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BSF Enterprise PLC
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BSF Enterprise PLC
("BSF" or the "Company")

Kerato Limited - Update

BSF (LSE: BSFA), (OTCQB: BSFAF), the Main Market listed biotech company and owner of pioneering UK-based tissue engineering company 3D Bio-Tissues Ltd (3DBT) and corneal tissue replacement company Kerato Ltd, provides an update on the technical and commercial development of Kerato.

Kerato Update

BSF's 100% owned Kerato was recently established as an independent company to commercialise 3DBT's advanced intellectual property in lab-grown human corneal products and accelerate the progression toward clinical trials.

Kerato uses cells and collagen to produce corneas in the laboratory that are comparable to those of human donors. The Company has a dedicated commercial team and has recently appointed a Managing Director, Sarah Greenhalgh, to oversee the development of product offerings and the execution of the product and sales strategy.

Two applications are being developed for Kerato's bioengineered biomimetic corneas that address the global shortage of donor human corneas for medical and research applications. Currently, 50 per cent of the world does not have access to human donor corneas, with 13 million people on the waiting list for replacements.

Implantable Medical Device

The Implantable Medical Device will focus on solutions in two key areas. The first will be a corneal stroma equivalent, with >100µm thickness. Anatomically, located between the outer epithelium and the inner endothelium, the stroma is the thickest layer of the cornea and plays a pivotal role in normal visual function.

The second focus will be on developing corneal fillers, providing stable treatments for corneal thinning or misshaping, to enable refractive surgery, or correct refractive errors including myopia and hyperopia, as well as bioactive patches to support the repair of damaged corneas following injury or surgery.

Kerato is currently working on a timeline to launch the Medical Device in 2028. This gives sufficient time for optimising the standard operating procedures and implementing GMP manufacturing over the next 18 months before commencing Clinical Trials in 2026. There are a number of grant funding streams that Kerato has identified to help finance the clinical trials.

Kerato is looking to directly work with clinicians, supplying a transformative medical device for the artificial cornea and corneal implant market valued today at $422m with a Compound Annual Growth Rate (CAGR) of 7.4 per cent[1].

Ocular Toxicity Testing Platform

Building on a strategic relationship with one of America's largest consumer goods companies, which successfully evaluated Kerato's lab-grown corneas as potential alternatives in testing the safety and efficacy of their wide range of chemical and pharma products, Kerato is now developing a new Ocular Toxicity Testing Platform, named Keratox ™, to enable companies to test and understand a range of ocular toxicity endpoints through a sustainable and cost-effective method.

The platform will provide an in-house, high throughput solution that can be incorporated into existing R&D pathways, providing an early indication of a formulation's ocular toxicity profile with reference to the United Nations Globally Harmonized System of Classification and Labelling of Chemicals. This enables companies to "fail fast", thereby supporting innovation. Globally, the *in vitro* toxicology testing market is worth over $12bn with a CAGR of 12 per cent[2].

The Company is currently working to enhance tissue optimisation and undertake user testing before launching the platform to market in 2026.

Che Connon, Managing Director of BSF Enterprise, commented: "With 13 million people across the world waiting for a cornea replacement to transform their sight and quality of life, there is a global need for a solution. Our plan at Kerato is two-fold: develop novel medical devices that can accelerate the use of lab-grown corneas as

a medical solution; and provide an Ocular Toxicity Testing Platform that can support innovation as global corporations continue to invest heavily in new products that rely upon improved safety testing."

Sarah Greenhalgh, Managing Director of Kerato, commented: "Our aim at Kerato is to develop and supply new technologies for corneal production. Our Ocular Toxicity Testing Platform will be transformative in this respect, as we provide a new testing method that can be seamlessly implemented within existing R&D pathways and scaled, helping to meet the growing global demand for an alternative and sustainable process."

For further enquiries, please visit www.bsfenterprise.com or contact:

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Notes to Editors
BSF Enterprise PLC (BSF) is focused on unlocking the next generation of biotechnological solutions - using cell-based tissue engineering to help generate cultured meat, lab-grown leather, as well as human corneas, collagen growth and skin substitutes, as part of a radical transformation to deliver sustainable solutions across a variety of sectors.

It owns 100% of 3D Bio-Tissues (3DBT), a tissue engineering with patent-protected IP that is already producing human corneas for testing to help restore vision to millions of people. Building on this success, it aims to produce the UK's first high quality lab-grown meat and leather from its laboratory in Newcastle, transforming the meat-production industry and the leather industry towards an ethical and sustainable practice.

BSF aims to deliver growth to shareholders through the continued commercialisation of 3DBT's IP, which has multiple applications, as well as through M&A. It aims to deveolop a suite of technologies that underpins the development of tissue templating for corneas, meat and leather, and license out the IP to manufacturers, wholesalers and distributors to help manufacture the products at scale.

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[1] Artificial Cornea and Corneal Implant Market Size & Share | 2028 (theinsightpartners.com) accessed 20/02/24

[2] Exploring Opportunities in the In-Vitro Toxicology Testing (globenewswire.com) accessed 20/02/24

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