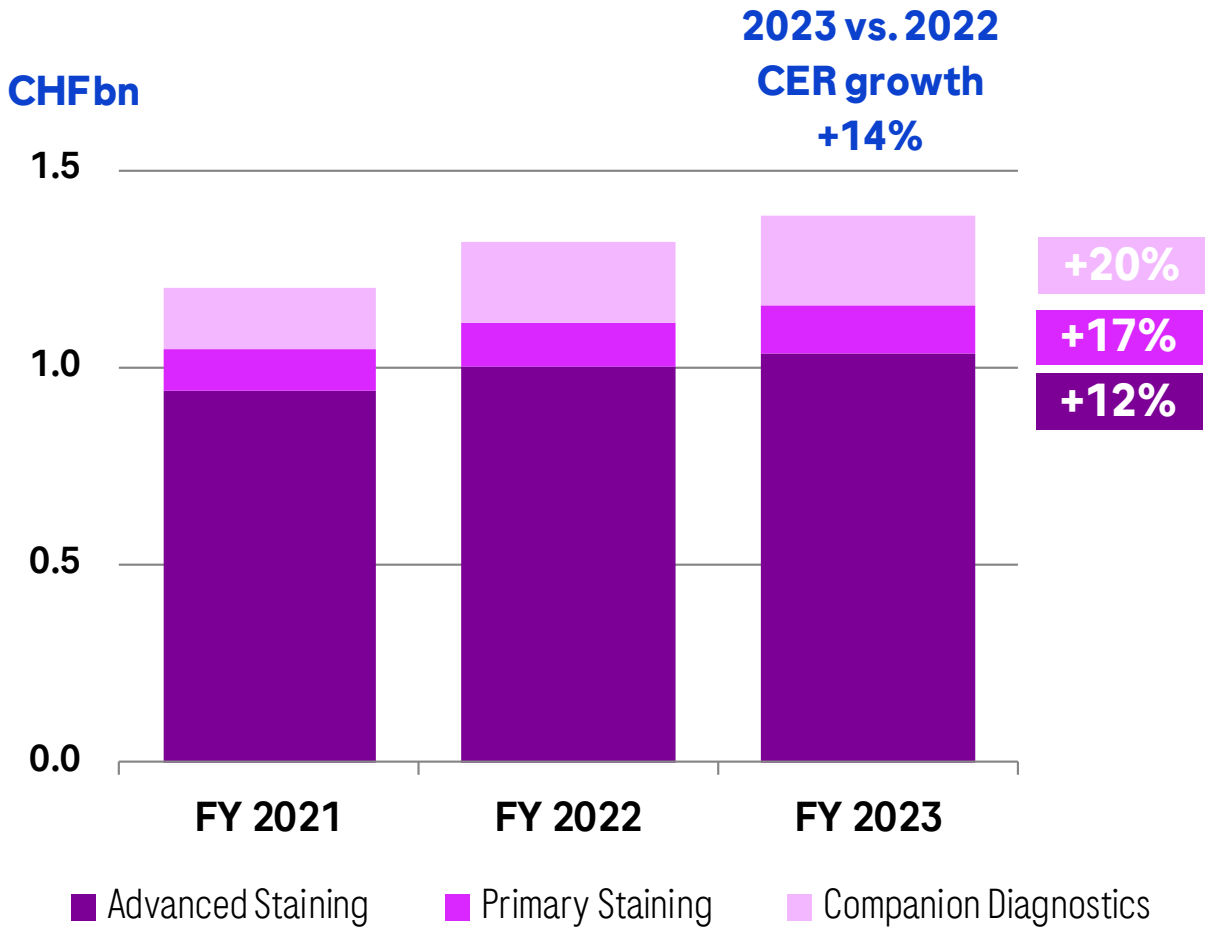
CER=Constant Exchange Rates; [1] incl. Roche Information Solutions; underlying growth of Core Lab excluding Roche Information Solutions: +9%

