
Roche

Roche

YTD September 2021 sales

Basel, 20 October 2021

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

Group

Severin Schwan
Chief Executive Officer

YTD Sep 2021 performance

Outlook

YTD Sep 2021: Continued strong performance; Guidance raised

- **Guidance raised: Sales growth** to **“mid-single digit”** from “low- to mid-single digit”, **Core EPS growth broadly in line with sales growth**
- **Group sales up +8%**
  - **Diagnostics** with double digit growth in Q3 (+18%), despite high base, **strong recovery of base business**
  - **Pharma** continued growth in Q3 +5% (Q2:+4%), **strong performance of new products** (capturing >50% of Pharma sales)
- **Good development of pipeline**
  - Pharma: 14 Phase III trials initiated; 17 NMEs in late stage (pivotal)
  - Diagnostics: Significant launches in Q4 (cobas® 5800, cobas® pulse, AVENIO FoundationOne kit & NAVIFY Oncology 1.0)
- **Strong news flow over the next 1.5 years**
  - Faricimab and PDS in ophthalmology, Polivy and CD20xCD3 bi-specifics in hematology, AT-527 in SARS-CoV-2, Tecentriq in the adjuvant setting in various cancer types, tiragolumab + Tecentriq combo in 4 different cancer types, giredestrant (SERD) in HR+ breast cancer
  - BTD for gantenerumab in Alzheimer’s disease in Q3

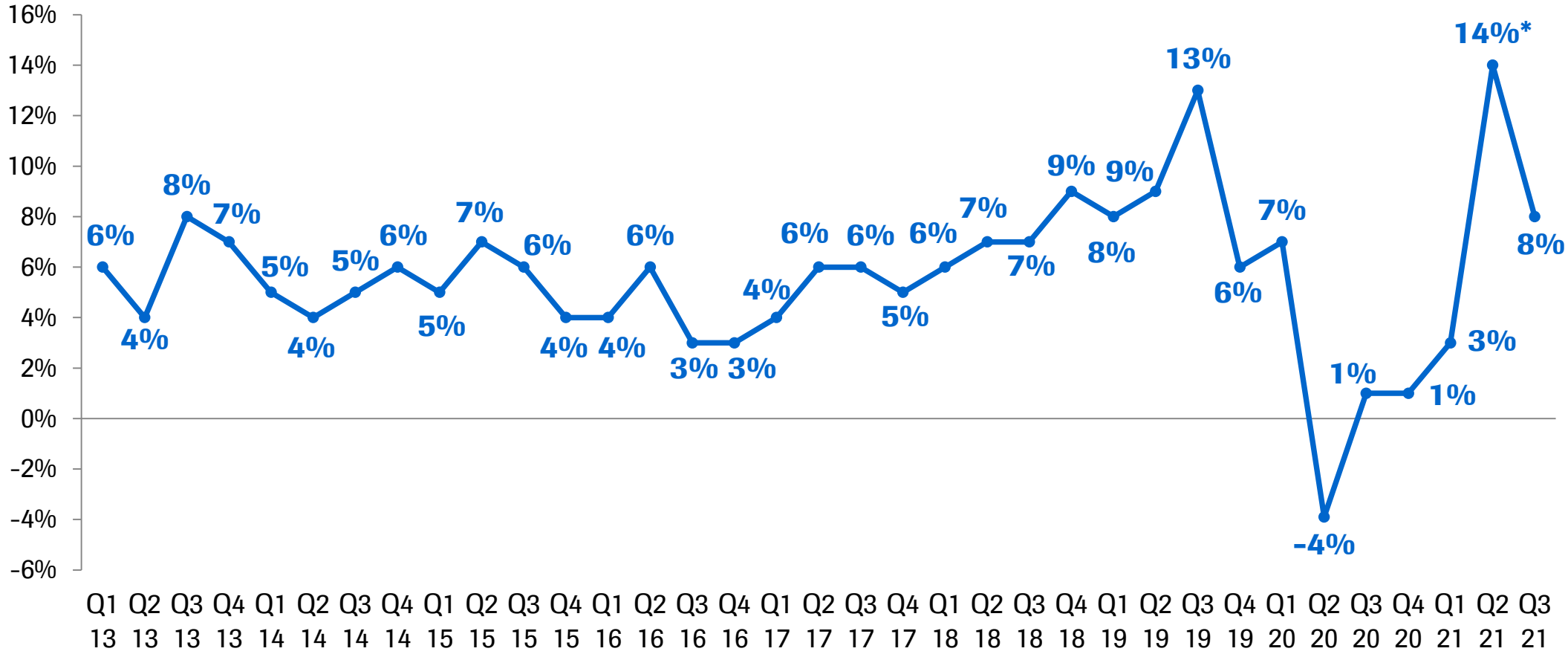
Growth rates at CER (Constant exchange Rates)

YTD Sep 2021: Sales growth driven by Diagnostics Division

	2021 CHFbn	2020 CHFbn	Change in % CHF	Change in % CER
Pharmaceuticals Division	**33.4**	34.3	**-3**	**0**
Diagnostics Division	**13.3**	9.7	**38**	**39**
Roche Group	**46.7**	44.0	**6**	**8**

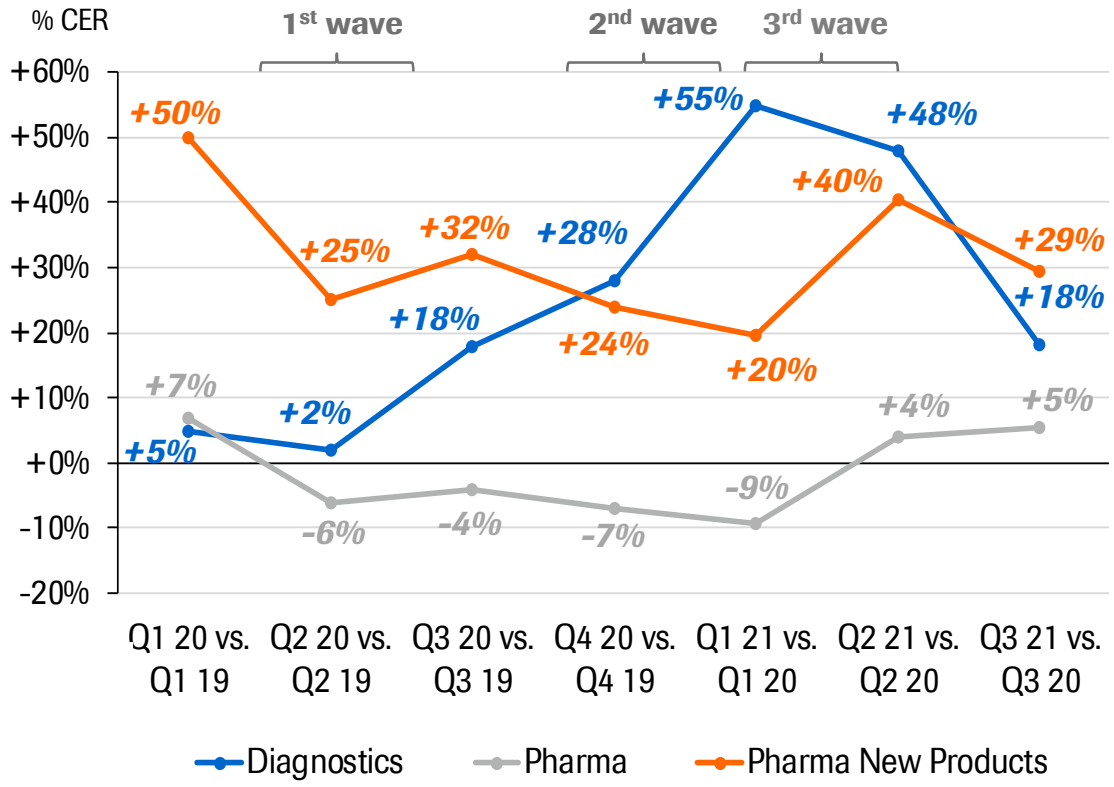
CER=Constant Exchange Rates

Q3 2021: Strong sales growth



Growth rates at CER (Constant exchange Rates); * Q2 2020 sales severely impacted by COVID-19 pandemic onset

Q3 2021: Strong business momentum



Pharmaceuticals

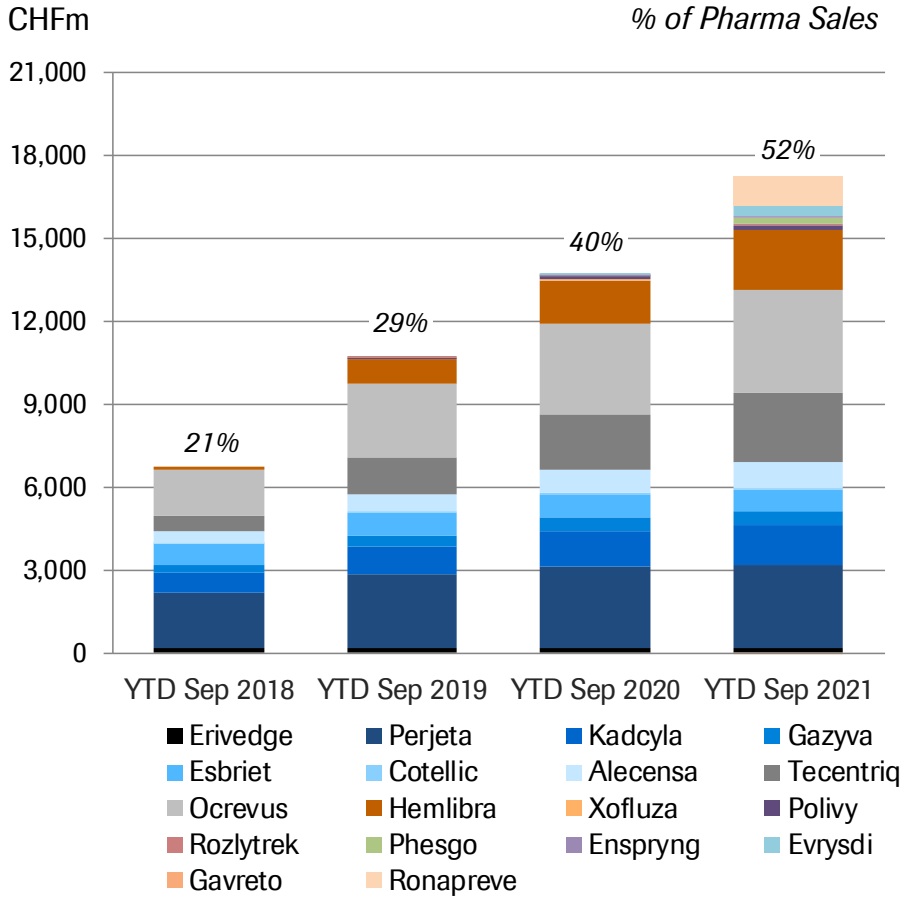
- Recovery in Q3 2021 expected to continue in Q4 2021
- Impact from biosimilars, expected to flatten in the coming quarters

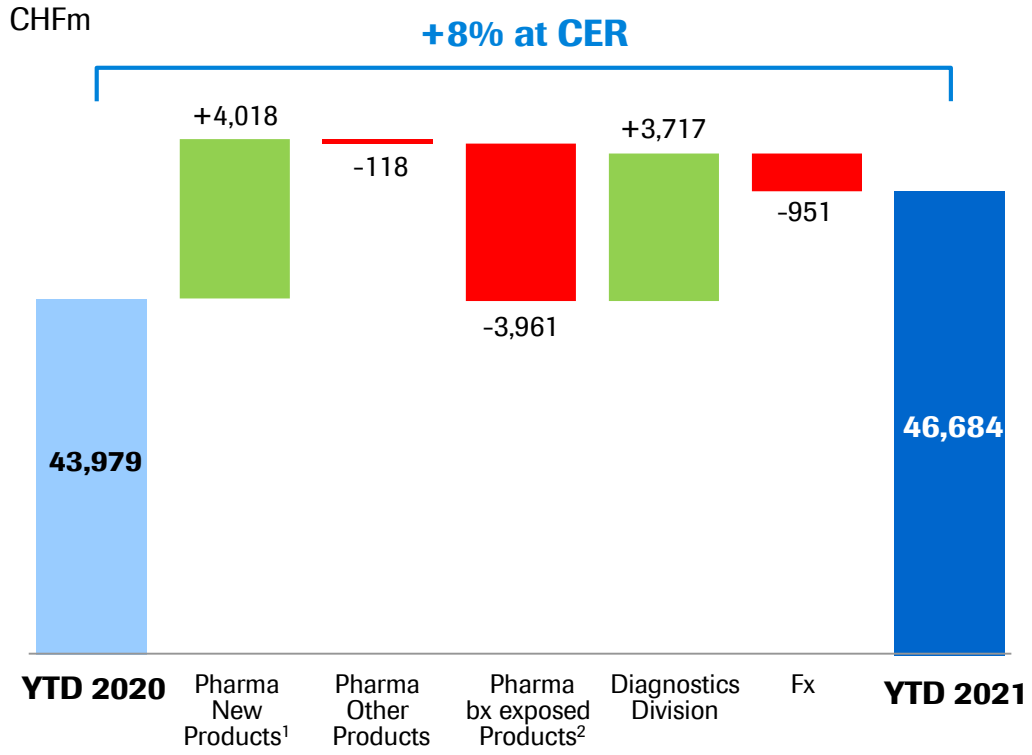
Diagnostics

- Strong routine testing growth, +11% in Q3 2021
- COVID-19 business expected to show similar pattern in Q4 2021

Growth rates at CER (Constant Exchange Rates)

YTD Sep 2021 Pharma: New products with continued momentum compensating for biosimilar impact





YTD Sep values in reported CHFm, variances in CERm; [1] Pharma New Products: Erivedge, Perjeta, Kadcyla, Gazyva, Esbriet, Cotellic, Alecensa, Tecentriq, Ocrevus, Hemlibra, Xofluza, Polivy, Rozlytrek, Phesgo, Enspryng, Evrysdi, Gavreto, Ronapreve; [2] Pharma Bx exposed products: Avastin, Herceptin, MabThera/Rituxan

YTD Sep 2021 performance

Outlook

Pharma: Significantly advancing patient care

39 Breakthrough Therapy Designations received since 2013

Year	Molecule	Indication
2021	***gantenerumab***	*Alzheimer's disease*
	Venclexta + azacitidine	*higher-risk MDS*
2020	***tiragolumab +Tecentriq***	*1L PD-L1+ NSCLC*
	mosunetuzumab	*3L+ FL*
	Tecentriq	*unresectable or metastatic ASPS*
	Esbriet	*uILD*
2019	***Gavreto***	*RET fusion-positive NSCLC*
	Gavreto	*RET mutation-positive MTC*
	Cotellic	*Histiocytic neoplasms*
	Gazyva	*Lupus nephritis*
	rhPentraxin-2 (PRM-151)	*IPF*
	Venclexta + Gazyva	*1L unfit CLL*
	Kadcyla	*Adjuvant HER2+ BC*
2018	***SPK-8011***	*Haemophilia A*
	Enspryng	*NMOSD*
	Xolair	*Food allergies*
	Tecentriq + Avastin	*1L HCC*
	Hemlibra	*Haemophilia A non-inhibitors*
	Rozlytrek	*NTRK+ solid tumors*
2017	***Polivy + BR***	*R/R DLBCL*
	Venclexta + LDAC	*1L unfit AML*
	Zelboraf	*BRAF-mutated ECD*
	Rituxan	*Pemphigus vulgaris*

