30 June 2022

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

De Novo FDA submission for Tristel Duo ULT

Tristel plc (AIM: TSTL), the manufacturer of infection prevention products, reports that it has submitted its De Novo request for approval to the FDA, the United States regulatory body responsible for medical device disinfectants. Tristel Duo ULT is used for the disinfection of ultrasound probes.

Tristel Duo ULT is a high-level disinfectant foam that can be used on ultrasound probes used for intra-cavitary and skin surface diagnostic procedures. Ultrasound probe disinfection is one of Tristel's most important areas of focus within the hospital infection prevention market and accounts for approximately 40% of the Company's global revenue which analysts forecast at £28 million for the current financial year.

To the Company's knowledge, Tristel Duo ULT is the first disinfectant to make a De Novo request to the FDA, reflecting the novelty of the product. Duo ULT is widely used throughout Europe, the Middle East, Asia, and Australasia and during the Company's current financial year the product will have been used in over 8 million disinfection procedures of ultrasound probes worldwide.

The FDA's De Novo review and approval process stipulates a 150-day decision timeframe. Additional data requests are commonplace, and the FDA website states that the average duration for review and approval is approximately 11 months.

The Company is also proceeding with the state registration of another version of Duo which has been approved by the United States EPA for the disinfection of general medical surfaces. The Company has received 24 state approvals and anticipates that all others will have been received by the end of 2022.

The Company will manufacture and distribute both Duo products via its commercial partnership with Parker Laboratories, New Jersey ("Parker"). Parker is a leading manufacturer in the USA market for the conductive gels and sheaths that are used in all ultrasound procedures, and Parker has a nationwide distribution network.

Paul Swinney, Chief Executive of Tristel plc, comments: *"After five years of testing and data generation we are very pleased to have finally submitted our De Novo request for approval to the FDA. We have made an investment of £2.8 million in the project which has all been expensed.*

"The United States is the largest ultrasound market in the world and our competitors will be the same as those we compete with in all our other markets worldwide. To our knowledge no new high-level disinfectant has been approved by the FDA and introduced into the United States since 2011, other than variants of previously approved products. Duo ULT is recognised as a leading high-level disinfectant throughout the rest of the world, and our entry into the United States market will be a significant inflection point for the Company."

Tristel holds a shareholder open day at its Newmarket headquarters on 18 July and will release a trading update on the day.

The information contained within this announcement is deemed to constitute inside information as stipulated under the Market Abuse Regulations (EU No. 596/2014) which is part of UK law by virtue of the European Union (Withdrawal) Act 2018. Upon the publication of this announcement, this inside information is now considered to be in the public domain.