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

FDA clearance for Tristel OPH

Ophthalmic high-level disinfectant now approved for immediate sale in the US

Tristel plc (AIM: TSTL), the manufacturer of infection prevention products, announces that the US Food and Drug Administration ("FDA") has completed its review of the Company's 510(k) filing for Tristel OPH, and has granted its clearance for immediate sale. Tristel OPH is a high-level disinfectant ("HLD") foam for use on ophthalmic medical devices, including re-usable tonometers, pachymeters, lenses, retinal imaging probes, A-scan and B-scan biometry probes that make contact with the cornea.

With c.16 million ophthalmic procedures taking place every year in North America, the Board believes that FDA clearance has the potential to transform ophthalmic disinfection practice in the region.

Until now, the only FDA-cleared HLD method available for ophthalmic devices involves soaking in an open tray. This method is slow, given the long contact times required to be effective, and has as a result proven to be impractical to implement at point of care. In addition, the use of chemicals, such as sodium hypochlorite or hydrogen peroxide in an open tray, leads to occupational health concerns and may require costly implementation of ventilation. Prolonged exposure in a chemical soak can also lead to device damage.

To address the problems, some clinics have turned to costly single-use devices, for which there is not always an option, while others have compromised by using low-level disinfectants options, such as alcohol wipes.

In comparison, Tristel OPH has a short contact time of two minutes, is compatible with all widely used ophthalmic medical devices, is easily used at the point of care and is instantly deployable.

The Company has already established local US manufacturing with its partner Parker Laboratories, and numerous leading eye institutes in the US have already approached Tristel to become early adopters in anticipation of FDA clearance for Tristel OPH.

Matt Sassone, Chief Executive Officer of Tristel, commented: *"We are delighted to receive FDA clearance for our second high level disinfectant product in the US. Tristel OPH directly addresses a long-standing unmet need in ophthalmic device reprocessing—offering a fast, safe and practical alternative to the outdated and often hazardous methods still in use.*

"Tristel OPH is the first FDA-cleared HLD specifically validated for use on ophthalmic devices meeting user requirements for efficacy, device compatibility and in-use safety.

"Our commercial strategy builds on the valuable learnings from launching Tristel ULT in the US. With an experienced local team and endorsement from ophthalmic device manufacturers we are well prepared to support early adopters and drive sustained growth in this important market.

"We are very excited to bring this new product to market in the US and perfectly timed to be showcased at the APIC (Association for Professionals in Infection Control and Epidemiology) conference in Phoenix, AZ mid-June, the largest annual event in the US for reaching critical Infection Preventionist community and decision makers."

The information communicated in this announcement is inside information for the purposes of Article 7 of Regulation 596/2014.

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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 (ClO_2) 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