14 new Ph III studies initiated YTD

- Kadcyla + Tecentriq (KATE 3) in 2L+ HER2+ PDL1+ mBC
- giredestrant (IidERA) in ER+ adj. BC
- Kadcyla + Tecentriq (ASTEFANIA) in HER2+ eBC high-risk
- Tecentriq (IMvigor011) in ctDNA+, high-risk MIBC
- rhPTX-2 (STARSCAPE) in IPF
- Gazyva (MAJESTY) in membranous nephropathy
- faricimab (BALATON & CAMINO) in branch & central RVO
- PDS with ranibizumab (Velodrome) in wAMD (36w interval)
- fenebrutinib in RMS (FENhance 1/2)
- SRP-9001 (EMBARK) in DMD (collaboration with Sarepta)
- Enspryng (Luminesce) in Myasthenia Gravis
- AT-527 (MORNINGSKY) in adult pts with SARS-COV-2

Neuroscience · Infectious Diseases · Immunology
Oncology/Hematology · Ophthalmology

2021 outlook raised

Sales growth to "mid-single digit" from "low- to mid-single digit"

Group sales growth[1]	• Mid-single digit (from low- to mid-single digit)
Core EPS growth[1]	• Broadly in line with sales growth
Dividend outlook	• Further increase dividend in Swiss francs

[1] At Constant Exchange Rates (CER); based on the current assessment of the COVID-19 impact

Pharmaceuticals Division

Bill Anderson
CEO Roche Pharmaceuticals

YTD Sep 2021: Pharmaceuticals Division sales

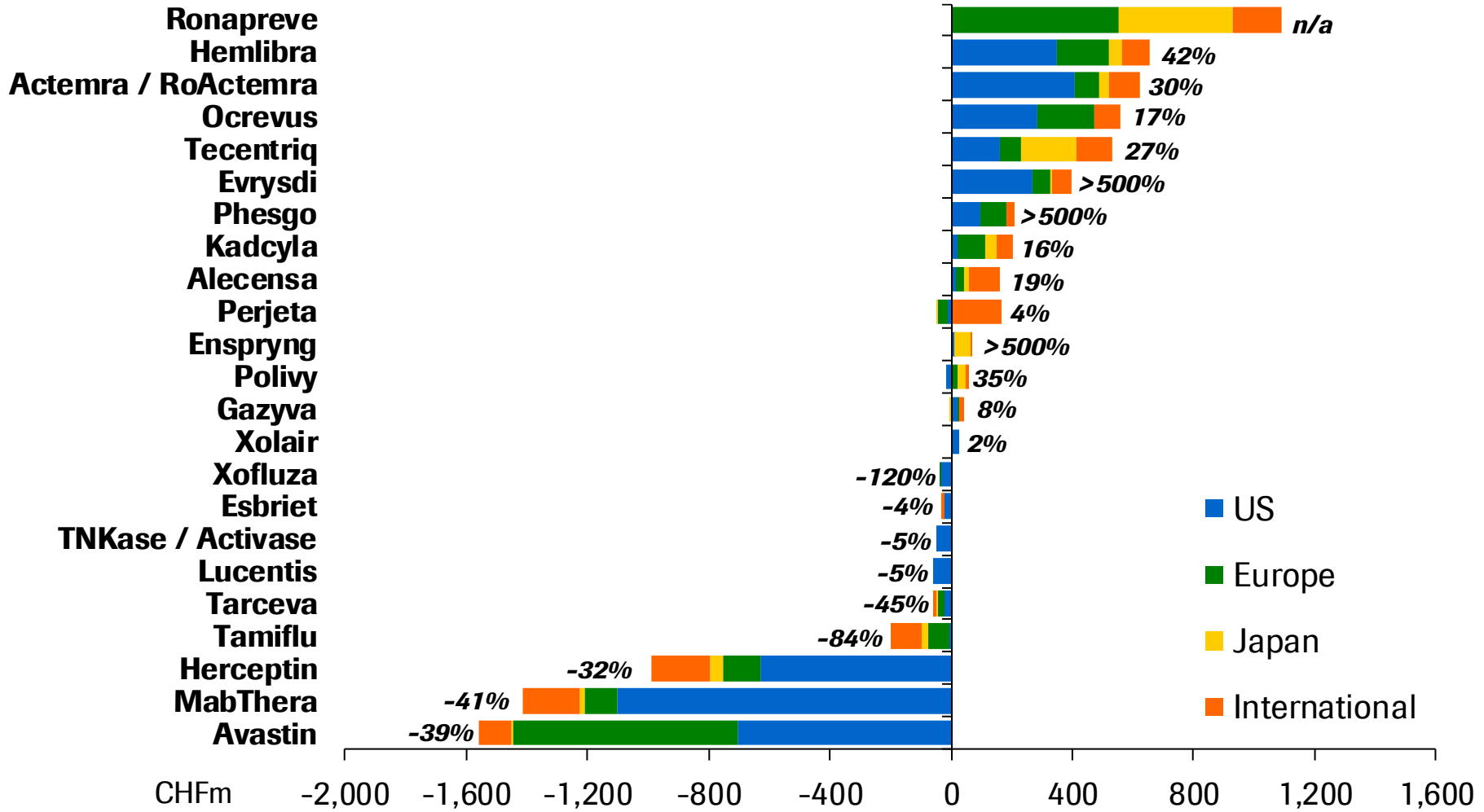
New products compensating for biosimilars despite COVID-19 impact

	2021 CHFm	2020 CHFm	Change in % CHF	Change in % CER
Pharmaceuticals Division	**33,379**	**34,317**	**-3**	**0**
United States	16,707	18,389	-9	-5
Europe	6,610	6,268	5	3
Japan	3,186	2,802	14	20
International	6,876	6,858	0	2

CER=Constant Exchange Rates

YTD Sep 2021: Continued portfolio rejuvenation

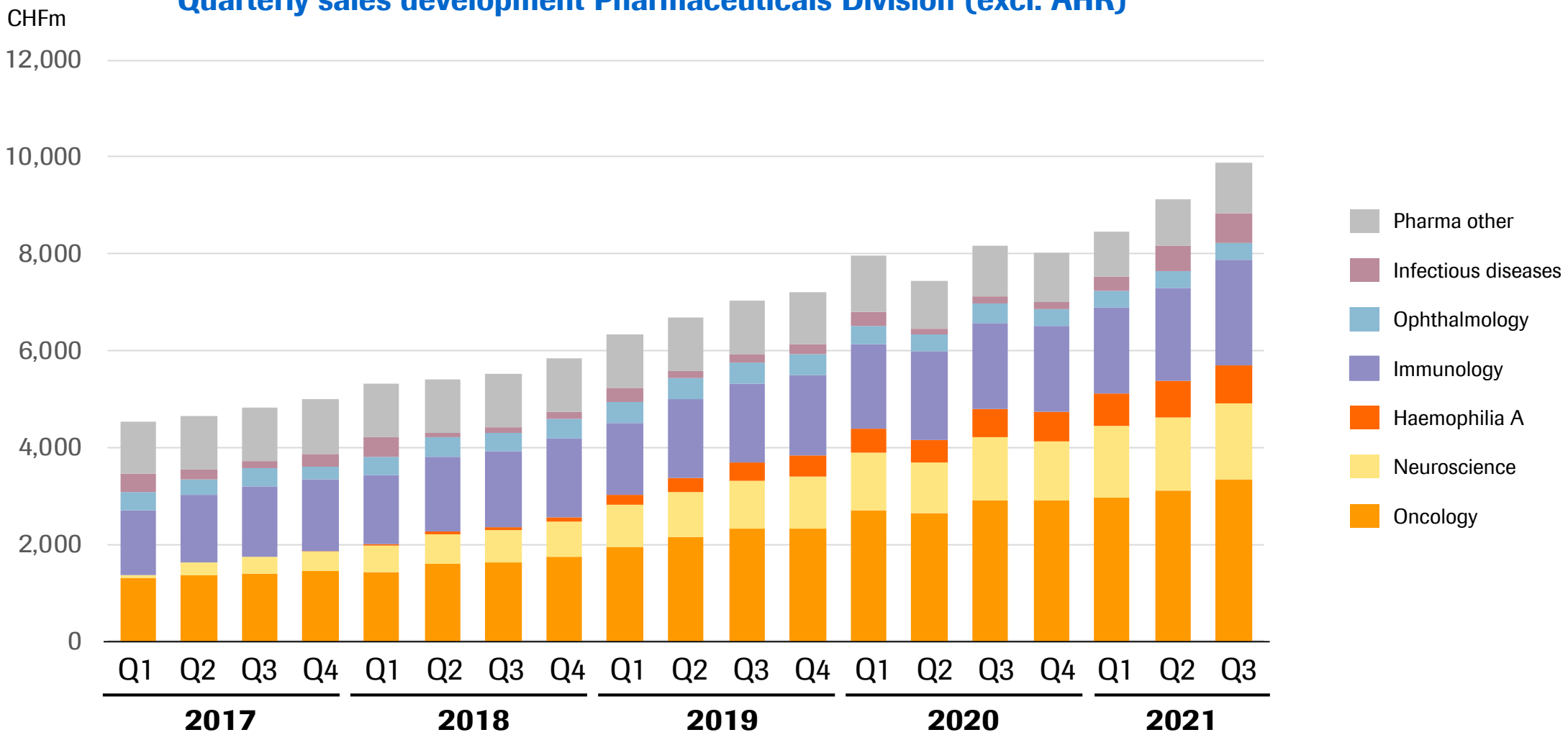
*>50% of sales from new products**



Absolute values and growth rates at Constant Exchange Rates (CER); * Erivedge, Perjeta, Kadcyla, Gazyva, Esbriet, Cotellic, Alecensa, Tecentriq, Ocrevus, Hemlibra, Xofluza, Polivy, Rozlytrek, Phesgo, Enspryng, Evrysdi, Gavreto, Ronapreve

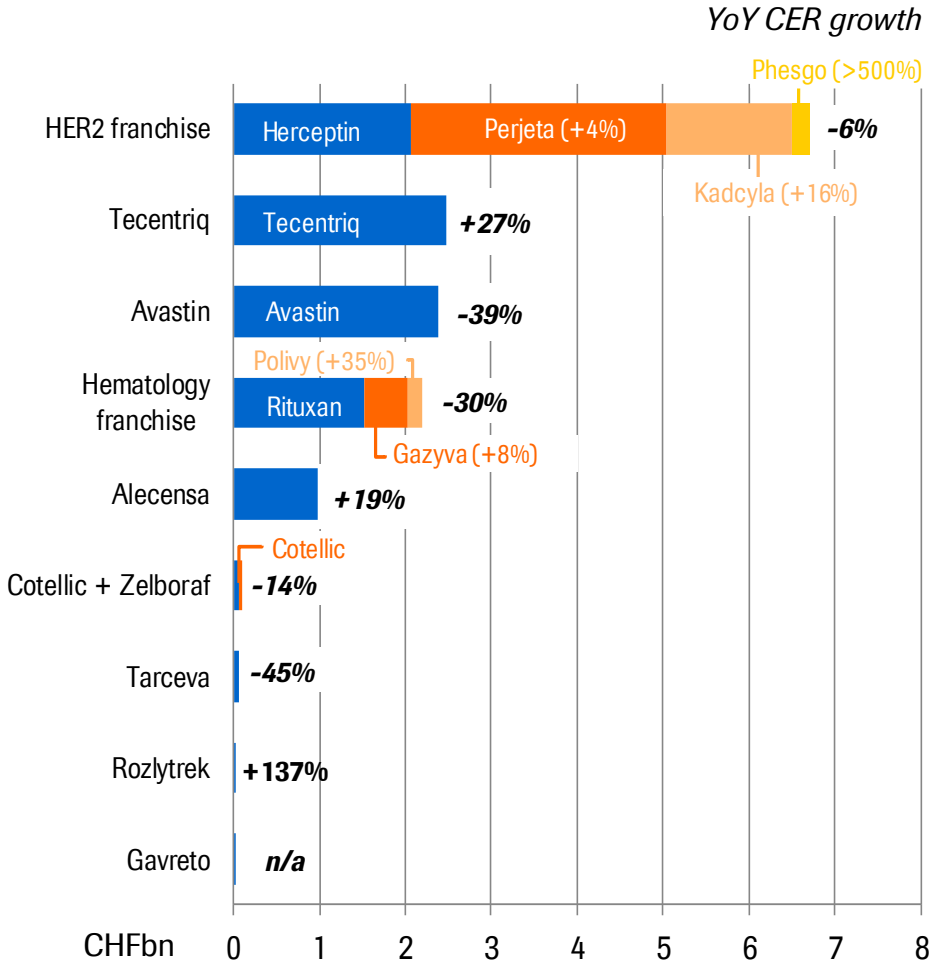
Pharma growth dynamic excl. AHR* further improving

Quarterly sales development Pharmaceuticals Division (excl. AHR)



* AHR=Avastin, Herceptin, MabThera/Rituxan; all absolute values in Constant Exchange Rates (avg. FY 2020); "Pharma Other" comprises the tail end products

YTD Sep 2021: Oncology still impacted by biosimilars & COVID-19



HER2 franchise

- Kadcyla (+16%) with growth in all regions due to adjuvant BC
- Perjeta (+4%) growth cannibalized by Phesgo launch
- Phesgo: Successful launch (CHFm 213) in US and EU ongoing

Avastin franchise

- Biosimilar erosion in all regions

Tecentriq

- Growth (+27%) driven by 1L HCC and 1L SCLC

Hematology franchise*

- Venclexta: Strong growth driven by 1L AML and 1L and R/R CLL
- Gazyva (+8%): Growth due to 1L FL and in 1L CLL
- Polivy (+35%): Growth in R/R DLBCL; Positive Ph III (POLARIX) results in 1L DLBCL to be presented in H2 2021

Alecensa

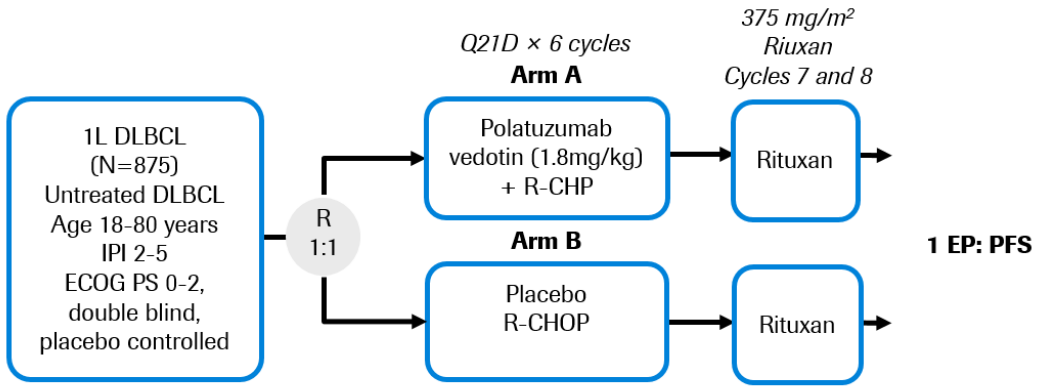
- Growth (+19%) driven by all regions

CER=Constant Exchange Rates; 2021 YTD Sep Oncology sales: CHF 15.4bn; CER growth -14%; * Venclexta sales booked by AbbVie and therefore not included (HY-2021 sales of USD 840m); Polivy in collaboration with Seagen; BC=breast cancer; HCC=hepatocellular carcinoma; SCLC=small cell lung cancer; AML=acute myeloid leukemia; R/R CLL=relapsed/refractory chronic lymphocytic leukemia; FL=follicular lymphoma; DLBCL=diffuse large B cell lymphoma