Molecular Lab



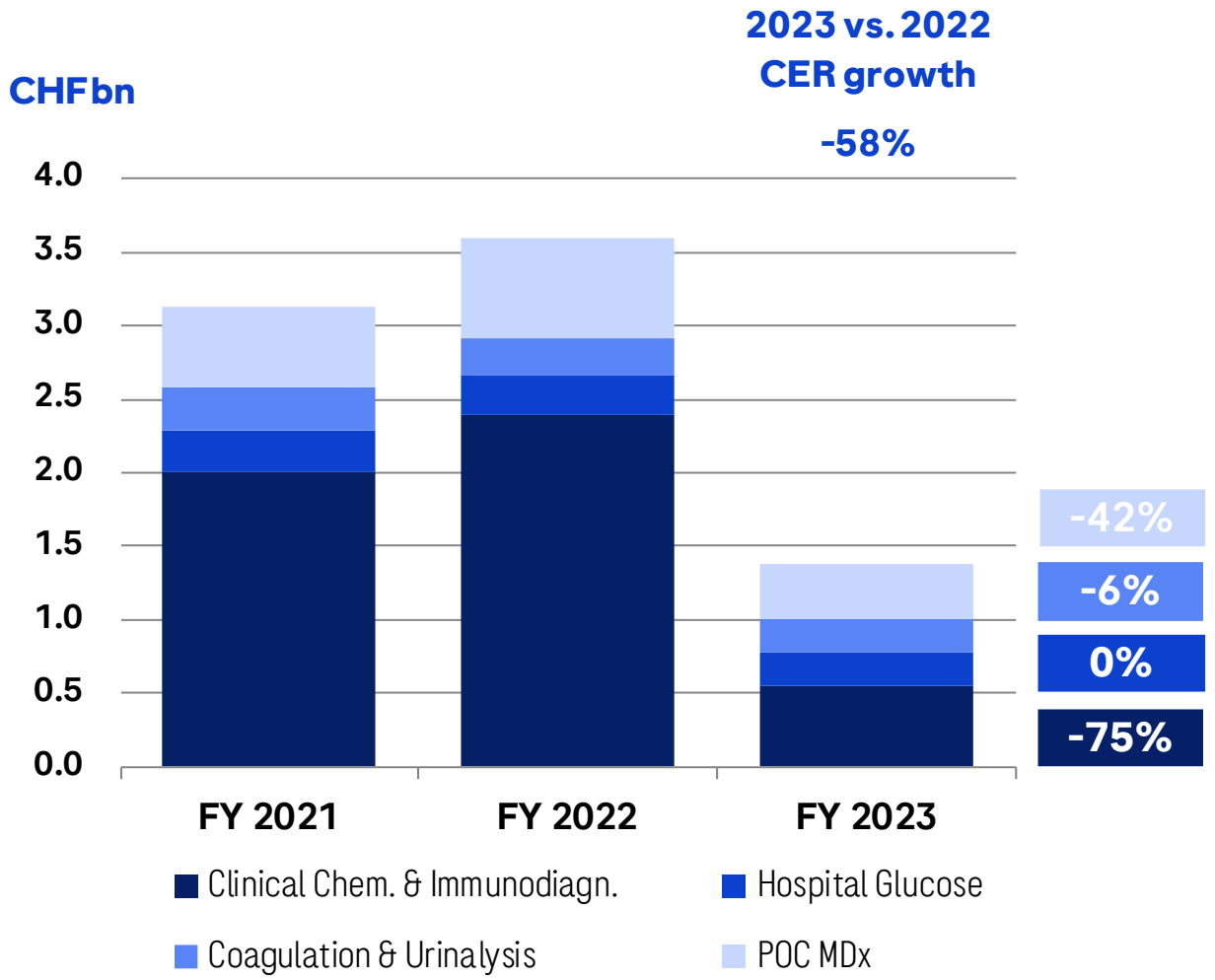
CER=Constant Exchange Rates

Pathology Lab



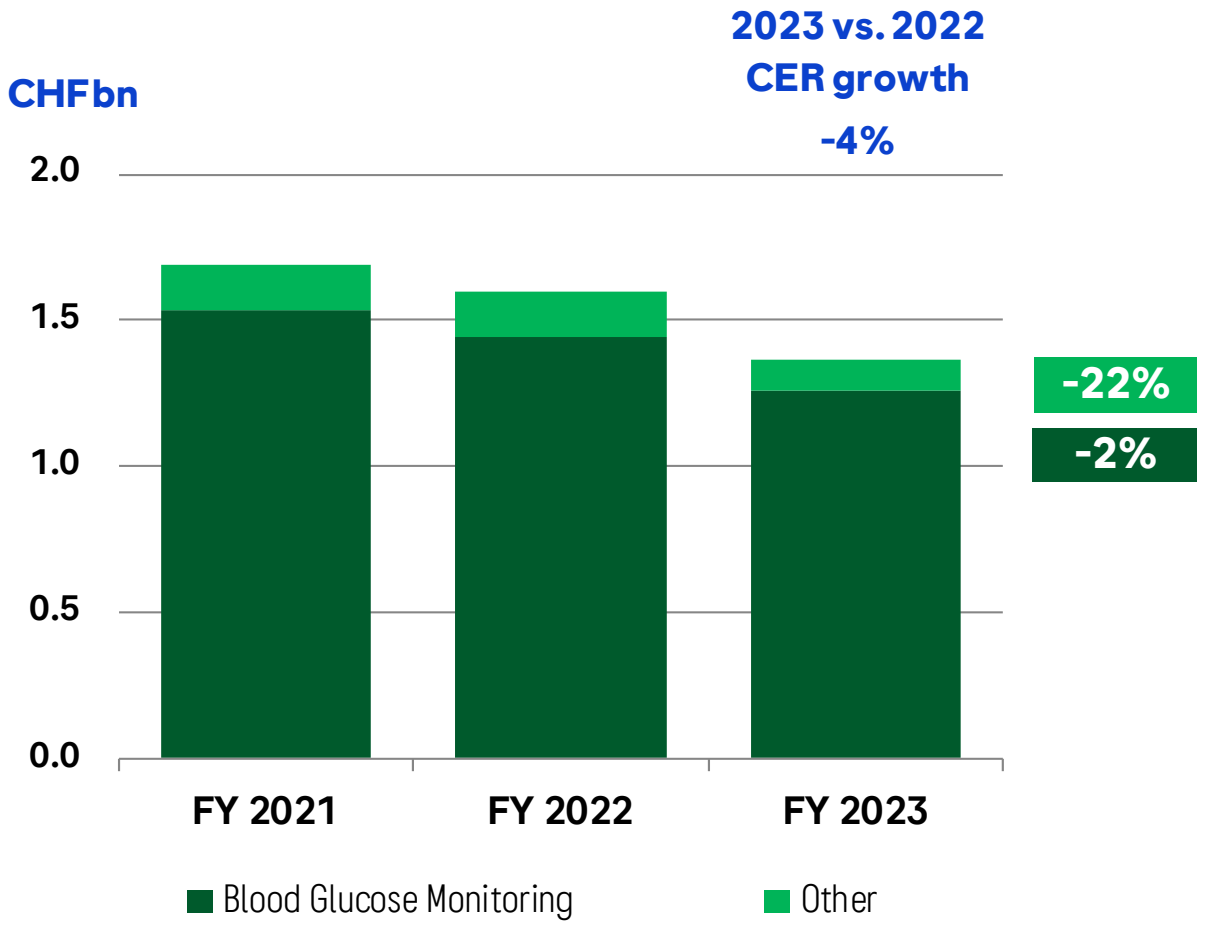
CER=Constant Exchange Rates

Point of Care



CER=Constant Exchange Rates

Diabetes Care



CER=Constant Exchange Rates

Roche Group development pipeline

Marketed products development programmes

Roche Pharma global development programmes

Roche Pharma research and early development (pRED)

Genentech research and early development (gRED)

