

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

Additional information submitted to the FDA for Tristel OPH

Tristel plc (AIM: TSTL), the manufacturer of infection prevention products, confirms it has submitted the additional information requested by the U.S. Food and Drug Administration (FDA) for Tristel OPHa high-level disinfectant foam for use on ophthalmic medical devices, including re-usable tonometers, pachymeters and lenses that make contact with the cornea. The Company now expects a decision from the FDA by the end of June 2025.

As announced in [September 2024](#), the 510(k) filing for Tristel OPH will use Tristel ULT as its predicate device. Tristel ULT, a high-level disinfectant labelled for use on endocavity ultrasound probes and skin surface transducers, was cleared for sale in the US by the FDA in June 2023, following the Company's De Novo submission.

With c.16 million ultrasound procedures taking place every year in North America, the Board continues to believe that FDA clearance has the potential to transform ophthalmic disinfection practice in the region. Tristel OPH addresses operational inefficiencies arising from complex and time-consuming decontamination practice. In addition, very few semi-critical ophthalmic devices are subject to effective high-level disinfection in the US. Low-level disinfectant options such as alcohol wipes are used as an alternative, or devices may be soaked in sodium hypochlorite (Milton) or hydrogen peroxide in open trays with long contacts times.

Matt Sassone, Chief Executive Officer of Tristel, commented: *"We are extremely pleased to have submitted the additional information to the FDA for Tristel OPH. The ophthalmic opportunity within the US remains strong and we continue to make good progress on establishing our commercial route to market."*

"With the timing of submission, a month ahead of the ultimate deadline, we have given ourselves the best opportunity to have the FDA decision in time for the APIC Association for Professionals in Infection Control and Epidemiology conference in Phoenix, AZ mid-June, the largest annual event in the USA for reaching critical Infection Preventionist community and decision makers."

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About Tristel plc

Tristel plc is a global infection prevention company focussed on the manufacture and supply of products using its unique proprietary chlorine dioxide (ClO₂) chemistry. The Company is a market leader in manual decontamination of medical devices, supplying hospitals under the [Tristel](#) brand, and under the [Cache](#) brand provides products for sporicidal surface disinfection, a more sustainable alternative to commonly used pre-wetted plastic wipes.

Tristel's head office and manufacturing facility is located in Snailwell, near Cambridge, and operates globally employing approximately 270 people across 16 subsidiaries selling into 40+ countries. The Company targets annual revenue growth of between 10% and 15% and an EBITDA margin of at least 25% and the business is profitable, with no debt and has a progressive dividend policy.

The Company has been listed on the London Stock Exchange's AIM market since 2005 (AIM: TSTL).

For more information about Tristel's product range please visit: <https://tristel.com>

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