Hematology franchise

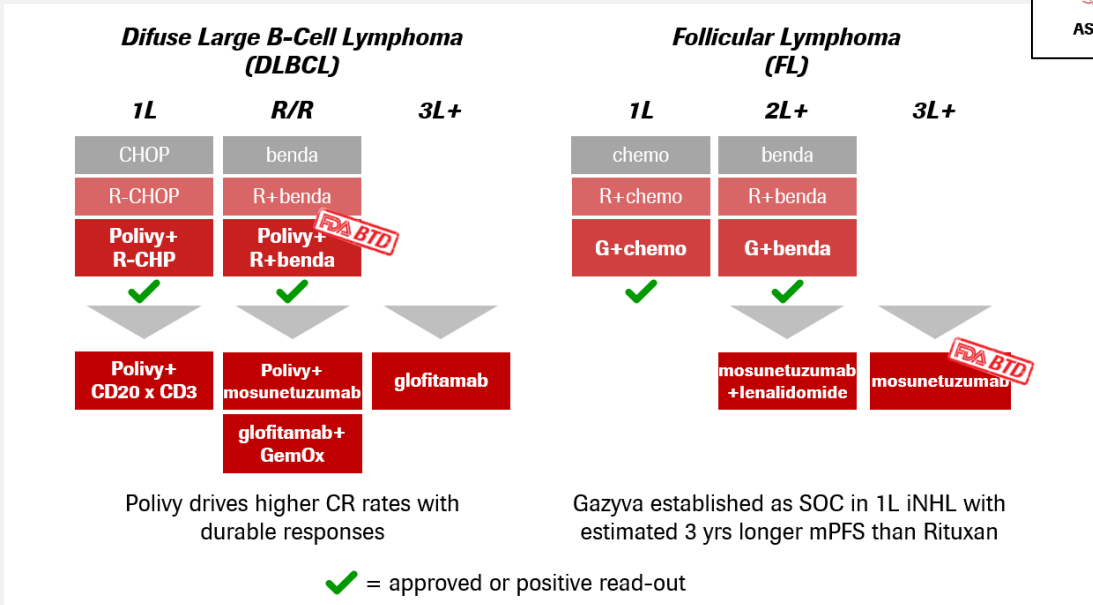
First positive Ph III (POLARIX) in a curative setting in the last 20 years

Ph III (POLARIX) trial design in 1L DLBCL



- Positive Ph III (POLARIX) results for Polivy + R-CHP in 1L DLBCL to be presented at upcoming conference
- First positive results in a curative setting in the last 20 years

Shaping the standard of care in NHL



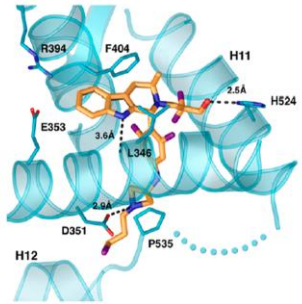
- Early filings for glofit in 3L+ DLBCL in Q1 2022 and for mosun in 3L+ FL in Q4 2021 on track
- Ph III (SUNMO) Polivy + mosun in 2L+ DLBCL to start in Q4 21
- Ph III (STARGLO) glofit + GemOx in 2L+ DLBCL started in Q1 21
- Ph III (CELESTIMO) mosun + lenalidomide in 2L+ FL to start in Q4 21

DLBCL=diffuse large B-cell lymphoma; NHL=Non-Hodgkin lymphoma; R=Rituxan; CHP=cyclophosphamide, doxorubicin, prednisone; DLBCL=diffuse large B cell lymphoma; FL=follicular lymphoma; R/R=relapsed/refractory; PFS=progression free survival; GemOx=gemcitabine, oxaliplatin; G=Gazyva; BR=bendamustine+Rituxan; benda=bendamustine; mosun=mosunetuzumab; glofit=glofitamab; Polivy in collaboration with Seagen

HR+/HER2- breast cancer: Giredestrant a next generation SERD

Encouraging Ph II neoadjuvant interim results presented

Selective ER degrader (SERD)



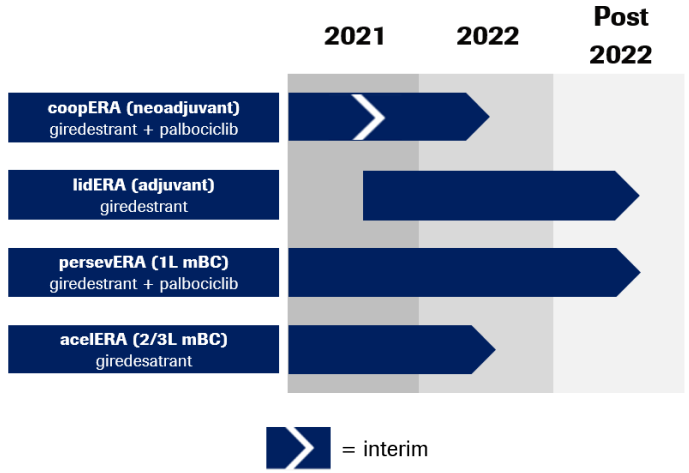
- Potentially best-in-class efficacy being 7-15x more potent than other SERDs in development
- Differentiated MOA leads to immobilization of the ER prior to its degredation
- Standardized dose and similar exposure in mono and combination settings

Ph II (coopERA) interim results in neoadjuvant setting

Ki67 reduction and complete cell cycle arrest (CCCA)

	Giredestrant n = 44	Anastrozole n = 39
Relative reduction at Week 2 from baseline		
Geometric mean (95% CI)	**–80%** (–85%, –72%)	**–67%** (–75%, –56%)
P-value (proportional change)	0.0222†	
CCCA (≤2.7%)		
Week 2 (%)	11 (25.0%)	2 (5.1%)
Difference between arms (95% CI)	–19.87% (–36.84%, –2.91%)	

Trial program

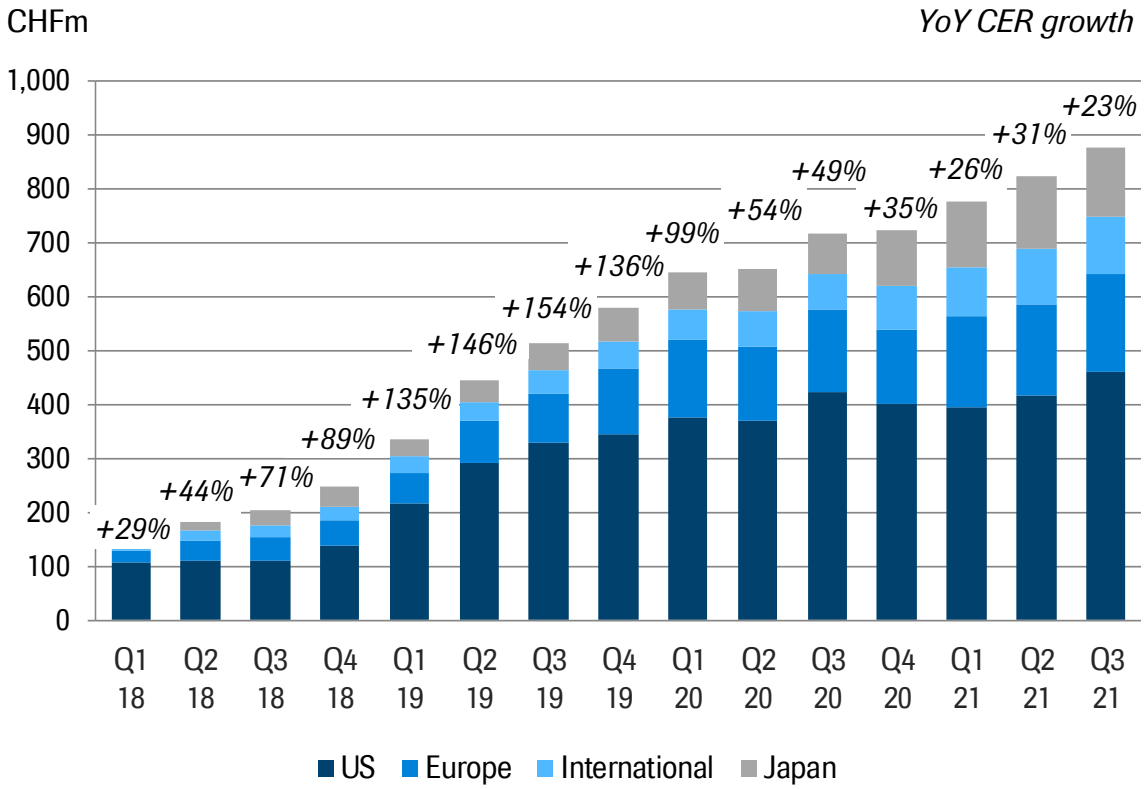


- Encouraging impact on proliferation (-80% relative reduction in Ki67 at week 2)
- 25% of tumors with complete cell cycle arrest (CCCA) at week 2
- Safety consistant with known safety profile; Efficacy supportive of 30mg dose
- Ph III (lidERA) giredestrant vs SOC in the adjuvant setting started in Q3 2021
- Ph II (acelERA) in 2/3L mBC results expected mid 2022

Hurvitz S.A. et al., ESMO 2021; HR=hormone receptor; SERD=selective ER degrader; MOA=mechanism of action; ER=estrogen receptor; DDI=drug drug interaction; mBC=metastatic breast cancer; SOC=standard of care

Tecentriq overview: Growth driven by first-in-class indications

Landmark results in adj. NSCLC filed globally and US approval achieved



Tecentriq Q3 update

Lung franchise (NSCLC, SCLC)

- EU: Growth driven by 1L SCLC
- US/EU/Japan/China: Adjuvant PDL1+ NSCLC (IMpower010) filed (RTOR in the US)
- US: IMpower010 accelerated approval achieved

GI franchise (HCC)

- US/EU/Japan: Growth driven by 1L HCC

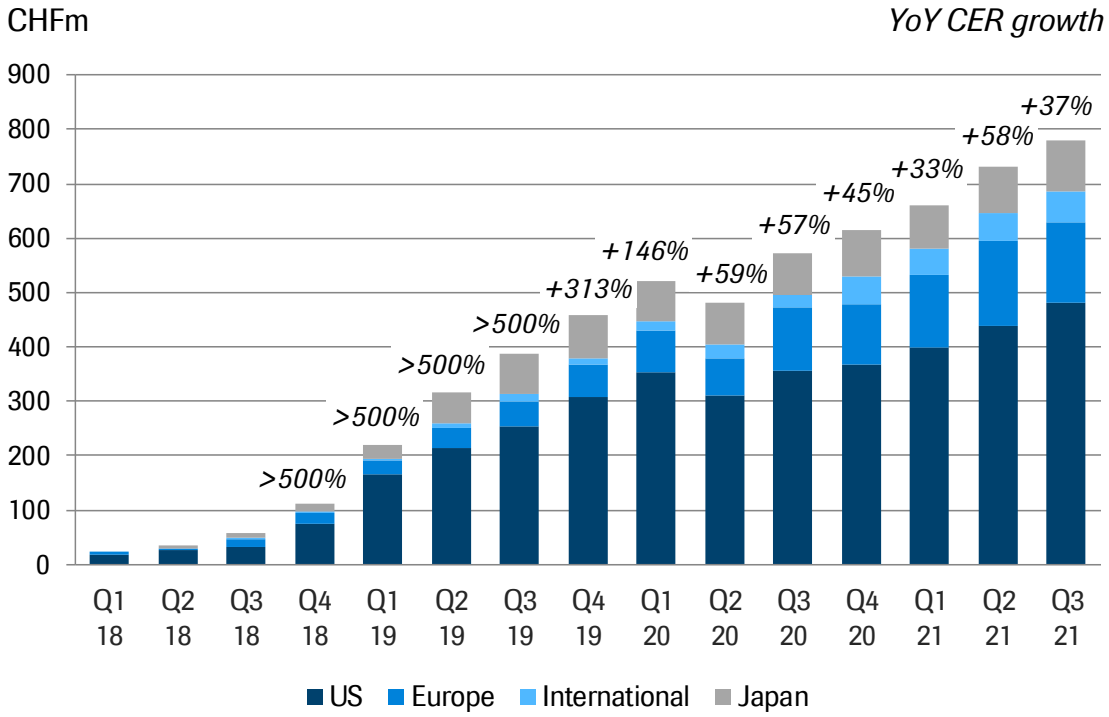
Outlook 2021

- Ph III (IMforte) Tecentriq + lurbinectedin in 1L maintenance SCLC to be initiated

CER=Constant Exchange Rates; NSCLC=non small cell lung cancer; SCLC=small cell lung cancer; HCC=hepatocellular cancer; RTOR=real time oncology review; lurbinectedin in collaboration with Jazz Pharmaceuticals

Hemophilia A Franchise: Hemlibra growing strongly

31% US/EU-5 patient share reached



Hemophilia Q3 update

- US/EU: Gaining market share in non-inhibitors
- #1 prescribed prophylaxis in the US for people with Hemophilia A; >12,500 patients treated globally
- Hemlibra continues to penetrate across all patient types
- EU: Hemophilia A in mild/moderate patients (HAVEN 6) filed

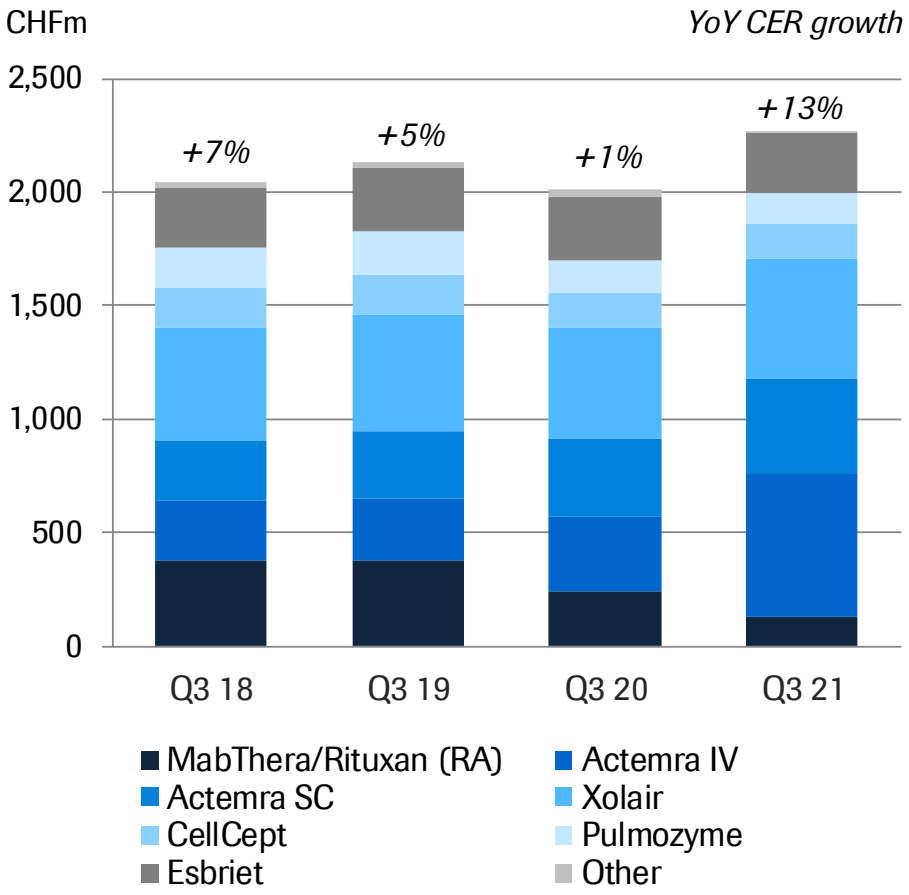
Outlook 2021

- US/EU: Further patient share gains in non-inhibitors

CER=Constant Exchange Rates

Immunology franchise remains impacted by COVID-19

Actemra for COVID-19
FDA
Emergency Use Authorization



Immunology Q3 update

Actemra (+57%)