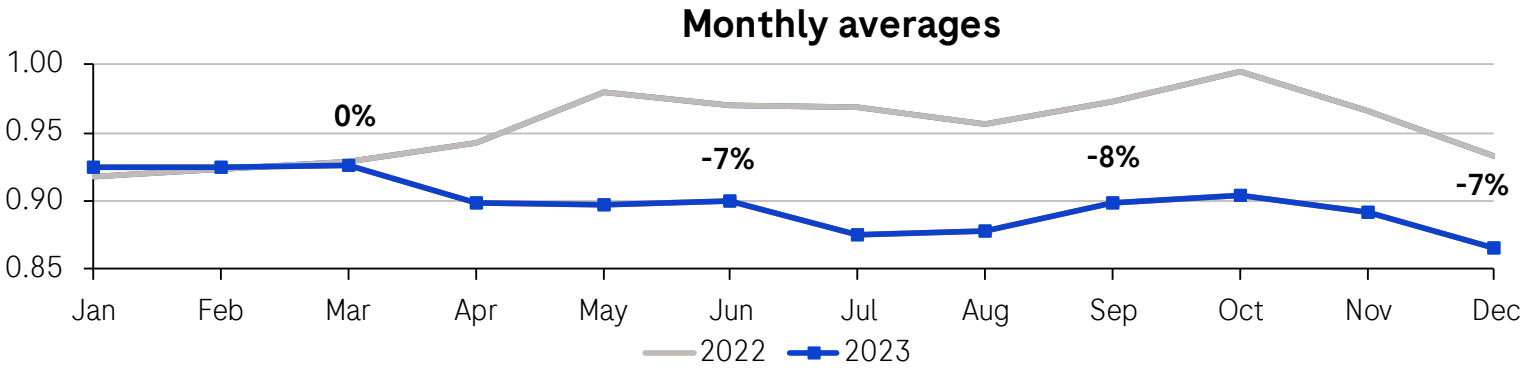
Spark

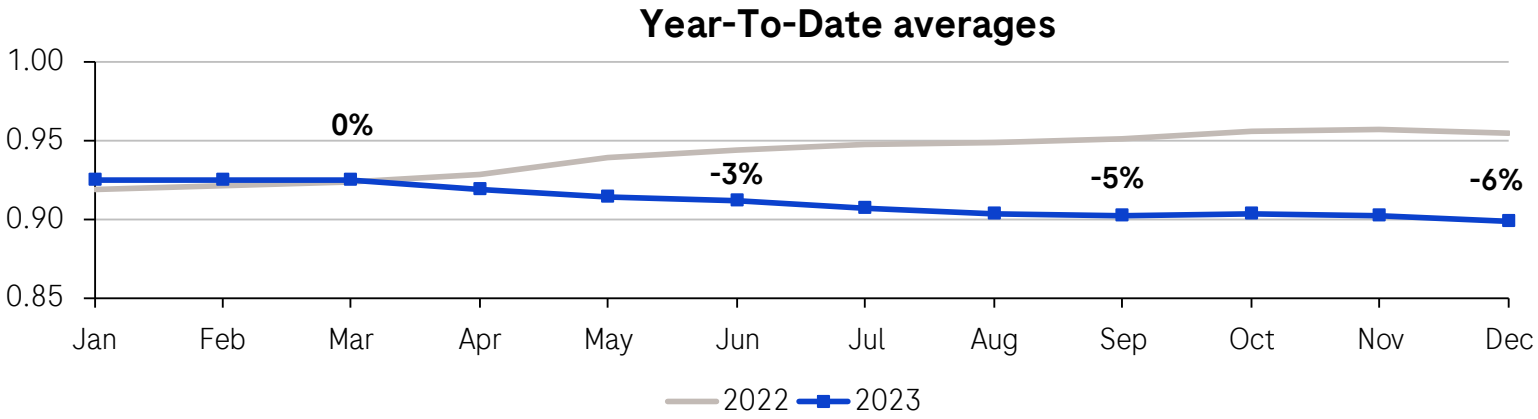
Pharma sales appendix

Diagnostics sales appendix

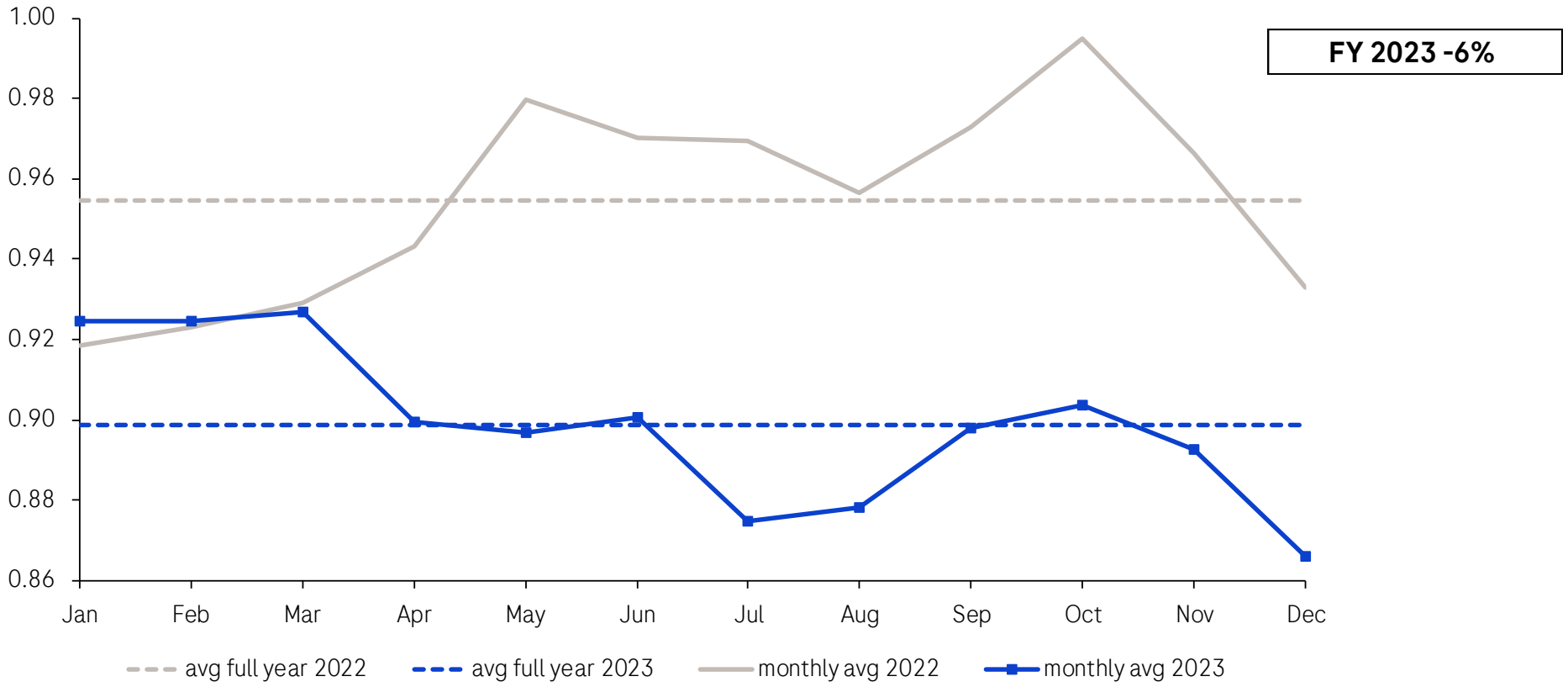
