23 January 2024

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

Canadian regulatory approval for Tristel ULT
US FDA submission on schedule for Tristel OPH

Tristel ULT approved by Health Canada as a high-level disinfectant
for use on endocavity ultrasound probes and skin surface transducers

Tristel plc (AIM: TSTL), the manufacturer of infection prevention products utilising its proprietary chlorine dioxide technology, announces that Health Canada has approved Tristel ULT as a Class II Medical Device for endocavity ultrasound probes and skin surface transducers. The timing of this regulatory approval comes well ahead of the Company's original aim for gaining approval before the end of H1 FY 2025 and allows commercial launch during FY 2024.

Health Canada approval, alongside approval from the US Food and Drug Administration ("FDA") received in June 2023, means that Tristel ULT can now be manufactured and sold throughout the whole of North America by Tristel's commercial partner Parker Laboratories Inc. ("Parker") as a high-level disinfectant for ultrasound instruments.

Parker completed its first production run of Tristel ULT in October 2023 and is actively introducing the product to its United States distribution network. This activity will now be extended to the Canadian market. The first hospital users in the United States are trialling and purchasing the product. Tristel will provide a more detailed update in its interim results on 26 February 2024.

North American ophthalmic market
Tristel is preparing its dossier for Tristel OPH, a high-level disinfectant for use on ophthalmic instruments, for submission to the FDA and has requested a pre-submission meeting with the agency. The review meeting date is scheduled for early March 2024. The Company anticipates completing its submission seeking 510(k) approval in the summer and receiving FDA approval by the end of the year.

Tristel OPH was approved by Health Canada in June 2021. Tristel OPH was launched into the Canadian ophthalmic market as a high-level disinfectant for ophthalmic instruments including re-usable tonometers and lenses that contact the cornea during the Company's last financial year. The product is being distributed throughout the country by Innova Medical Ophthalmics Inc., Toronto, a subsidiary of Advancing Eyecare, Jacksonville, Florida. Tristel OPH is being used by public health authorities in all the major Canadian provinces.

Paul Swinney, CEO of Tristel commented: *"Our North American business strategy focuses on entering each of the key market segments that we dominate in other countries. Ultrasound is our largest segment globally in terms of disinfection procedure events, followed by ENT, cardiology and airway management. Ophthalmology is a very significant global opportunity in terms of disinfection events, but in all countries very few procedures that should be performed with a high-level disinfectant in fact are.*

"Tristel OPH is the world's only high-level disinfectant specifically designed and labelled for use on ophthalmic instruments and is currently being used for two million disinfection events across all our markets. However, we estimate that globally the number of tonometer uses for glaucoma assessment total several hundred million annually.

“We are making good progress building out the North American business strategy that we have communicated to our shareholders. This latest approval of Tristel ULT in Canada and our anticipated entry into the United States ophthalmic market later this year, leveraging our growing penetration of the Canadian market, establishes the foundation for the substantial business we intend to build across the continent.”

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The information contained within this announcement is deemed by the Company to constitute inside information as stipulated under the Market Abuse Regulation ("MAR") EU no.596/2014. Upon the publication of this announcement via Regulatory Information Service ("RIS"), this inside information is now considered to be in the public domain.