- WHO recommends IL-6 inhibitors for hospitalized COVID-19 patients
- Remains leading RA monotherapy in EU-5; shift from IV to SC

Esbriet (-5%)

- COVID-19 impact on new patient starts

Xolair (+8%)

- Remains leader in biologics asthma market; growth in CIU
- Self-injection (home use) approved in US in Q2

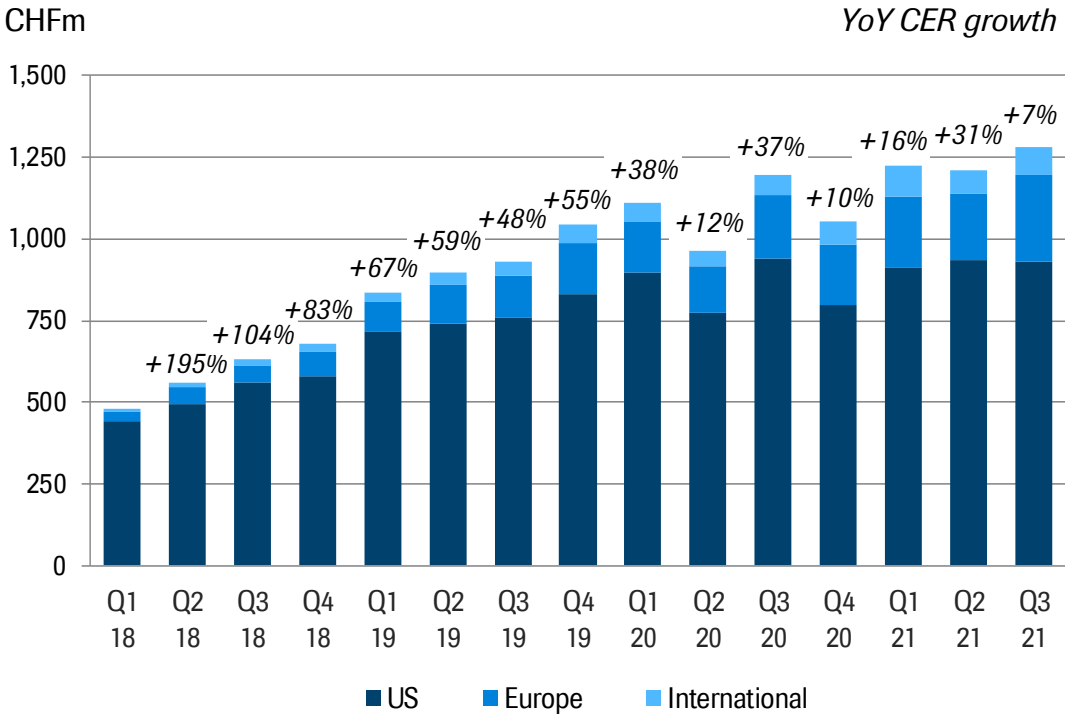
Outlook 2021

- Ph III (ALLEGORY) Gazyva in systemic lupus erythematosus (SLE) to start in Q4 2021

CER=Constant Exchange Rates; WHO=world health organization; RA=rheumatoid arthritis; IV=intravenous; SC=subcutaneous; CIU=chronic idiopathic urticaria

MS franchise: Ocrevus total US market share increases to 29%

MS late stage development programs progressing well



Q3 update

- US impacted by SARS-CoV-2 delta wave
- Higher dose Ocrevus: Ph III (MUSETTE) in RMS and Ph III (GAVOTTE) in PPMS recruiting strongly
- Fenebrutinib (BTKi): Ph III programs in RMS (FENhance I/II) and PPMS (FENtrepid) recruiting
- Up to 8-year follow up data in RMS and PPMS presented at ECTRIMS

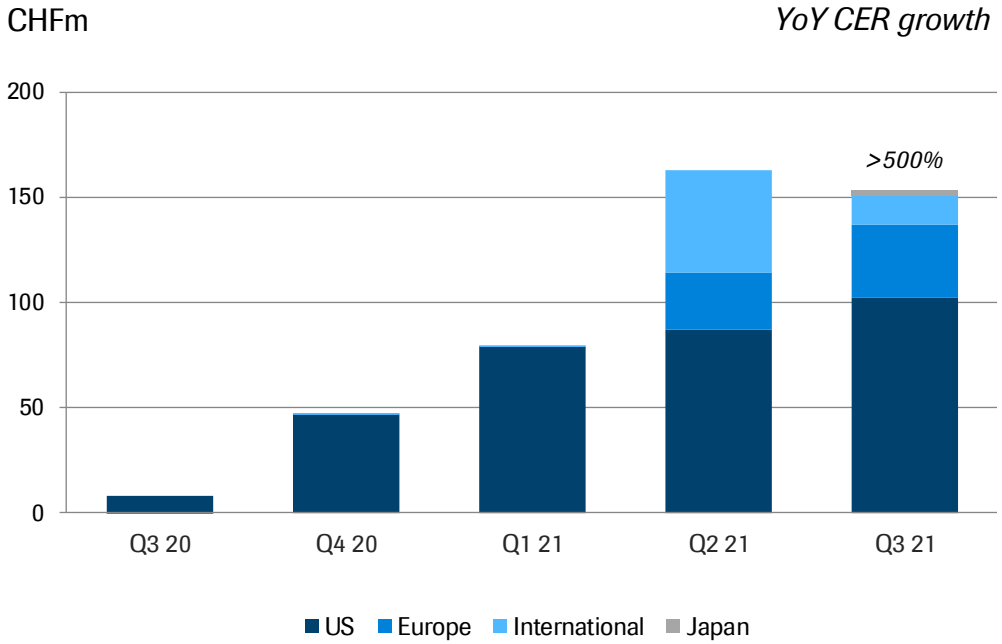
Outlook 2021

- Continued growth expected with further impact from COVID-19

CER=Constant Exchange Rates; MS=multiple sclerosis; RMS=relapsing MS; PPMS=primary progressive MS

SMA franchise: Evrysdi with strong US and EU launches

Most prescribed US treatment with ~20% total share after <14 months



Q3 update

- ~4,000 patients treated world wide (commercial, clinical trials, compassionate use)
- US: >550 HCPs from >400 sites have prescribed Evrysdi
- EU: Strong launch in early launch countries
- ~2/3 of all treated patients switched from Spinraza and/or Zolgensma; 1/3 naive patients

Outlook 2021

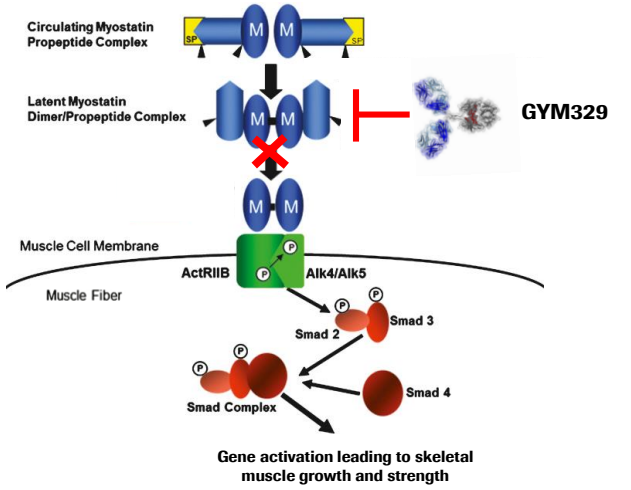
- Continued growth and market share gains expected
- Ph II/III (MANATEE) Evrysdi + GYM329 in SMA to be initiated

CER=Constant Exchange Rates; SMA=spinal muscular atrophy; HCP=health care professional; GYM329 in collaboration with Chugai

SMA franchise: Anti-latent myostatin recycling antibody

Ph II/III combination study with Evrysdi initiated

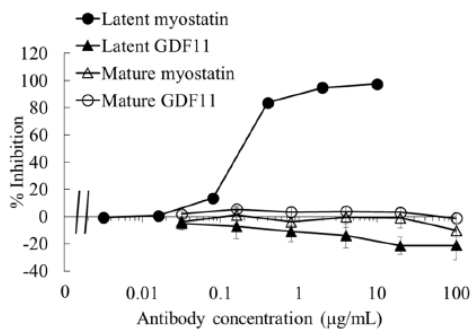
Anti-latent myostatin recycling antibody (GYM329)



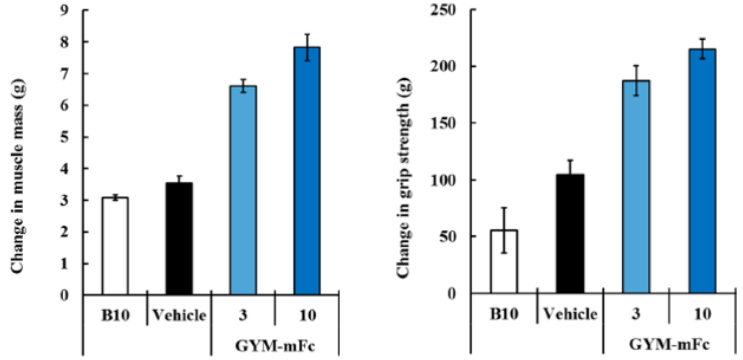
- GYM329 binds to the myostatin precursor protein inhibiting its activation by proteases
- Myostatin is a key negative regulator of skeletal muscle growth and strength

Preclinical GYM329 data in mouse models of muscle disease

Efficient inhibition of latent myostatin, but not GDF11



Increase in muscle mass and strength in mouse models



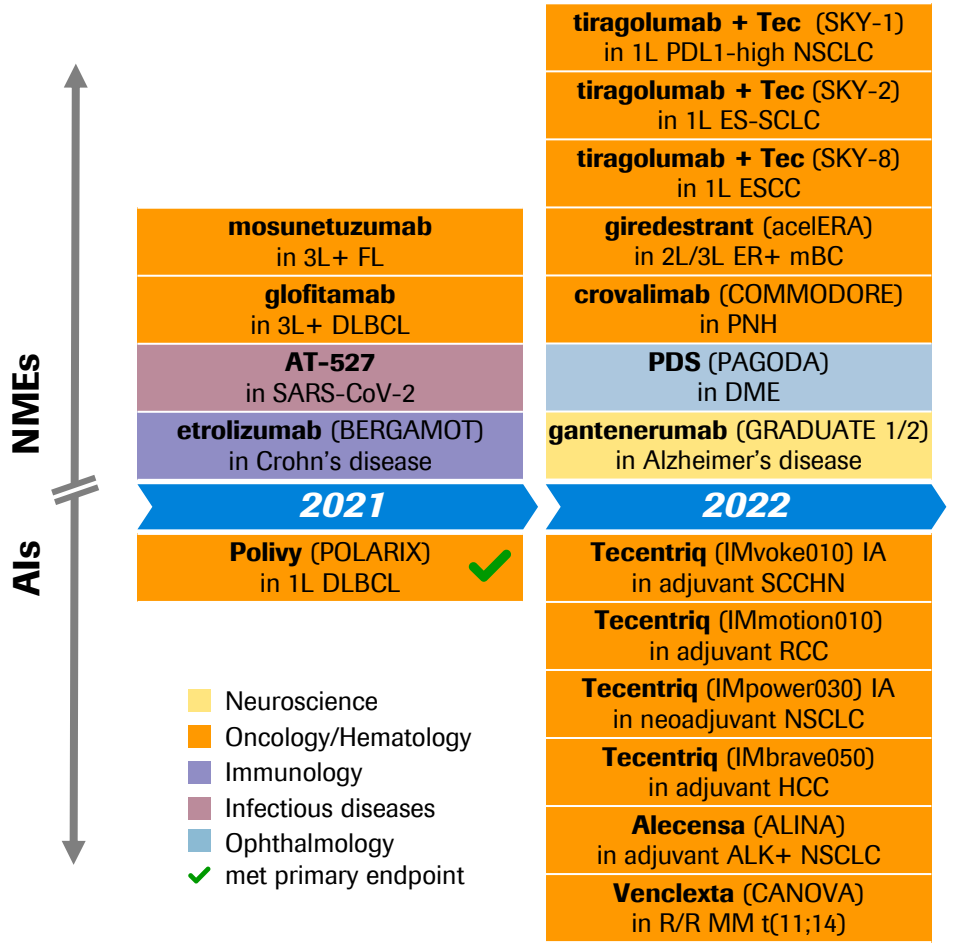
- Contrary to other drugs in development, GYM329 efficiently inhibits myostatin, but not the related muscle hormone GDF11, making it highly specific
- In an animal model of SMA disease a combination of GYM329 + SMN2 splicing modifier* improved muscle size and strength
- Ph I completed; No safety signals in healthy volunteers; Ph II/III start expected in Q1 22

Muramatsu H. et al., Nature Scientific reports (2021) 11:2160; *SMN-C1; SMA=spinal muscular atrophy; GYM329 in collaboration with Chugai

Our replace and extend strategy is progressing well

Replace ongoing franchises		Entering new franchises
MabThera/Rituxan	Gazyva, Venclexta, Polivy, mosunetuzumab, glofitamab	**Oncology:** Tecentriq (mUC, SCLC, HCC, mM, adj. NSCLC), ipatasertib (mCRPC), giredestrant (HR+ BC)
Herceptin	Perjeta, Kadcyla, Phesgo	**Non-malignant hem:** Hemlibra, SPK-8011, crovalimab (PNH, aHUS)
Avastin	Tecentriq, Alecensa, Rozlytrek, tiragolumab	**Neuroscience:** Ocrevus (RMS, PPMS), fenebrutinib (RMS, PPMS) Enspryng (NMOSD, gMG), Evrysdi, GYM329 (SMA), gantenerumab (AD), SRP-9001 (DMD)
Lucentis	Port delivery system (PDS) faricimab	**Infectious diseases:** Ronapreve (COVID-19), AT-527 (COVID-19)
Tamiflu	Xofluza	**Immunology:** etrolizumab (CD), Gazyva (LN, MN, SLE)
Esbriet	rhPentraxin-2	

Strong news flow ahead (data readout)



mUC=metastatic urothelial carcinoma; SCLC=small cell lung cancer; HCC=hepatocellular carcinoma; mM=metastatic melanoma; mCRPC=metastatic castration resistant prostate cancer; HR=hormone receptor; BC=breast cancer; PNH=paroxysmal nocturnal hemoglobinuria; aHUS=atypical hemolytic uremic syndrome; RMS=relapsing multiple sclerosis; PPMS=primary progressive MS; NMOSD=neuromyelitis optica spectrum disorder; SMA=spinal muscular atrophy; AD=Alzheimer's disease; DMD=duchenne muscular dystrophy; CD=Crohn's disease; LN=lupus nephritis; MN=membranous nephropathy; SLE=systemic lupus erythematosus; FL=follicular lymphoma; DLBCL= diffuse large B cell lymphoma; NSCLC=non-small cell lung cancer; ESCC=esophageal squamous cell carcinoma; DME=diabetic macular edema; IA=interim analysis; SCCHN=squamous cell carcinoma of the head and neck; RCC=renal cell carcinoma; HCC=hepatocellular carcinoma; MM=multiple myeloma

