5 June 2023

TRISTEL plc
("Tristel" or the "Company")

FDA De Novo approval

Tristel ULT approved by the FDA as a high level disinfectant for use on endocavity ultrasound probes and skin surface transducers

Tristel expects to gain significant market share in the world's largest ultrasound market

Tristel plc (AIM: TSTL), the manufacturer of infection prevention products utilising proprietary chlorine dioxide technology, announces that the USA Food and Drug Administration ("FDA") has completed its review of the Company's De Novo request for classification (Class II) of Tristel ULT as a high level disinfectant, and has granted its approval for immediate sale.

Tristel DUO, the Company's intermediate level disinfectant approved by the USA Environmental Protection Agency for use on the ultrasound console and the non-invasive parts of the endocavity probe, is now registered in all states of the USA.

The Company estimates that over 215 million ultrasound scans are carried out in the United States annually. Approximately 20% of these scans require high level disinfection and the remainder require low or intermediate level disinfection. With the FDA approval, Tristel has two products approved in the USA that can meet the disinfection needs for all ultrasound scans. This is a unique competitive position.

The United States nationwide launch of Tristel ULT will commence in October this year, following Tristel DUO's market introduction late last year. The Company has already established a manufacturing base with Parker Laboratories Inc., New Jersey, and will utilise Parker's national distribution network for the ultrasound market. Parker is the largest supplier of ultrasound transmission gels in the USA. As both a gel and an appropriate disinfectant must be used in every ultrasound scan procedure, the combination of Tristel and Parker products promises a powerful combination.

Whilst Tristel is a new market entrant in the USA, the Company is very familiar with the competitive landscape which is almost identical in the other 40 plus countries in which Tristel operates. Approximately half of Tristel's global revenue is generated from the ultrasound market.

Further details of the Company's North American commercial strategy will be outlined to equity analysts and investors through a series of presentations over the next few weeks. Further details will be announced in due course.

Paul Swinney, Chief Executive of Tristel, said: *"This FDA approval enables our full-blown entry into the United States ultrasound market and is a significant inflection point for the Company. We will now be present in the single largest ultrasound market in the world. This milestone achievement will allow us to significantly increase our global revenue along with our profit potential as we put Tristel's and Parker's resources behind Tristel ULT and DUO in the USA."*

The information communicated in this announcement is inside information for the purposes of Article 7 of Regulation 596/2014.

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