Foreign exchange rates information

CHF/USD

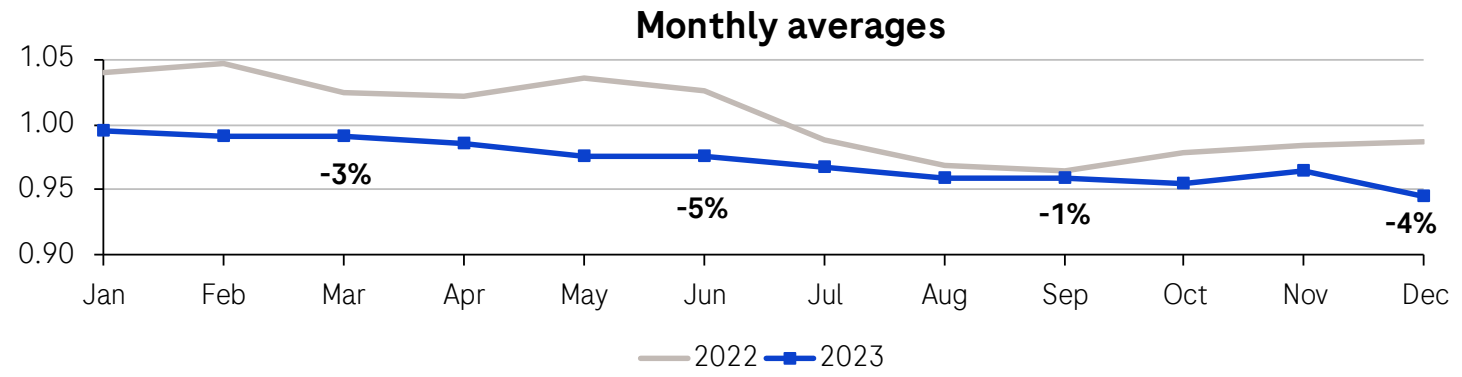

Monthly averages
1.00
0.95
0.90
0.85
0%
-7%
-8%
-7%
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
2022
2023

