



27 March 2023

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

**Successful submission of additional data to the US FDA**

***Additional Information Request completed on-time for De Novo submission  
FDA decision expected before 30 June 2023***

Tristel plc (AIM: TSTL), the manufacturer of infection prevention products utilising proprietary chlorine dioxide technology, announces that it has successfully submitted the additional data requested by the US Food and Drug Administration (FDA) to enable the FDA's decision to grant market clearance for its Duo ULT high-level disinfectant. A decision is expected before 30 June 2023.

In September last year, the Company received the FDA's detailed response to its De Novo submission made in June 2022. The agency grants the applicant a 180-day period in which to generate and submit the additional data requested. Tristel has successfully accomplished this within the agreed timescale.

The FDA will now commence its final review of the De Novo submission and the agency's internal rules require it to make its decision by the Company's financial year-end.

The FDA approval will enable Duo's use for high-level disinfection of intra-cavity ultrasound probes. Duo is already approved by the US Environmental Protection Agency for use on skin-surface ultrasound transducers.

Disinfection of ultrasound probes and transducers accounts for approximately 40% of Tristel's global revenue. The United States is the largest single ultrasound market in the world and access to the US market will be a significant inflection point for the Company.

The Company has already established a manufacturing base in North America and has put in place nationwide distribution in anticipation of FDA clearance.

**Paul Swinney, Chief Executive of Tristel, said:** *"We have been on a five-year journey to gain FDA approval and submitting this last data set is an important milestone for the Company. If we are successful in June, we will be able to introduce an innovative and lower cost decontamination product to the United States healthcare market, significantly increasing our future global revenue and profit potential."*

**Tristel plc**

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