12 September 2024

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

FDA 510(k) submission for Tristel OPH

Premarket Notification 510(k) medical device filing for high-level disinfection of ophthalmic devices

Tristel plc (AIM: TSTL), the manufacturer of infection prevention products, announces that it has filed a Premarket Notification 510(k) with the US Food and Drug Administration ("FDA") for Tristel OPH, a high-level disinfectant ("HLD") foam for use on ophthalmic medical devices, including re-usable tonometers, pachymeters and lenses that make contact with the cornea.

The 510(k) filing for Tristel OPH will use Tristel ULT as its predicate device. Tristel ULT, a HLD 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.

The Board believes that FDA clearance has the potential to transform ophthalmic disinfection practice in North America. According to the Spaulding classification[1], semi-critical devices require reprocessing with a HLD because they touch mucous membranes or non-intact skin, which is the case for nearly all ophthalmic devices. Very few semi-critical ophthalmic devices are subjected to an effective HLD in the US. Low-level disinfectant options such as alcohol wipes are used as an alternative, or devices may be soaked in sodium hypochlorite (bleach) or hydrogen peroxide in open trays with long contacts times.

Tristel OPH is the only HLD in the world designed specifically for ophthalmic devices and if 510(k) filing is successful it would become the only FDA cleared HLD, effective with short contact times and no requirement to soak devices in chemicals in an open tray, available for use in the c. 16m ophthalmic procedures that require HLD annually in the US, such as glaucoma diagnosis and cataract surgeries.

Tristel OPH was approved by Health Canada as a Class II Medical Device in June 2021.

Matt Sassone, Chief Executive Officer of Tristel, commented: "*We are delighted to have completed our FDA 510(k) filing for Tristel OPH in line with the original US product development plan set out by the Company in June last year. We believe that our unique product designed specifically for high level disinfection of ophthalmic devices has the potential to transform infection prevention practices in the US. We continue to target FDA clearance by the end of 2024 and look forward to updating shareholders as we put in place a distribution agreement for the US later this year.*"

Notes
[1]The Spaulding Classification (1968) developed by Dr. Earle H. Spaulding, defines how an item for patient care (e.g. medical device) should be disinfected based on its intended use.

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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, in a format which is a 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 250 people across 14 subsidiaries selling into 60 countries.

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.