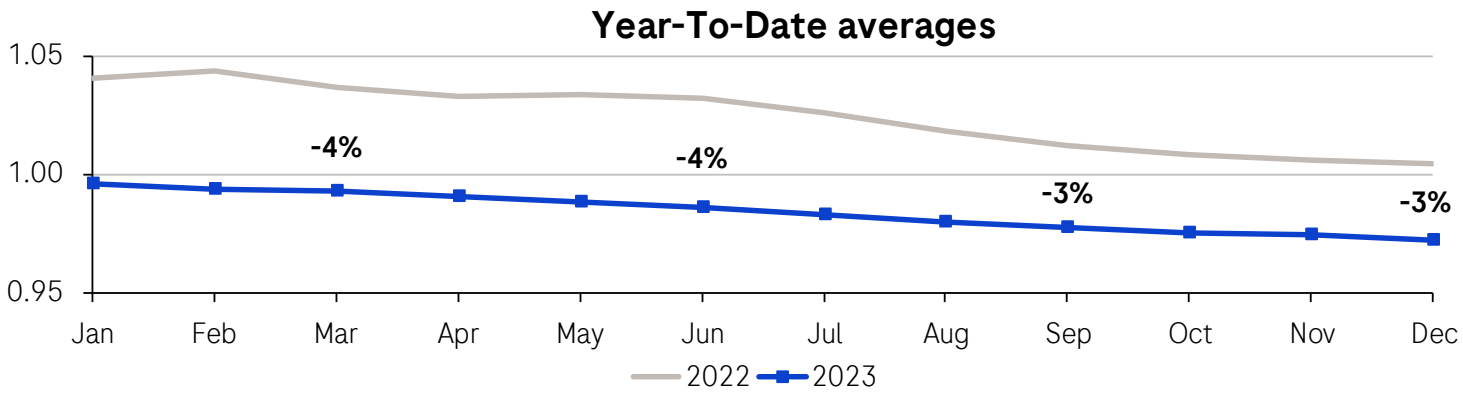

Year-To-Date averages
1.00
0.95
0.90
0.85
0%
-3%
-5%
-6%
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
2022
2023

CHF/USD

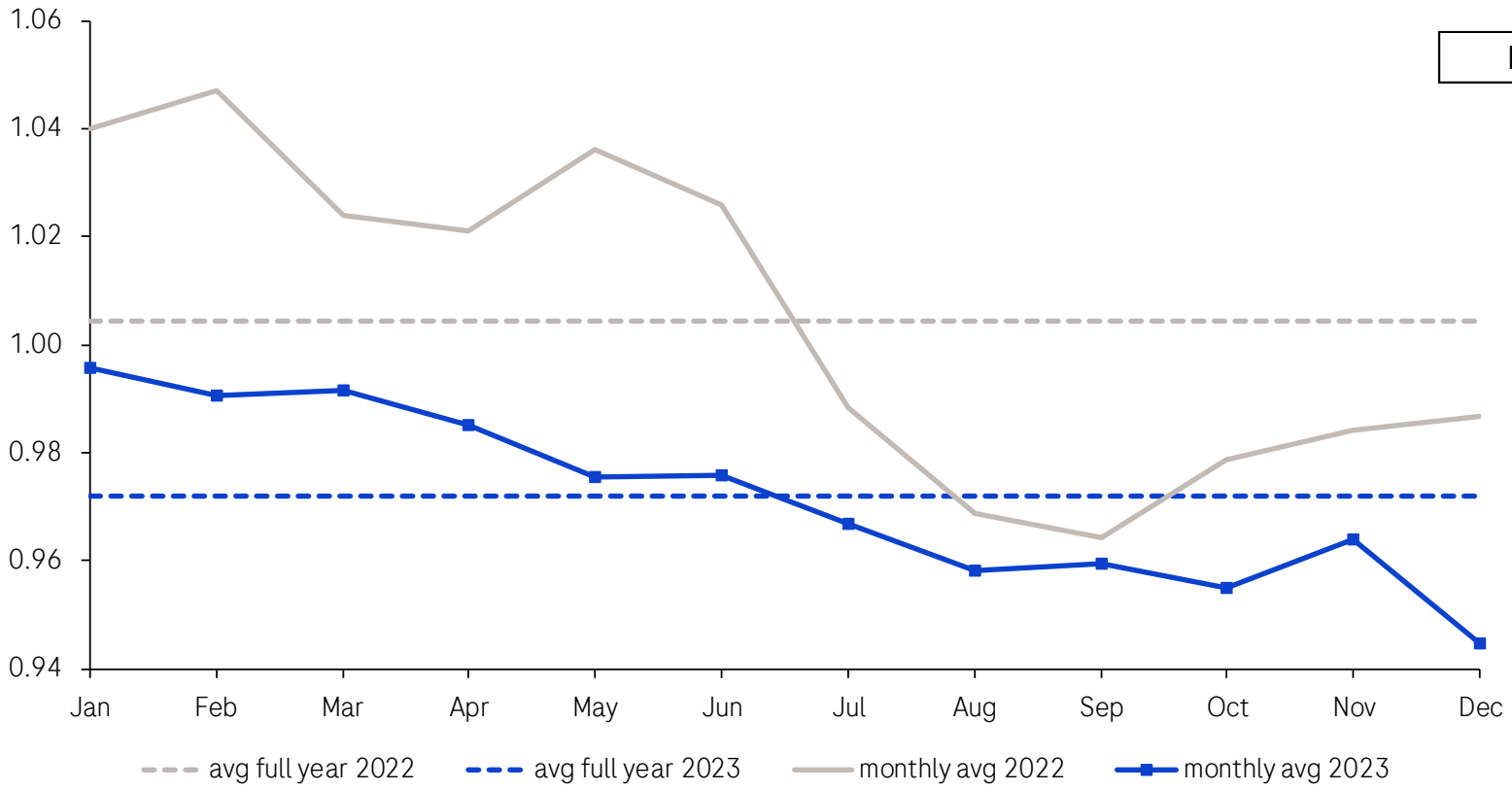

1.00
0.98
0.96
0.94
0.92
0.90
0.88
0.86
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
FY 2023 -6%
avg full year 2022
avg full year 2023
monthly avg 2022
monthly avg 2023