2021: Key late-stage news flow*

	Compound	Indication	Milestone	
Regulatory	**Xofluza**	Healthy patients; High risk patients; Post exposure	EU approval	✓
	Evrysdi	SMA type 1/2/3	EU approval	✓
	faricimab	DME/nAMD	US/EU joint filing (DME+AMD)	✓
	Tecentriq	1L PDL1+ NSCLC	EU approval	✓
	Venclexta + azacitidine	1L unfit AML	EU approval	✓
	Ronapreve	SARS-CoV-2	EU approval	
	PDS ranibizumab	nAMD (continuous delivery)	US/EU filing; US approval	
Phase III / pivotal readouts	**faricimab**	nAMD	Ph III TENAYA/LUCERNE	✓
	Ronapreve	SARS-CoV-2 Outpatient	Ph III Study 2067	✓
	Ronapreve	SARS-CoV-2 Post-exposure prophylaxis	Ph III Study 2069	✓
	Tecentriq	Adjuvant NSCLC	Ph III IMpower010	✓
	Evrysdi	SMA type 1/2/3 switching study	Ph II JEWELFISH	✓
	mosunetuzumab	3L+ FL	Ph Ib GO29781	
	Polivy + R-CHP	1L DLBCL	Ph III POLARIX	✓
	glofitamab	3L+ DLBCL	Ph Ib NP30179	
	Tecentriq + chemo	Adjuvant SCCHN	Ph III IMvoke010	**2022**

Additional 2021 news flow:

- **Ronapreve:** EMA positive scientific opinion for COVID-19
- **Actemra/RoActemra:** US approval for SSc-ILD
- **Xolair**: US approval for prefilled syringe for self-injection
- **Actemra:** US EUA for treatment of COVID-19 in hospitalized adults and children
- **Enspryng:** EU approval for NMOSD
- **AT-527**: Ph2 interim results (viral load reduction) for hospitalized patients
- **Ronapreve**: Positive Ph II/III (2066 study) results for sero-negative hospitalized patients
- **Tecentriq**: US accelerated approval for adjuvant PDL1+ NSCLC

Digitalization Event	*ASH*
November 17	**December 15**
16:00-17:30 CET	**16:00-17:30 CET**
15:00-16:30 GMT	**15:00-16:30 GMT**

* Outcome studies are event-driven: timelines may change; EUA=Emergency use authorization

Diagnostics Division

Thomas Schinecker
CEO Roche Diagnostics

YTD Sep 2021: Diagnostics Division sales

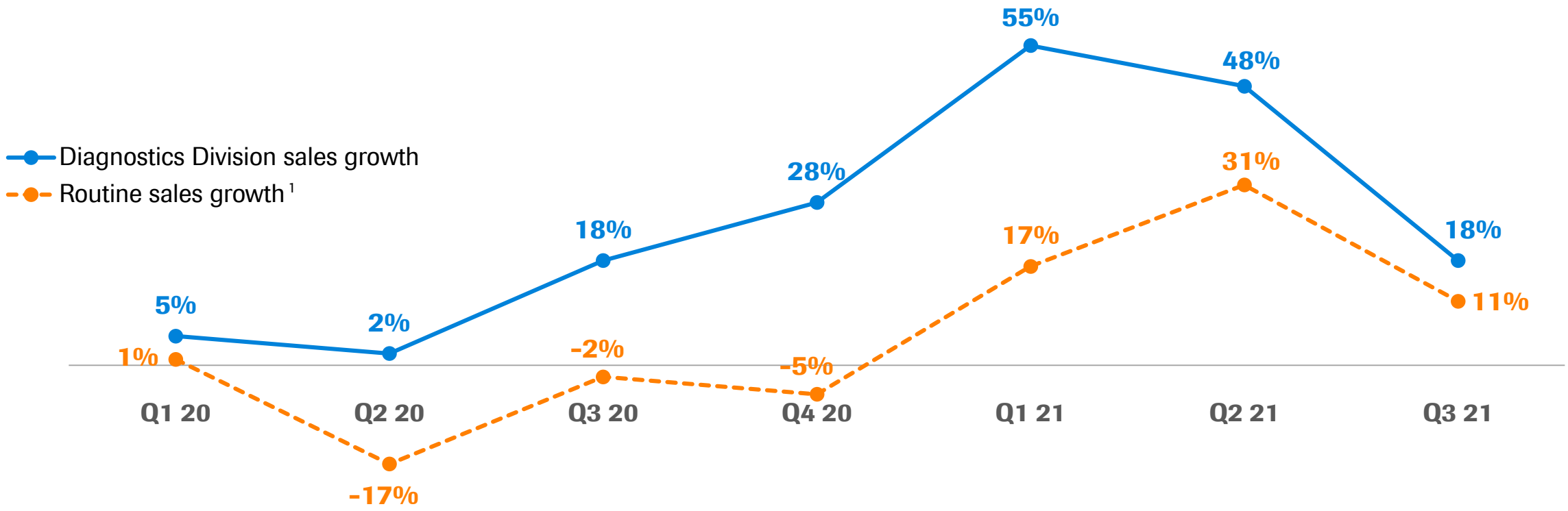
Very strong growth driven by COVID-19 and routine testing

	2021 CHFm	2020 CHFm	Change in % CHF	Change in % CER
Diagnostics Division	**13,305**	**9,662**	**38**	**39**
Core Lab	5,610	4,487	25	26
Molecular Lab	3,454	2,578	34	36
Point of Care	2,058	541	280	279
Diabetes Care	1,294	1,261	3	4
Pathology Lab	889	795	12	14

CER=Constant Exchange Rates; underlying growth of Core Lab excluding Roche Information Solutions: +25%

Diagnostics Division sales growth by quarter

Maintaining strong routine testing growth

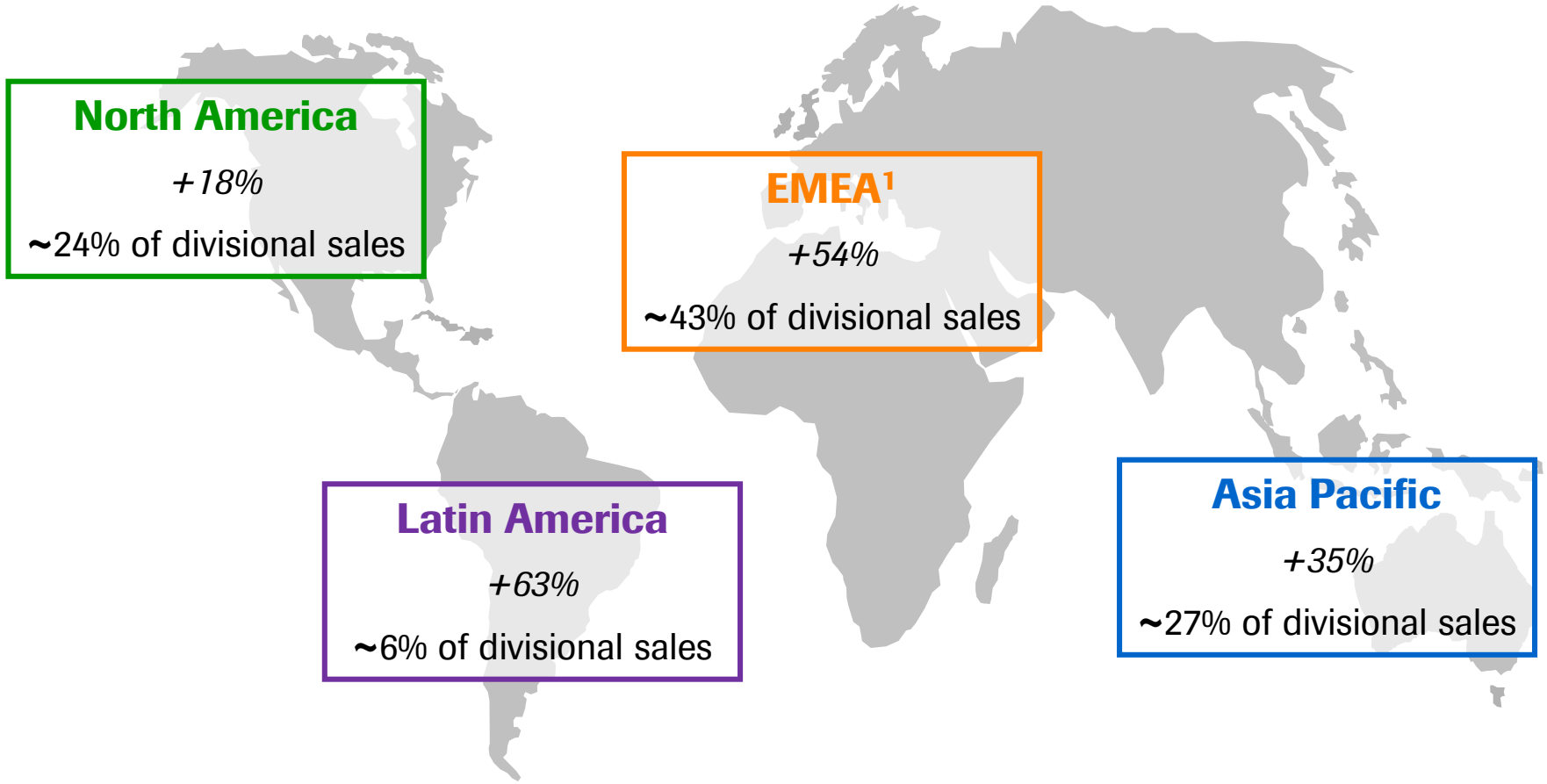


COVID-19 sales	Q1: 0.1bn	Q2: 0.6bn	Q3: 0.6bn	Q4: 1.1bn	Q1: 1.2bn	Q2: 1.3bn	Q3: 1.0bn

Growth rates at CER (Constant exchange Rates); [1] Quarterly sales growth excluding COVID-19 sales

YTD Sep 2021: Diagnostics Division regional sales

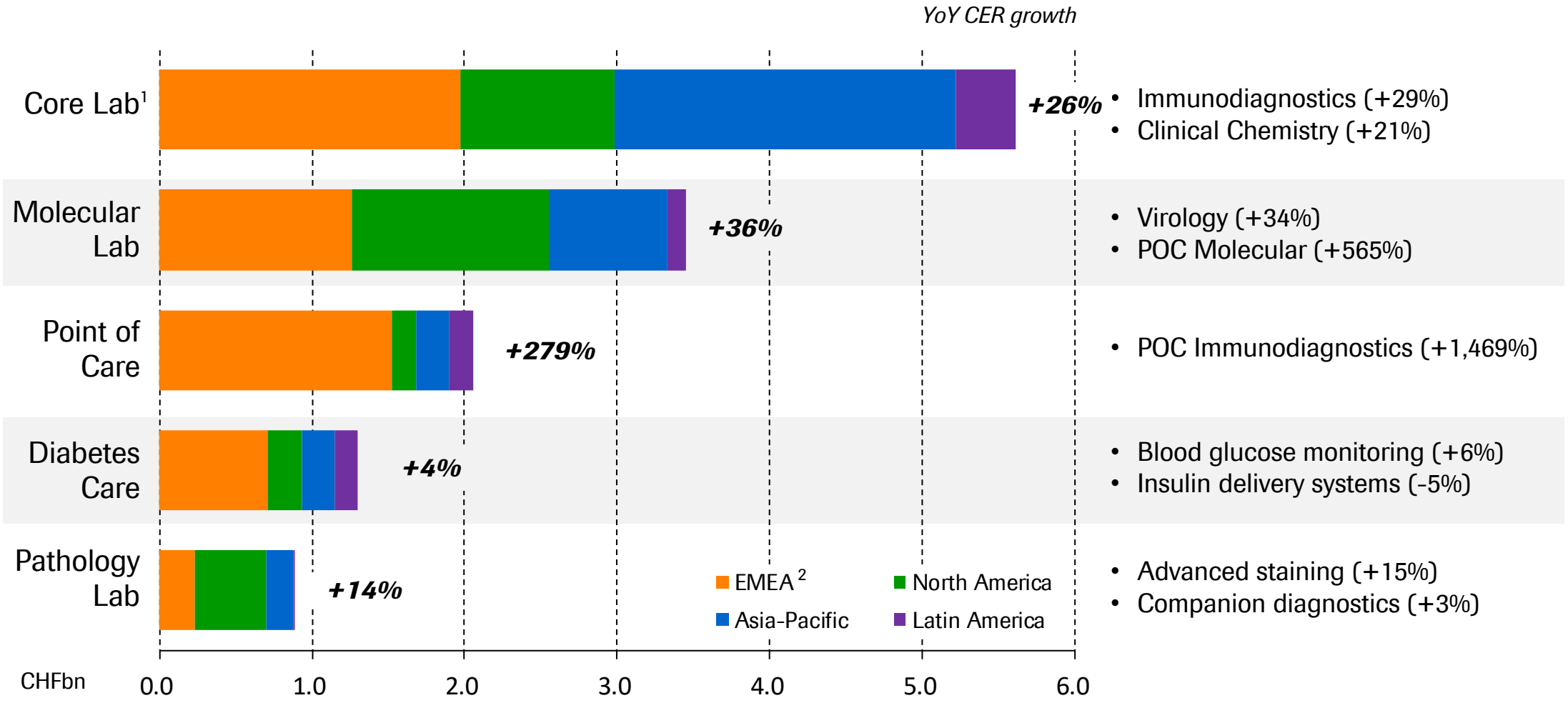
Very strong growth in all regions



Growth rates at CER (Constant exchange Rates); [1] Europe, Middle East and Africa

YTD Sep 2021: Diagnostics Division highlights

Very strong growth across all businesses



- Immunodiagnostics (+29%)
- Clinical Chemistry (+21%)

- Virology (+34%)
- POC Molecular (+565%)

- POC Immunodiagnostics (+1,469%)

