24 June 2021

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

Regulatory approval for EPA, Canada and South Korea

Tristel plc (AIM: TSTL), the manufacturer of infection prevention products, announces that it has received three significant regulatory approvals.

United States Environmental Protection Agency (EPA)
Tristel received its first approval from the EPA for its foam-based disinfectant for surfaces in April 2018. We successfully enhanced the performance claims of the product with a second approval in January 2019 and then registered the product in three States before curtailing the nationwide registration programme until a third submission could be made to bolster further the competitive positioning of the product. This submission was made in October 2020 and we have now received the third approval for Jet. This expands the product's efficacy claims to include mycobacteria, and all efficacy claims are within a contact time of two minutes. We expect to complete State-by-State registration by the end of June 2022, including California where our existing registration will require amendment, which can be a lengthy process.

We have appointed Parker Laboratories, New Jersey, as our United States manufacturing partner for Jet and will sell the product through Parker's nationwide network of distributors on a non-exclusive basis, commencing in FY23. Other distribution channels will be put in place ahead of the US launch.

Health Canada
Tristel Duo OPH has been approved by Health Canada as a class 2 medical device and is included in Health Canada's Medical Device License Listing. Duo OPH is a high-level disinfectant intended for use on ophthalmic instruments including ultrasound devices and re-usable tonometers and lenses that contact the cornea.

We sell Duo OPH in over 15 countries and worldwide sales in FY21 will be approximately £650,000. Duo OPH is the only specialist high-level disinfection product for ophthalmic devices in the world. Awareness of the need for high-level disinfection in diagnostic eye care is growing, although COVID-19 caused ophthalmologists and optometrists in all countries to curtail their activities in 2020.

Parker Laboratories will manufacture the product and we are in discussions with potential distribution partners in Canada.

An explanation of the infection risks in ophthalmology can be found Click here

South Korea Ministry of Food and Drug Safety
We obtained approval for the Tristel Sporicidal Wipe from the Korean Ministry of Food and Drug Safety in March 2019. The application had taken four years as our chlorine dioxide chemistry had to achieve approval as a new drug. The Sporicidal Wipe is the key component in our Trio Wipes System, which is widely used for small endoscopic devices used in ear, nose and throat clinics.

Tristel Duo ULT has now been approved as a high-level disinfectant for ultrasound devices, and with Trio will be sold throughout South Korea by HP&C Ltd., Tristel's distributor since 2013.

Duo is a hand-held dispenser which applies the Company's powerful chlorine dioxide chemistry as a foam to the surface of medical devices. Tristel Duo is widely used throughout Europe, the Middle East and the Asia-Pacific region and the Company is seeking approval for Duo ULT from the United States Food and Drug Administration (FDA). Worldwide sales of all Duo branded products for medical device disinfection, including Duo ULT and Duo OPH, will exceed £4.3m in FY21.

Paul Swinney, CEO of Tristel commented: *"Every regulatory approval we achieve represents an important milestone in our progress, and these three approvals are very significant.*

"The enhanced claim set that we have achieved for Jet now justifies taking the product through state-wide registration in the USA and gearing up our manufacturing and distribution partnership with Parker Laboratories.

"The approval of Duo OPH by Health Canada represents our first successful registration of a medical device high-level disinfectant in North America. We are actively pursuing a submission to the USA FDA for Duo ULT and we are buoyed by this successful application in Canada.

"The approval in South Korea increases the visibility of our chlorine dioxide technology in the country and extends our distributor's involvement into more clinical areas within a hospital."

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