CHF/EUR


Monthly averages
1.05
1.00
0.95
0.90
-3%
-5%
-1%
-4%
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
2022
2023


Year-To-Date averages
1.05
1.00
0.95
-4%
-4%
-3%
-3%
Jan
Feb
Mar
Apr
May
Jun
Jul
Aug
Sep
Oct
Nov
Dec
2022
2023

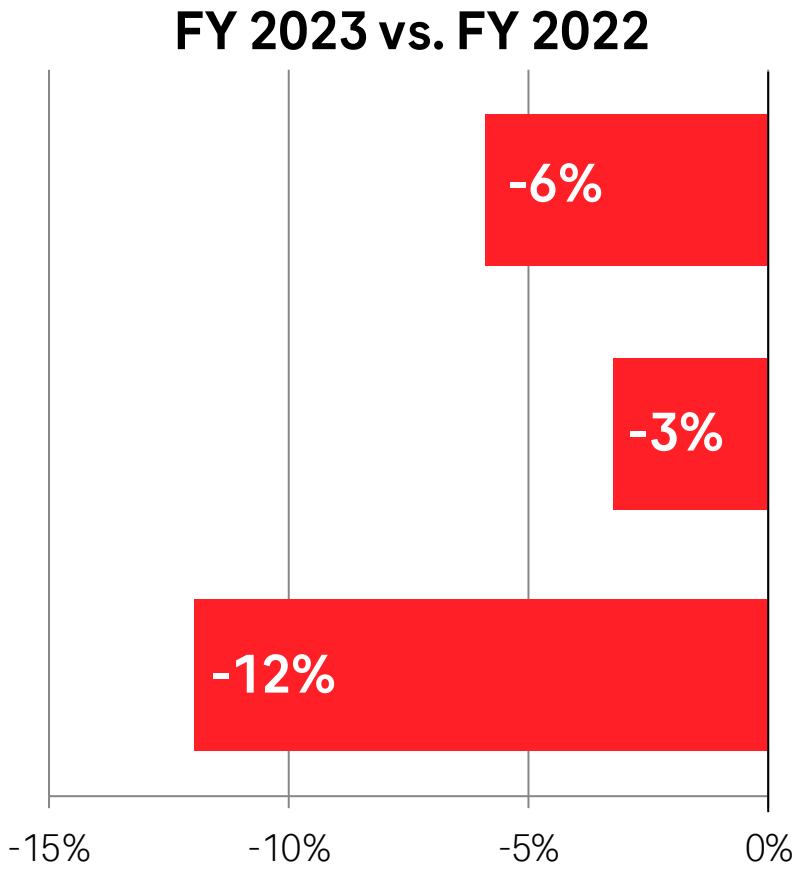
CHF/EUR



FY 2023 -3%

Average CHF Exchange Rates

	FY 2023	FY 2022
USD	0.90	0.95
EUR	0.97	1.00
JPY	0.64	0.73

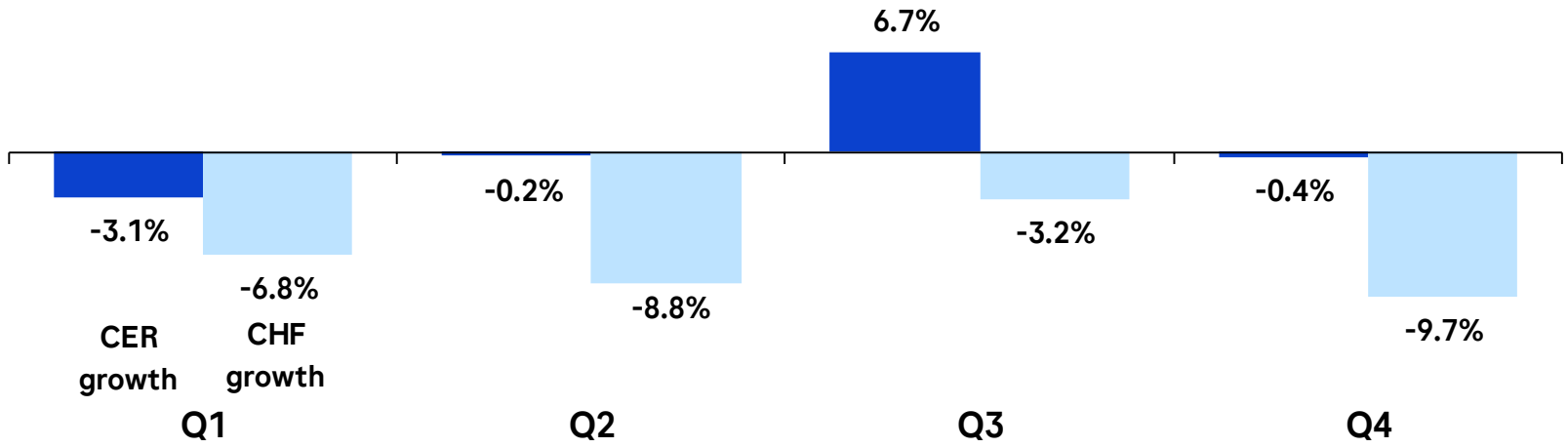


Exchange rate impact on sales growth

Q4 2023: negative impact of JPY, CNY, USD and EUR

Development of average exchange rates versus prior year period

	Q1	Q2	Q3	Q4
CHF / USD	0.2%	-6.8%	-8.6%	-8.0%
CHF / EUR	-4.3%	-4.8%	-1.3%	-2.9%
