29 September 2022

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

North America update

US Launch of EPA registered Tristel DUO
FDA De Novo Submission update

Tristel plc (AIM: TSTL), the manufacturer of infection prevention products, provides an update on progress in addressing the commercial opportunity in the United States ultrasound market with products utilising its proprietary chlorine dioxide technology.

Launch of Tristel DUO into the North American Market
Tristel announces that it has now launched Tristel DUO into the North American market in conjunction with the Company's manufacturing and distribution partner, Parker Laboratories ("Parker"). Parker is a leading manufacturer in the USA market for the conductive gels and sheaths that are used in all ultrasound procedures, and has a nationwide distribution network.

Tristel DUO is a disinfecting foam approved by the USA Environmental Protection Agency (EPA) for the cleaning and disinfection of general medical surfaces – including skin surface ultrasound transducers. DUO is widely used throughout Europe, the Middle East, Asia, and Australasia and during the Company's current financial year the product will be used in over 11 million ultrasound probe disinfection procedures worldwide.

The launch is coordinated across three conferences and trade shows taking place simultaneously this week: the American Society of Diagnostic Medical Sonography in Atlanta (29 Sept – 1 Oct); the American Association of Vascular Access in Minneapolis (30 Sept – 3 Oct), and the American Emergency Nurses Association in Denver (30 Sept – 3 Oct).

Neal Buchalter, President of Parker Laboratories, commented: *"Tristel's products are used in 35 countries and for millions of disinfection procedures every year. We're proud of this new partnership with Tristel, as it reflects our continued commitment to improving the safety of any procedure involving ultrasound equipment."*

https://www.parkerlabs.com/wp-content/uploads/2022/09/Parker-Tristel-Duo-Strategic-release_-FINAL-2.pdf

FDA De Novo Submission – additional information request
In June Tristel achieved a major milestone event by making its De Novo submission to the USA Food and Drug Administration (FDA) for its Tristel DUO ULT product which is used as a high-level disinfectant for ultrasound intra-cavity probes. Following the FDA's complete review of the submission, it has provided the Company with an Additional Information request.

As previously outlined to shareholders, Additional Information requests are commonplace within the De Novo submission process, and therefore the previous guidance on the average duration for review and approval of approximately 11 months remains accurate for this submission. The Company and its advisors are confident that the 180-day timeline set by the FDA to return the information will be met. The overall expected timescale for the process is unchanged.

Paul Swinney, CEO of Tristel plc, comments: *"We are delighted to have products entering the North American hospital market in partnership with Parker Laboratories who are specialists in the ultrasound arena. In all the countries in which we operate, hospital ultrasound is one of our most important segments. We have high hopes for our EPA approved product.*

"Our opportunities will expand enormously with an accompanying FDA approval and it is good the review of our submission is progressing. Additional Information requests are expected in this process and we are confident that we will be in a position to return the requested information on time. Nothing has changed in terms of our overall

view on the timescale for the completion of this process and the likelihood of success. We remain excited about the opportunity America holds in terms of potential revenue and profit contributions.

"Our global outlook remains positive. We have a highly focussed business, we now have products available in the largest single healthcare market in the world, an exciting pipeline of new product innovations, and a strong balance sheet to support our growth."

The information communicated in this announcement contains inside information for the purposes of Article 7 of the Market Abuse Regulation (EU) No. 596/2014.

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About Parker Laboratories (www.parkerlabs.com).
Parker Laboratories is a leading global medical product company that develops, manufactures, and sells ultrasound and electromedical contact media and accessories, as well as leading lines of instrument cleaners and disinfectants. A worldwide leader in ultrasound medical products for over 60 years, Parker has consistently been at the forefront of technological advances in the industry. Its flagship product, Aquasonic®100 ultrasound transmission gel, is the world standard for medical ultrasound.