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Tissue Regenix Group PLC
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Tissue Regenix Group plc

('Tissue Regenix', the 'Group' or the 'Company')

CE & UKCA certification for OrthoPure® XT

Tissue Regenix Group plc (AIM: TRX), the regenerative medical devices company, announces that it has received CE certification under the EU Medical Device Regulation ('EU MDR') and UK Conformity Assessed ('UKCA') certification under the UK Medical Device Regulation ('UK MDR') for OrthoPure® XT, its biological tendon replacement technology. The OrthoPure® XT device previously received the CE certification under the EU Medical Device Directive, but the EU MDR represents the recent improvements in standards for safety and efficacy of medical devices.

The CE and UKCA certifications are essential for business continuity in markets that recognise the CE Mark and the UK. This provides Tissue Regenix with uninterrupted access to the €140+ billion European medical device market, positioning the Company for continued revenue growth and further international expansion for OrthoPure® XT.

The highest of standards implemented by these regulatory bodies demonstrate Tissue Regenix's continued commitment to quality and safety, as well as reinforcing the Company's reputation as a compliant, future-ready manufacturer under increasingly stringent regulatory expectations. Achieving CE and UKCA certifications marks a significant step in the Company's strategic growth journey and has also helped the Company to determine a foundation for streamlined approvals for other international regulatory pathways.

As a part of these certifications, OrthoPure® XT has now been approved for a 24-month shelf life which removes barriers to market and will increase adoption among healthcare institutes. It also offers opportunities for new tender bids, hospital contracts, and distributor partnerships that now require MDR certification.

The OrthoPure® XT decellularised xenograft ligament utilises Tissue Regenix's patented dCELL® technology and is the only available, non-human biologic graft for certain knee ligament reconstruction procedures on the market. OrthoPure® XT can be used in the reconstruction of knee ligaments in the multi-ligament injured knee, as well as primary anterior cruciate ligament ('ACL') procedures when an autograft is not an option, and revision ACL procedures.

Daniel Lee, CEO of Tissue Regenix, commented:*"We are incredibly pleased to have received CE and UKCA certifications for OrthoPure® XT. This recognises that our product meets the higher standards and requirements put in place by EU and UK MDR and will open the door for expansion of the OrthoPure product family more efficiently through an established MDR framework. Recognition by these regulatory frameworks is also a testament to the Group's ability to successfully execute regulatory transitions and our continued commitment to quality and safety increases customer and clinician confidence in our products."*

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About Tissue Regenix (www.tissueregenix.com)

Tissue Regenix is a leading medical device company in regenerative medicine. The Company's patented decellularisation technology (dCELL®) removes DNA and other cellular material from animal and human soft tissue, leaving an acellular tissue scaffold that is not rejected by the patient's body and can be used to repair diseased or damaged body structures.

Current applications address many crucial clinical needs in sports medicine, foot and ankle injuries, and wound care.

In August 2017, Tissue Regenix acquired CellRight Technologies®. This biotech company specialises in regenerative medicine and is dedicated to developing high-quality, innovative tissue scaffolds to enhance healing opportunities in defects created by trauma and disease. CellRight's human tissue products may be used in spine, trauma, general orthopaedic, dental and ophthalmological surgical procedures.

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