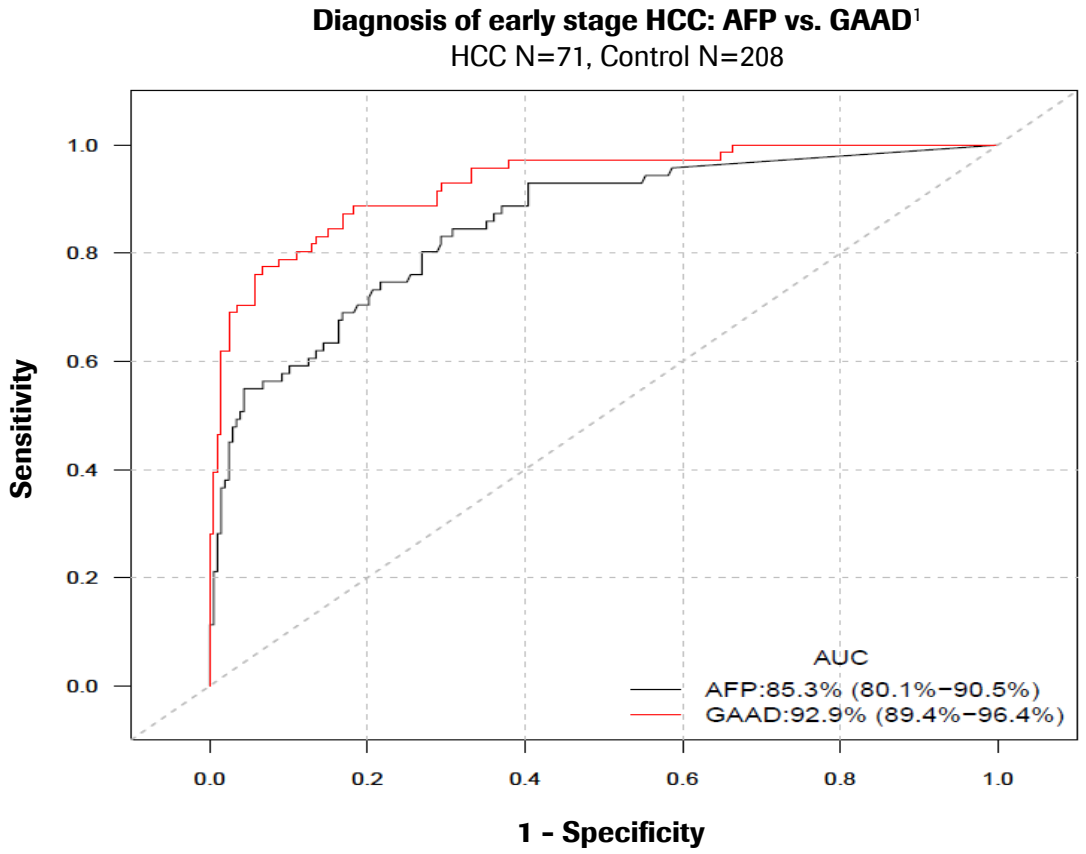
- Blood glucose monitoring (+6%)
- Insulin delivery systems (-5%)

- Advanced staining (+15%)
- Companion diagnostics (+3%)

CER=Constant Exchange Rates; POC=point of care; [1] Underlying growth of Core Lab excluding Roche Information Solutions: +25%; [2] EMEA=Europe, Middle East and Africa

Elecsys® GAAD receives CE mark

First IVD algorithm for early detection of hepatocellular carcinoma



- 830K deaths per year caused by hepatocellular carcinoma[2]
- Algorithm combines gender and age with the results of two blood-based biomarkers (Elecsys® AFP and PIVKA-II)
- Early detection allows for potentially curative therapy with considerable improvement in survival: 5-year survival ranges up to 80% (vs 5% in general HCC population)[3] [4]
- Elecsys® GALAD in development for CE launch in 2022

GAAD=Gender, Age, AFP and PIVKA-II (DCP); GALAD=Gender, Age, AFP, AFP-L3 and PIVKA-II (DCP); AFP=Alfa-fetoprotein; HCC=hepatocellular carcinoma; PIVKA-II=protein induced by vitamin K absence-II; AUC=area under the curve; BDD=Breakthrough Device Designation; [1] Henry Chan et al. Performance Evaluation of the Elecsys® GAAD Assay for the Detection of Hepatocellular Carcinoma Across Different Disease Stages and Etiologies Presented at ISHVLD; [2] WHO: Globocan 2020; [3] Hashem B. El-Serag, Therap Adv Gastroenterol. 2011 Jan; 4(1): 5–10; [4] Ju Dong Yang. Detect or not to detect very early stage hepatocellular carcinoma? The western perspective. Clinical and Molecular Hepatology 2019;25:335-343

Claim extension of Elecsys® Brahms PCT assay

Monitoring patients on antibiotic therapies improves outcomes and reduces cost of care

Higher patient impact
Strongly increasing our outreach

50 million[1]

Diagnosis
Severe bacterial infection

+

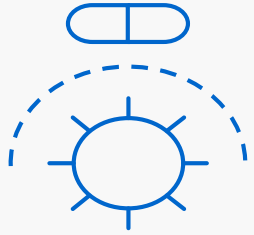
NEW

420 million[2]

Monitoring
Antibiotic therapy

More patient benefit
Better care and treatment for patients on antibiotics

Targeted use of antibiotics



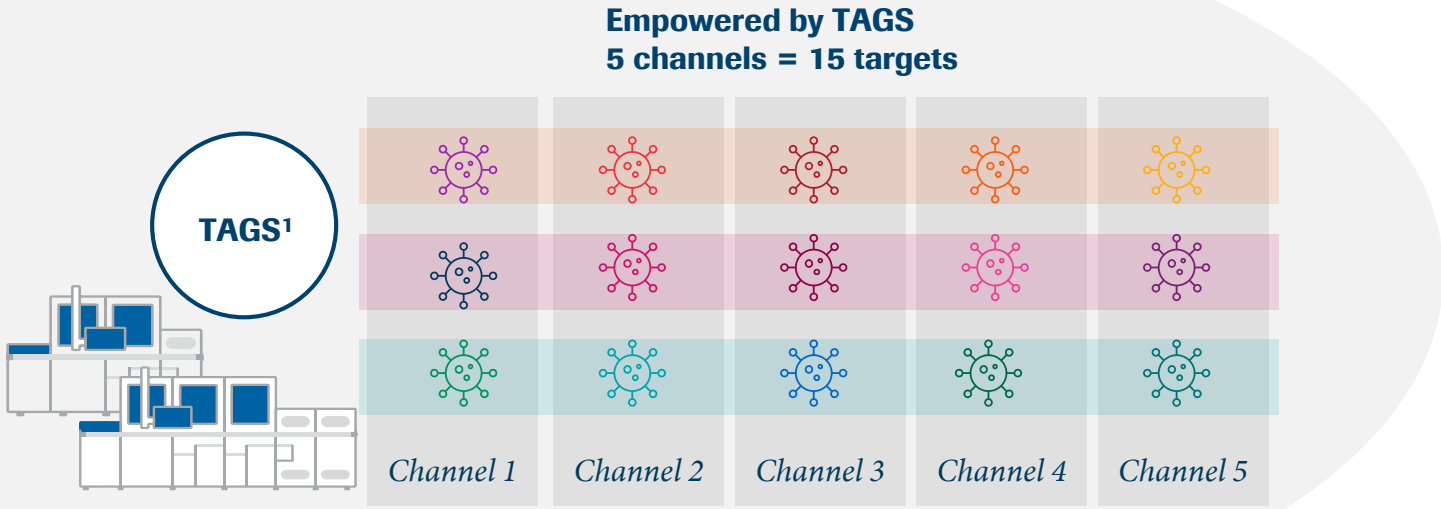
Helping to **combat** resistance

Reducing **unnecessary** cost

PCT=Procalcitonin; [1] Rudd et al (2020), calculation based on sepsis which is a severe bacterial infection. Lancet 395(10219):200-211; [2] Global, regional, and national incidence, prevalence, and years lived with disability for 354 diseases and injuries for 195 countries and territories, 1990–2017: a systematic analysis for the Global Burden of Disease Study 2017

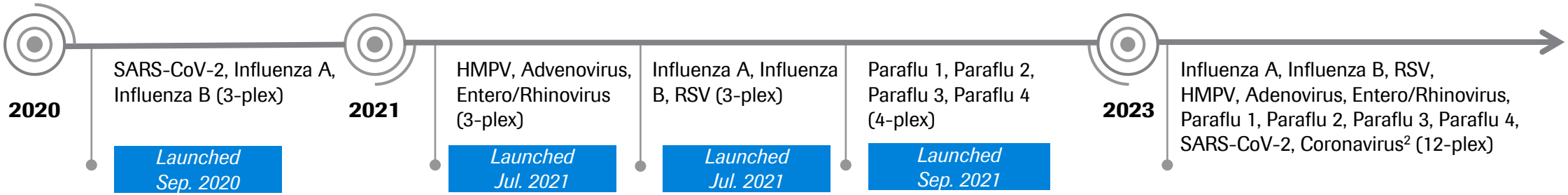
Launch of three respiratory test panels on cobas 6800/8800

Breaking the barriers of syndromic testing



- High unmet medical need: differential diagnosis between viruses
- Utilizes the cobas® 6800/8800 installed base

Respiratory Panels Timeline (*launch timing per year is illustrative*):



[1] TAGS=Temperature Activated Generation of Signal; [2] Common cold coronaviruses including HKU1, OC43, NL63, 229E

Definitive share purchase agreement with TIB Molbiol[1]

>45 CE IVD & >100 RUO tests available on existing Roche platforms

Respiratory				
Coronavirus	**Mutations**	**Mutations Cont.**	**Influenza**	**Resp. Virus**
MERS Coronavirus UpE	SARS-CoV-2 Spike A23063T N501Y	SARS-CoV-2 Spike D253G	Influenza A*	Enterovirus*
MERS Coronavirus Orf1a	SARS-CoV-2 Spike del H69_V7	SARS-CoV-2 Spike L452R	Influenza A H1 (H1N1)*	Parechovirus (hPeV)*
Coronavirus HKU1	SARS-CoV-2 Spike D614G	SARS-CoV-2 Spike P681R	Influenza A H3	Metapneumovirus (hMPV)*
Coronavirus OC43	SARS-CoV-2 Spike Y453F (mink)	SARS-CoV-2 Spike E484Q	Influenza A H5	Bocavirus (hBoV)*
Coronavirus 229E	SARS-CoV-2 Spike P681H	SARS-CoV-2 Spike D253G	Influenza A H7 (H7N9)	Respiratory Syncytial Virus (RSV)*
Coronavirus NL63	SARS B117 (Spike del+501)	**Parainfluenza**	Influenza A H7 (H7N9) (640)	**Atypical Pneumonia**
panCoronavirus	SARS B1351 (484K+501Y)	Parainfluenza 4 (hPIV-4) NP gene*	Influenza A H9	Pneumocystis jirovecii (PCP)
SARS-CoV-2 (COVID-19) N-gene	SARS-CoV-2 Spike E484K	Parainfluenza 3 (hPIV-3) M gene*	Influenza B*	Mycoplasma pneumoniae
SARS-CoV-2 (COVID-19) E-gene*	SARS-CoV-2 Spike A570D	Parainfluenza 2 (hPIV-2) L gene*	**Resp. Bacteria**	Chlamydophila psittaci
SARS-CoV-2 (COVID-19) E+N-gene	SARS-CoV-2 Spike K417N	Parainfluenza 1 (hPIV-1) HN gene*	Bordetella pertussis	Chlamydia pneumoniae
SARS-CoV-2 (COVID-19) RdRP-gene	SARS-CoV-2 Spike V1176F	Parainfluenza (PIV-1,2,3,4)	Bordetella parapertussis	Legionella pneumophila
	SARS del69,70 +484K+501Y			

Gastroenteritis		
Parasites	**Bacteria**	**Virus**
Giardia*	Aeromonas*	Norovirus GG1*
Dientamoeba*	Yersinia*	Norovirus GG2*
Cryptosporidium*	Campylobacter*	Rotavirus A*
Blastocystis*	Shigella*	Adenovirus F (40,41)*
Entamoeba histolytica*	Salmonella*	Astrovirus*
	Plesiomonas	Sapovirus*
		Enterovirus*

MagNA Pure

LightCycler

Installed base

>2,000	>14,500

Carbapenemase
KPC
NDM1
OXA-48
OXA-23
GES
IMP
VIM

Antimicrobial Resistance
Mycoplasma Macrolide
MCR-1*

New Born
TREC
KREC

Filovirus
Ebola Zaire*

Tropical
Zika*
Dengue
Chikungunya
Plasmodium genus

EHEC
STX1-EHEC
STX2-EHEC
EAE-EHEC

Non-Culturable
T. Whipplei

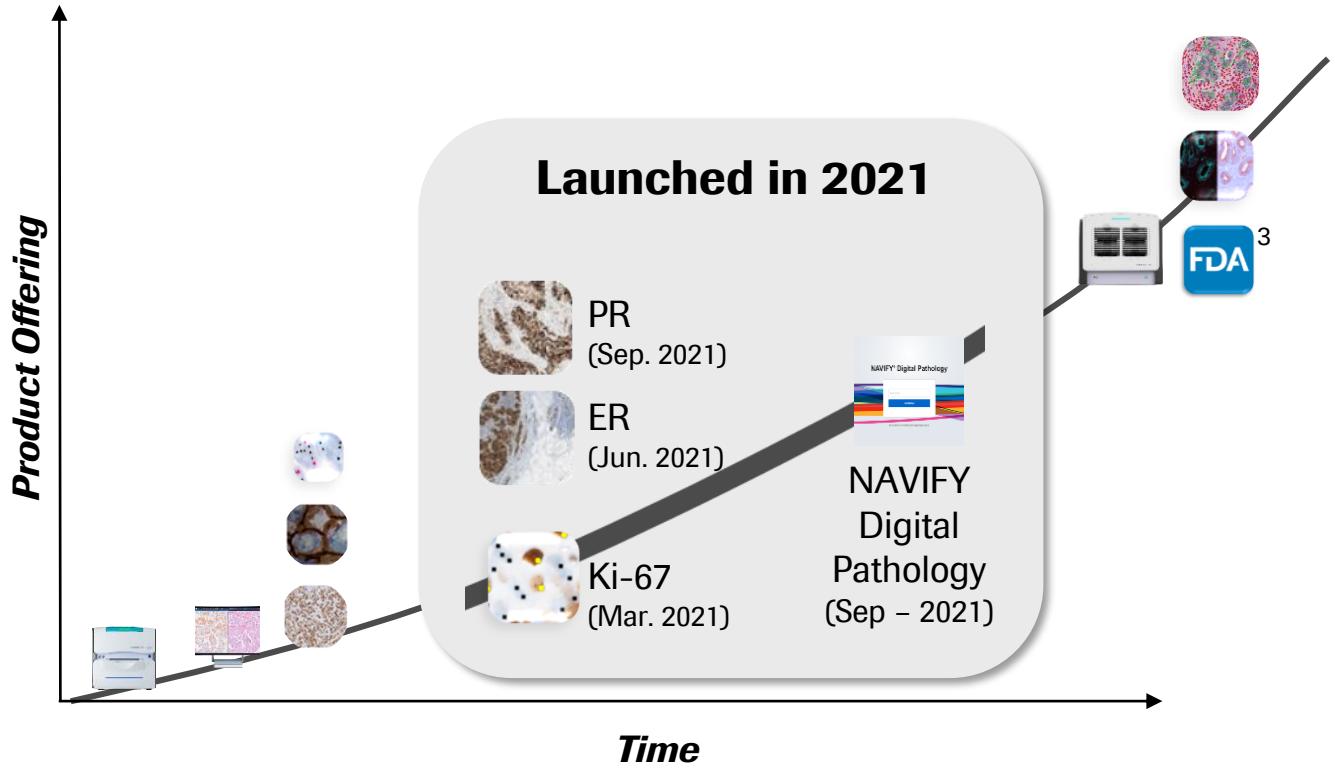
Bac. Meningitis
Escherichia coli uidA
Listeria monocytogenes
Streptococcus pneumoniae
Neisseria meningitidis
Streptococcus agalactiae
Haemophilus influenzae

[1] subject to regulatory clearance and closing; * CE-marked; RUO=Research Use Only

Roche Digital Pathology

Launching new breast panel algorithms and providing a powerful open environment for AI integration for pathologists

Expanding portfolio offering



- Enables the integration of third party algorithms into the NAVIFY Digital Pathology software[1]
- Provides a broader set of diagnostic tools both on premise and via cloud
- New Roche algorithms use whole slide analysis with state of the art deep learning AI
- Complete breast cancer algorithm panel [2] allows for faster and more accurate diagnosis

