



4 September 2023

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

Health Canada regulatory approval submission for Tristel ULT
Accelerated timetable to allow earlier commercial launch in Canada in H2 FY 2024

Tristel plc (AIM: TSTL), the manufacturer of infection prevention products, announces that it has submitted its application to Health Canada to approve Tristel ULT as a Class II Medical Device for endocavity ultrasound probes and skin surface transducers.

Tristel ULT is a hand-applied high-level disinfectant foam for medical devices and was approved by the United States Food and Drug Administration (FDA) in June this year ([RNS 5723B](#)) for use on endocavity ultrasound probes and skin surface transducers.

Tristel OPH, a high-level disinfectant for ophthalmic instruments, has already been approved by Health Canada as a Class II Medical Device in June 2021 ([RNS 9130C](#)).

Having submitted the application earlier in the current financial year than expected, the Company now expects a decision on its Tristel ULT application early next year compared to original guidance of H1 FY 2025 (i.e the 6 month period ending 31 December 2024). If the application succeeds this will allow commercial launch during H2 FY 2024 instead of during H2 FY 2025.

Tristel ULT will be manufactured by Tristel's North American business partner, Parker Laboratories Inc., New Jersey, and will be distributed to Canadian ultrasound users through Parker's distributor network.

Paul Swinney, Chief Executive Officer of Tristel, said: *"When we received our FDA approval for Tristel ULT in June we set out for our shareholders our commercial strategy for North America. This included the submission to the Canadian regulatory authority of Tristel ULT during the current financial year and its approval before the end of H1 FY 2025. I am pleased to report that we have accelerated our plans and can look forward to a commercial launch into the Canadian ultrasound market during our second half."*

"Tristel OPH, which is labelled for use on ophthalmic devices, has been successfully launched and is being sold to Canadian hospitals by our distribution partner Innova Medical."

"Parker Laboratories is well advanced in preparing to manufacture the Tristel foam disinfectants and we are on target to launch into the United States ultrasound market on or before 1 October 2023."

"We will provide a detailed update on our North America business plan and the progress we are making worldwide in our year-end results presentation scheduled for 16 October 2023."

For further information please contact:

Tristel plc

Paul Swinney, Chief Executive Officer
Liz Dixon, Chief Financial Officer

Tel: 01638 721 500

Walbrook PR Ltd

Paul McManus
Lianne Applegarth

Tel: 020 7933 8780 or tristel@walbrookpr.com

Mob: 07980 541 893
Mob: 07584 391 303

finnCap

Geoff Nash/ Charlie Beeson (Corporate Finance)
Sunila de Silva (ECM)

Tel: 020 7220 0500