CHF / JPY	-12.1%	-12.0%	-12.5%	-12.0%
CHF / CNY	-7.0%	-12.1%	-13.7%	-9.5%
Difference in CHF / CER growth	-3.7%	-8.6%	-9.9%	-9.3%



CER=Constant Exchange Rates

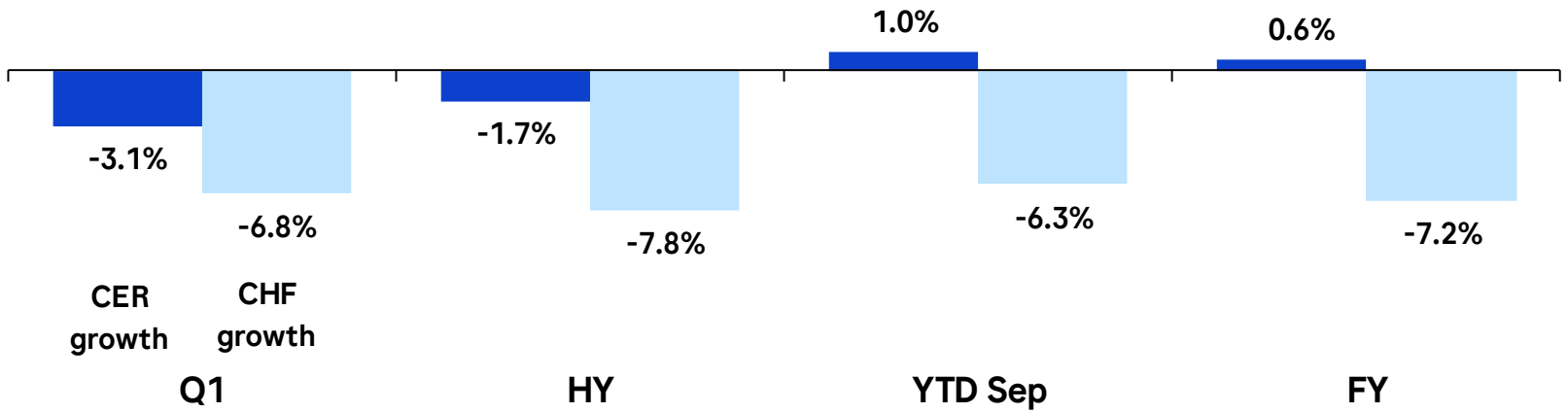
Exchange rate impact on sales growth

FY 2023: negative impact of JPY, CNY, USD and EUR

Development of average exchange rates versus prior year period

	Q1	HY	YTD Sep	FY
CHF / USD	0.2%	-3.4%	-5.1%	-5.9%
CHF / EUR	-4.3%	-4.5%	-3.4%	-3.2%
CHF / JPY	-12.1%	-11.9%	-12.0%	-12.0%
CHF / CNY	-7.0%	-9.6%	-11.0%	-10.5%
Difference in CHF / CER growth	-3.7%	-6.1%	-7.3%	-7.8%

Sales growth 2023 vs. 2022



CER=Constant Exchange Rates

Doing now what patients need next