AI=Artificial Intelligence; [1] First two agreements signed with PathAI and IBEX; [2] HER2 (4b5), Ki-67, ER, PR and HER2 Dual ISH algorithms; [3] Will be seeking FDA clearance of Breast Panel algorithms with external clinical studies in 2022

Key launches 2021

Area		Product	Description	Market[1]	
Instruments	Core Lab	cobas® pure integrated solutions	Low-to-medium volume SWA	CE	✓
		cobas® pro integrated solutions	New high throughput configurations of the cobas pro instrument	US & CE	✓
	Point of Care	cobas® pulse	Successor of Accu-Chek® Inform II	CE	
	Molecular Lab	cobas® 5800	Fully automated low throughput PCR system	CE	
		AVENIO Edge System	Automated sequencing library preparation and target enrichment instrument	WW	
	Diabetes Care	Accu-Chek Instant	New features for the monitoring system to increase performance and user experience	WW	✓
Tests	Core Lab	Elecsys® SARS-CoV-2 Antigen	Automated laboratory assay intended as an aid in the diagnosis of SARS-CoV-2 infection	US	
		Elecsys® NT-proBNP IU • extensions in Heart Failure • extension for Atrial Fibrillation Elecsys® TnT–hs 3 claim extensions in Coronary Arterial Disease	A set of 5 intended use extensions in the Coronary Arterial Disease, Atrial Fibrillation and Heart Failure Space	CE	✓
	Molecular Lab	AVENIO FoundationOne kit (RUO)	Decentralized kit of the FoundationOne test	WW	
		KAPA HyperPETE kit	New targeted sequencing portfolio using primer extension for small targets	WW	
Digital Solutions	Pathology Lab	uPath 2.0	First IVD release and version of Open API of the clinical pathologist workflow module for NAVIFY Digital Pathology & on-premise uPath	WW	✓
		RUO Algorithms	Whole slide image analysis algorithms (ER (SP1), Ki-67 (30-9), and PR (1E2))	WW	✓
	Insights	NAVIFY Oncology 1.0	Modular Oncology decision support solution	WW[3]	
		NAVIFY Pass 1.0	Solution for providers to communicate SARS-CoV-2 rapid antigen test results to a mobile app	US & CE[3]	✓
	Core Lab	Elecsys® GAAD Algorithm	Algorithm for early detection of HCC in patients with chronic liver disease.	CE	✓
	Diabetes Care	RocheDiabetes RemoteCare	Module within the RocheDiabetes Care Platform enabling remote interactions between HCPs and patients, including a patient dashboard, check-in and chat functionality	WW[3]	
		Accu-Chek SugarView	Meter-free blood glucose testing using a smartphone app and test strips	OUS[3]	✓

RDCP=Roche Diabetes Care Platform; [1] CE=European Conformity, US=FDA approval, WW=Worldwide, OUS=Outside the US; [2] Research Use Only; [3] Only a few selected countries

Finance

Alan Hippe
Chief Financial Officer

YTD Sep 2021: Highlights

Sales

- Group sales growth (+8%) driven by Diagnostics (+39%)

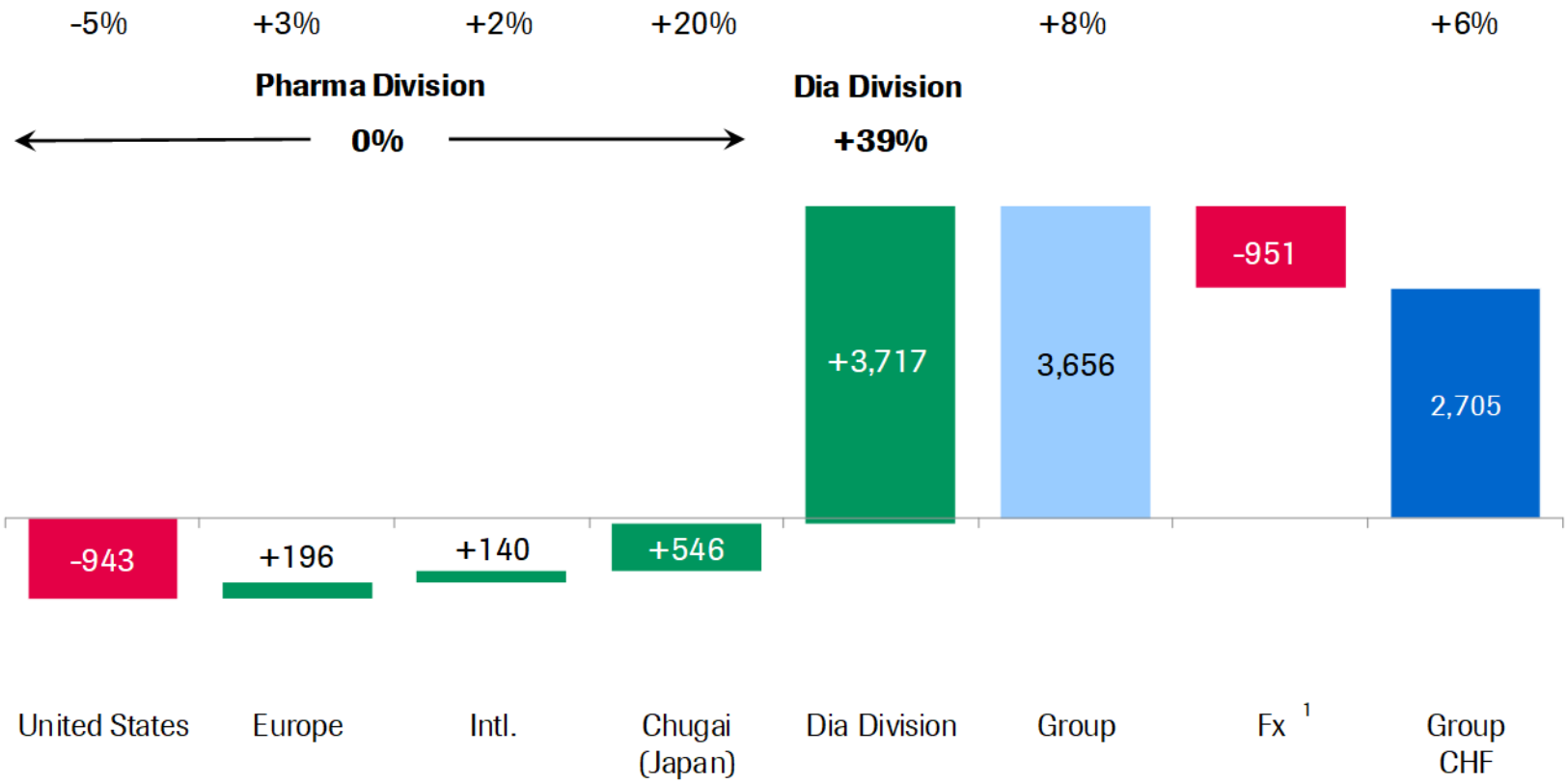
Currency impact on sales

- Negative currency impact due to most currencies, particularly USD

Growth rates at CER (Constant exchange Rates)

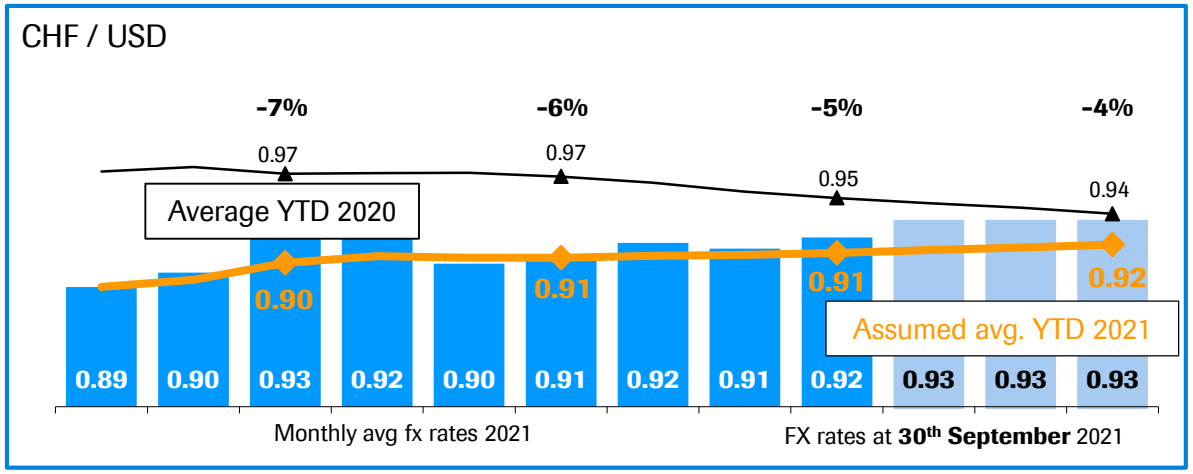
YTD Sep 2021: Group Sales

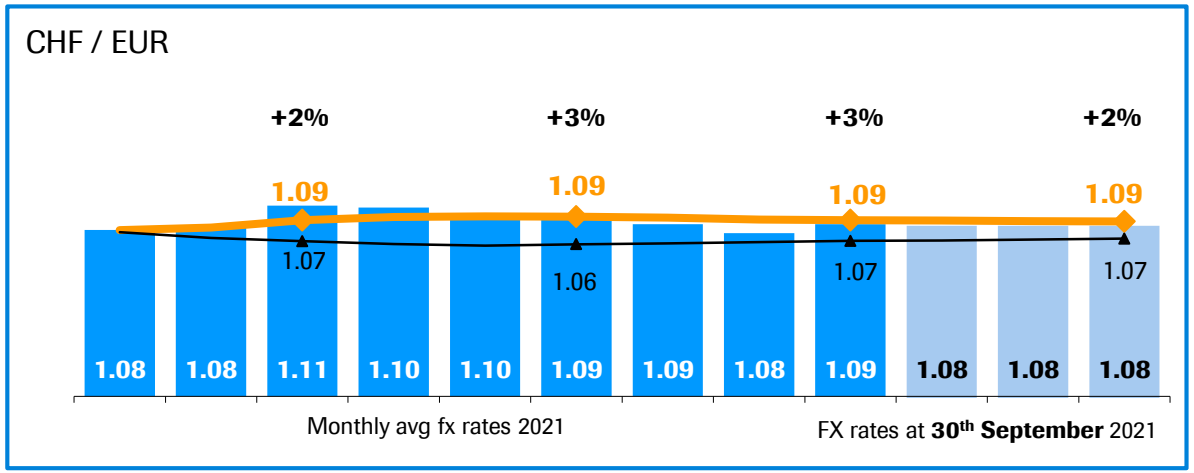
CER sales up by +8% driven by Diagnostics Division



Absolute values in CHFm at Constant Exchange Rates (avg full year 2020); [1] avg. full year 2021 to avg. YTD September 2021 fx impact

Currency impact expected to reduce as 2021 progresses





Assuming the 30 Sep 2021 exchange rates remain stable until end of 2021, 2021 impact [1] is expected to be (%p):

	Q1	HY	Sep YTD	FY
Sales	-4	-3	-2	-1
Core operating profit		-5		-2
Core EPS		-5		-2

[1] On group growth rates

Upcoming Virtual Event

Digitalization along the value chain

Wednesday, 17 November 2021
16:00 - 17:30 CET / 15:00 - 16:30 GMT

Presenters:
Alan Hippe, Chief Financial and IT Officer Roche
Mark McCarthy, Executive Director Human Genetics, gRED
Christian Gossens, Digital Biomarkers, Global Area Head, pRED
Jacqueline Law, Vice President, Head of Corporate Strategy, Flatiron Health
Steve Guise, Global Head, Pharma Informatics
Moritz Hartmann, Global Head of Roche Information Solutions, Roche Diagnostics

2021 outlook raised

Sales growth to "mid-single digit" from "low- to mid-single digit"

Group sales growth[1]	• Mid-single digit (from low- to mid-single digit)
Core EPS growth[1]	• Broadly in line with sales growth
Dividend outlook	• Further increase dividend in Swiss francs

[1] At Constant Exchange Rates (CER); based on the current assessment of the COVID-19 impact

Changes to the development pipeline
Q3 2021 update

New to phase I

2 NMEs:
RG6035 brainshuttle (BS)-CD20 - multiple sclerosis
RG6440 TGFβ (SOF10) - solid tumors

New to phase II

2 NMEs:
RG6149 astegolimab (Anti-ST2) - chronic obstructive pulmonary disease
RG6416 bepranemab (Anti-tau) - AD

New to phase III

2 AIs:
RG6171 giredestrant (SERD) – ER+ adj BC
RG6168 Enspryng – Myasthenia Gravis

New to registration

1 NME:
RG6413+RG6412 Ronapreve SARS-CoV-2 prophylaxis and ambulatory (EU)

1 AI:
RG1569 Actemra COVID-19 pneumonia (EU)

Removed from phase I

Removed from phase II

Removed from phase III

Approvals

1 AI approved in US:
RG7446 Tecentriq NSCLC adj

Status as of October 20, 2021

Roche Group development pipeline

Phase I (41 NMEs + 12 AIs)

RG6007	HLA-A2-WT1 x CD3	AML
RG6026	glofitamab monotherapy and combos	heme tumors
RG6058	tiragolumab combos	heme & solid tumors
RG6076	CD19-4-1BBL	heme tumors
RG6115	TLR7 agonist (4)	HCC
RG6160	cevostamab (FcRH5 x CD3)	r/r MM
RG6171	giredestrant (SERD)	ER+/HER2- BC
RG6180	autogene cevumeran±T	solid tumors
RG6185	belvarafenib (pan-RAF inh)+Cotellic	solid tumors
RG6189	FAP-CD40	solid tumors
RG6194	runimotamab (HER2 x CD3)	BC
RG6232	TYRP1 x CD3	metastatic melanoma
RG6234	-	multiple myeloma
RG6279	PD1-IL2v	solid tumors
RG6286	-	colorectal cancer
RG6290	MAGE-A4 ImmTAC	solid tumors
RG6292	CD25 MAb ± T	solid tumors
RG6323	IL15/IL15Ra-Fc	solid tumors
RG6330	KRAS G12C	solid tumors
RG6433	SHP2i	solid tumors
RG6440	TGFβ (SOF10)	solid tumors
RG7440	ipatasertib + rucaparib	mCRPC, solid tumors
	ipatasertib	prostate cancer, pretreated
RG7446	Morpheus platform	solid tumors
	T + Venclexta	maintenance 1L ES-SCLC
RG7601	Venclexta + AMG176	AML
	Venclexta ± azacitidine	r/r MDS
	Venclexta + gilteritinib	r/r AML
RG7802	cibisatamab ± T	solid tumors
RG7827	FAP-4-1BBL + combos	solid tumors
RG7828	mosunetuzumab monotherapy + combos	heme tumors

T=Tecentriq, BS=Brain shuttle

CHU	FIXa x FX	haemophilia
CHU	glypican-3 x CD3	solid tumors
CHU	codrituzumab	HCC
CHU	CD137 switch antibody	solid tumors
CHU	-	solid tumors & endometriosis
SQZ	PBMC vaccine	solid tumors
RG6287	-	IBD
RG6418	NLRP3 inh	inflammation
RG6315	-	immunologic disorders
RG6006	Abx MCP	bacterial infections
RG6084	PD-L1 LNA	HBV
RG6338	-	metabolic diseases
RG6035	BS-CD20	multiple sclerosis
RG6091	UBE3A LNA	Angelman syndrome
RG6182	-	neurodegenerative diseases
RG6237	-	neuromuscular disorders
RG7637	-	neurodevelopmental disorders
RG6120	VEGF-Ang2 DutaFab	nAMD
RG6179	-	DME
RG6312	-	geographic atrophy
RG7921	-	nAMD
CHU	PTH1 recep. ago	hypoparathyroidism

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

Metabolism
Neuroscience
Ophthalmology
Other

RG-No - Roche/Genentech
CHU - Chugai managed
IONIS – IONIS managed

SQZ - SQZ Biotechnology managed

[1]One AI combination previously contributing as two entities
[2]combination platform

Phase II (26 NMEs + 12 AIs)

RG6058	tiragolumab + T	NSCLC
	tiragolumab + T + chemo	1L non-squamous NSCLC
	tiragolumab + T + chemo	neoadj-adj NSCLC
	tiragolumab + T	cervical cancer
	tiragolumab + T	1L PD-L1+ mSCCHN
RG6139	PD1 x LAG3	solid tumors
RG6171	giredestrant (SERD)	neoadjuvant ER+ BC
	giredestrant (SERD)	2/3L ER+/HER2- mBC
RG6180	autogene cevumeran + pembrolizumab	1L melanoma
RG6354	rhPTX-2 (PRM-151)	myelofibrosis
RG6357	SPK-8011	hemophilia A
RG6358	SPK-8016	hemophilia A with inhibitors to factor VIII
RG7601	Venclexta + carfilzomib	r/r MM t(11;14)
RG7769	PD1 x TIM3	solid tumors
CHU	Oncolytic Type 5 adenovirus	esophageal cancer
RG6149	astegolimab (Anti-ST2)	COPD
RG6173	anti-tryptase	asthma
RG7835	IgG-IL2	autoimmune diseases
RG7880	efmarodocokin alfa	inflammatory diseases
IONIS	ASO factor B	IgA nephropathy
RG6413+RG6412[1]	Ronapreve	SARS-CoV-2 hospitalised
RG7854/RG7907/ RG6346[2]	TLR7 ago(3)/CpAM (2)/siRNA	HBV
RG6359	SPK-3006	Pompe disease
RG7992	FGFR1 x KLB MAb	NASH
RG6100	semorinemab	Alzheimer's
RG6102	BS-gantenerumab	Alzheimer's
RG6416	bepranemab	Alzheimer's
RG6356	micro-dystrophin (SRP-9001)	DMD
RG7412	crenezumab	familial Alzheimer's healthy pts
RG7816	GABA Aa5 PAM	ASD
RG7906	ralmitaront	schizophrenia
RG7935	prasinezumab	Parkinson's
RG6147	HtrA1	geographic atrophy
RG6367	SPK-7001	choroideremia
RG7774	-	retinal disease
IONIS	ASO factor B	geographic atrophy

Status as of October 20, 2021

Roche Group development pipeline

Phase III (13 NMEs + 39 AIs)

RG3502	Kadcyla + T	2L+ HER-2+ PD-L1+ mBC
	Kadcyla + T	HER-2+ eBC high-risk
RG6013	Hemlibra	mild to moderate hemophilia A
RG6026**	glofitamab + chemo	2L+ DLBCL
RG6058	tiragolumab + T + chemo	1L SCLC
	tiragolumab + T	1L PD-L1+ NSCLC
	tiragolumab + T	locally advanced esophageal cancer
	tiragolumab + T	1L esophageal cancer
	tiragolumab + T	stage III unresectable 1L NSCLC
RG6107	crovalimab	PNH
RG6114	inavolisib (mPI3K alpha inh)	1L HR+ mBC
RG6171	giredestrant (SERD)	ER+/HER2- mBC
	giredestrant (SERD)	adj ER+ BC
RG6268	Rozlytrek ROS1+	1L NSCLC
RG7440	ipatasertib + abiraterone	1L CRPC
RG7596	Polivy	1L DLBCL
RG7446	Tecentriq + platinum chemo	NSCLC neoadj
	Tecentriq	NMIBC, high risk
	Tecentriq	RCC adj
	Tecentriq + cabozantinib	advanced RCC
	Tecentriq + cabozantinib	2L NSCLC
	T ± chemo	SCCHN adj
	T + capecitabine or carbo/gem	1L TNBC
	T + paclitaxel	TNBC adj
	T + Avastin	HCC adj
	T ± chemo	1L mUC
	Tecentriq	SC NSCLC
	Tecentriq	ctDNA+ high-risk MIBC

RG7601	Venclexta	r/r MM t(11:14)
	Venclexta + azacitidine	1L MDS
RG7828**	mosunetuzumab + lenalidomide	2L+ FL
RG7853	Alecensa	ALK+ NSCLC adj
RG3648	Xolair	food allergy
RG6354	rhPTX-2 (PRM-151)	idiopathic pulmonary fibrosis
RG7159	Gazyva	lupus nephritis
	Gazyva	membranous nephropathy
RG7413	etrolizumab	Crohn's
RG6152	Xofluza	influenza, pediatric (0-1 year)
	Xofluza	influenza, pediatric (1-12 years)
	Xofluza	influenza direct transmission
RG6422	AT-527	SARS-CoV-2
RG1450	gantenerumab	Alzheimer's
RG1594	Ocrevus higher dose	RMS & PPMS
RG6042	tominersen	Huntington's
RG6168	Enspryng	Myasthenia Gravis
RG7845	fenebrutinib	PPMS
RG7845	fenebrutinib	RMS
RG6321	port delivery system with ranibizumab	DME
	port delivery system with ranibizumab	DR
	port delivery system with ranibizumab	wAMD, 36-week
RG7716	faricimab	BRVO
	faricimab	CRVO

T=Tecentriq
*One NME combination previously contributing as two entities
** phI safety run-in ongoing

Registration (4 NMEs + 4 AIs)

RG6396	Gavreto (pralsetinib)[1]	RET+ NSCLC
	Gavreto (pralsetinib)[2]	RET+ MTC
RG7446	Tecentriq[2]	NSCLC adj
RG6321	port delivery system with ranibizumab	wAMD
RG7716	faricimab	DME
	faricimab	wAMD
RG6413+ RG6412*	Ronapreve[3]	SARS-CoV-2 prophylaxis and ambulatory
RG1569	Actemra[3]	COVID-19 pneumonia

[1] Approved in US, filed in EU
[2] Approved in US
[3] Filed in the EU

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

Status as of October 20, 2021

NME submissions and their additional indications

Projects in phase II and III

2021		2022		2023		2024 and beyond					
RG7828	**mosunetuzumab** 3L+ FL	RG6026	**glofitamab** 3L+ DLBCL	RG6058	**tiragolumab + T** 1L PD-L1+ NSCLC	RG6026	**glofitamab + chemo** 2L DLBCL	RG6180	**autogene cevumeran** 1L melanoma		
RG6413+ RG6412	**Ronapreve** SARS-CoV-2 prophylaxis and ambulatory ✓	RG6058	**tiragolumab + Tecentriq (T)** 1L SCLC	RG6058	**tiragolumab + T** 1L esophageal cancer[1]	RG6058	**tiragolumab + T** 1L PD-L1+ cervical ca	RG6354	**rhPTX-2 (PRM-151)** myelofibrosis	RG6100	**semorinemab** Alzheimer's
RG6413+ RG6412	**Ronapreve** SARS-CoV-2 hospitalised	RG6107	**crovalimab** PNH[1]	RG6114	**inavolisib** (mPI3K alpha inh) 1L HR+ BC	RG6058	**tiragolumab + T** locally adv esophageal cancer	RG7769	**PD1xTIM3** solid tumors	RG6102	**brain shuttle gantenerumab** Alzheimer's
RG6321	**port delivery system with ranibizumab** wAMD ✓	RG6171	**giredestrant (SERD)** 2L/3L ER+/HER2- mBC	RG6321	**port delivery system with ranibizumab** DME	RG6058	**tiragolumab + T** Stage III unresectable 1L NSCLC	RG7828	**mosunetuzumab + lenalidomide** 2L FL	RG6356	**micro-dystrophin SRP-9001** DMD
RG7716	**faricimab** DME ✓	RG7440	**ipatasertib + abiraterone** 1L CRPC	RG6321	**port delivery system with ranibizumab** DR	RG6058	**tiragolumab + T** 1L non-sq NSCLC	RG6149	**astegolimab (anti-ST2)** COPD	RG7816	**GABA Aa5 PAM** ASD
RG7716	**faricimab** wAMD ✓	RG7413	**etrolizumab** Crohn's	RG7716	**faricimab** BRVO/CRVO	RG6058	**tiragolumab + T** 1L PD-L1+ mSCCHN	RG6173	**Anti-tryptase** asthma	RG7845	**fenebrutinib** PPMS
		RG6422	**AT-527** SARS-CoV-2			RG6058	**tiragolumab+T+/- chemo** neoadj/adj NSCLC	RG6354	**rhPTX-2 (PRM-151)** IPF	RG7845	**fenebrutinib** RMS
		RG1450	**gantenerumab** Alzheimer's			RG6139	**PD1xLAG3** solid tumors	RG7880	**efmarodocokin alfa** (IL22-Fc) inflammatory diseases	RG7906	**ralmitaront** schizophrenia
						RG6171	**giredestrant (SERD)** 1L ER+/HER2- mBC	RG7907/ RG7854/ RG6346	**TLR7 ago (3)/ CpAM (2) /siRNA** HBV	RG7935	**prasinezumab** Parkinson's
						RG6171	**giredestrant (SERD)** Adj ER+ BC	RG7992	**FGFR1 x KLB MAb** NASH	RG6321	**port delivery system with ranibizumab** wAMD, 36-week refill

✓ Indicates submission to health authorities has occurred
Unless stated otherwise submissions are planned to occur in US and EU
[1] First filing in China

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

Status as of October 20, 2021

AI submissions for existing products

Projects in phase II and III

2021		2022		2023		2024 and beyond			
RG6152	**Xofluza** influenza, pediatric (1-12 yrs)			RG6152	**Xofluza** direct transmission	RG3502	**Kadcyla + Tecentriq** 2L+ HER-2+ PD-L1+ mBC		
RG1569	**Actemra**[1,2] COVID-19 pneumonia ✓	RG6396	**Gavreto (pralsetinib)** Tumour agnostic	RG6152	**Xofluza** influenza, pediatric (0-1 year)	RG3502	**Kadcyla + Tecentriq** HER-2+ eBC high-risk		
RG6013	**Hemlibra** Mild to moderate hemophilia A (EU)	RG7446	**Tecentriq** RCC adj	RG3648	**Xolair** Food allergy	RG7446	**Tecentriq + paclitaxel** TNBC adj	RG7159	**Gazyva** lupus nephritis
RG7446	**Tecentriq** NSCLC adj ✓	RG7446	**Tecentriq ± chemo** 1L mUC	RG7446	**Tecentriq** SC NSCLC	RG7446	**Tecentriq** High risk NMIBC	RG7159	**Gazyva** membranous nephropathy
RG7596	**Polivy** 1L DLBCL	RG7853	**Alecensa** ALK+ NSCLC adj	RG7446	**Tecentriq + cabozantinib** 2L NSCLC	RG7446	**Tecentriq + chemo** SCCHN adj	RG1594	**Ocrevus** higher dose RMS & PPMS
RG6396	**Gavreto (pralsetinib)** RET+ MTC (EU)	RG6268	**Rozlytrek (BFAST)** 1L NSCLC ROS1+	RG7446	**Tecentriq + cabozantinib** adv RCC	RG7446	**Tecentriq** ctDNA+ high-risk MIBC	RG6168	**Enspryng** Myasthenia Gravis
				RG7446	**Tecentriq + Avastin** HCC adj				
				RG7446	**Tecentriq**[2] NSCLC neo adj				
				RG7601	**Venclexta** r/r MM t(11:14)				
				RG7601	**Venclexta + azacitidine** 1L MDS				
				RG7446	**Tecentriq + capecitabine or carbo/gem** TNBC				

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

✓ Indicates submission to health authorities has occurred
Unless stated otherwise submissions are planned to occur in US and EU
[1]US FDA Emergency Use Authorization received
[2]Filed in the EU; [3]filing timeline based on data from interim analysis;

Status as of October 20, 2021

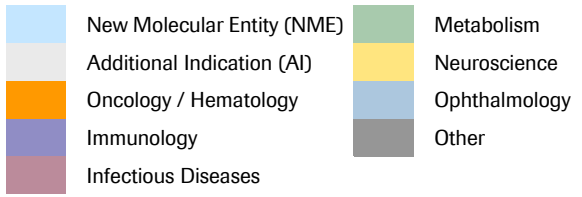
Major pending approvals 2021

US	
RG6321	**PDS with ranibizumab** wAMD Filed April 2021
RG7716	**faricimab** DME Filed May 2021
RG7716	**faricimab** wAMD Filed May 2021

EU	
RG6396	**Gavreto (pralsetinib)** **RET+ NSCLC** Filed May 2020
RG7446	**Tecentriq** NSCLC adj Filed June 2021
RG6321	**PDS with ranibizumab** wAMD Filed April 2021
RG7716	**faricimab** DME Filed May 2021
RG7716	**faricimab** wAMD Filed May 2021
RG6413+ RG6412	**Ronapreve** SARS-CoV-2 prophylaxis and ambulatory Filed Sept 2021
RG1569	**Actemra** COVID-19 pneumonia Filed Sept 2021

China	
RG7446	**Tecentriq** NSCLC adj Filed June 2021

Japan-Chugai	
RG7716	**faricimab** DME Filed June 2021
RG7716	**faricimab** wAMD Filed June 2021
RG7446	**Tecentriq** NSCLC adj Filed July 2021
RG6413+ RG6412	**Ronapreve** SARS-CoV-2 prophylaxis and ambulatory Filed Sept 2021



PDS=port delivery system

Status as of October 20, 2021

Major granted approvals 2021

US

RG7853	**Alecensa (BFAST)** 1L NSCLC ALK+ Jan 2021
RG1569	**Actemra** SSc-ILD March 2021
RG3648	**Xolair** Self-injection April 2021
RG7446	**Tecentriq** NSCLC adj Oct 2021

EU

RG6152	**Xofluza** influenza, otherwise healthy Jan 2021
RG6152	**Xofluza** influenza, high risk Jan 2021
RG6152	**Xofluza** post exposure prophylaxis Jan 2021
RG7916	**Evrysdi** SMA March 2021
RG6168	**Enspryng** NMOSD June 2021
RG7446	**Tecentriq** 1L non-sq + sq NSCLC Dx+ May 2021
RG7601	**Venclexta+ azacitidine** 1L AML May 2021

China

RG6152	**Xofluza** influenza, otherwise healthy April 2021
RG6152	**Xofluza** influenza, high risk April 2021
RG6013	**Hemlibra** Hemophilia A April 2021
RG7446	**Tecentriq** 1L non-sq + sq NSCLC Dx+ April 2021
RG6168	**Enspryng** NMOSD April 2021
RG7916	**Evrysdi** SMA May 2021
RG3502	**Kadcyla** 2L HER2+ BC June 2021
RG7159	**Gazyva** 1L FL and r/r FL June 2021
RG7446	**Tecentriq + pemetrexed** 1L non-sq NSCLC June 2021

Japan-Chugai

RG7596	**Polivy** r/r DLBCL March 2021
RG7916	**Evrysdi** SMA June 2021
RG6413+ RG6412	**Ronapreve** SARS-CoV-2 July 2021
RG105	**Rituxan** systemic sclerosis Sep 2021

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

Status as of October 20, 2021

Doing now what patients need next