

VitroGro® ECM CE Mark Approval Referred to MHRA

ASX Announcement 8 August 2012
Tissue Therapies Limited ABN 45 101 955 088

Announcement

Biomedical company, Tissue Therapies Limited ([ASX: TIS](#)) has been advised by the EU Notified Body, the British Standards Institute (BSI) that the CE Mark application for VitroGro® ECM has been referred to the UK Government Health Regulatory Body, the Medicines and Healthcare products Regulatory Agency (MHRA) for a final decision as to which Medical Device Directive Rule is appropriate for the classification of VitroGro® ECM; Device Rule 8 or Device Rule 13.

This is despite the earlier written advice received by Tissue Therapies from BSI which stated that all examiner queries had been answered by the Company to the satisfaction of BSI and that a CE Mark Certificate would be issued shortly. (Please see [ASX: TIS VitroGro® ECM Meets CE Mark Requirements](#), 16 July 2012.)

BSI has further advised the Company that the review by MHRA will take up to 30 calendar days, plus any additional days necessary for questions to the Company and for Tissue Therapies' staff to reply to MHRA. There are no additional charges for the MHRA review.

Once CE Mark is received, the Device Rule under which it is granted makes no practical, commercial difference to Tissue Therapies.

It is possible that the MHRA review may result in a further referral to the European Medicines Agency (EMA) for a review of the VitroGro® ECM manufacturing process. EMA is the European Union health regulatory agency.

This new delay is surprising and frustrating but it is a regulatory question as to which of two Device Rules is more applicable. Once this is resolved, we remain confident of receiving a final Device CE Mark approval.

The Company will release further information on the CE Mark approval process as it is received.

VitroGro[®] ECM Meets CE Mark Requirements

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What is VitroGro[®] ECM

VitroGro[®] ECM is a topically applied, biomimetic scaffold, comprising a synthetic extracellular matrix (ECM) protein.

How it works: VitroGro[®] ECM replaces the degraded matrix of a hard to heal wound. VitroGro[®] ECM binds to a prepared wound bed and provides a physical structure (a scaffold) for cell attachment, which is a primary requirement for subsequent cell functions critical for healing, such as cell proliferation and migration ^[1].

An optimal scaffold: One of the characteristics of hard to heal wounds is prolonged inflammation, which damages the native ECM that would normally guide the wound healing process ^[1,2,3,4]. Replacement of this damaged ECM is a beneficial strategy for treating hard to heal wounds ^[1]. VitroGro[®] ECM is ideal as an ECM replacement since its structural and functional elements mimic those present in the ECM at the early stages of normal wound healing.

Expert health economics modelling indicates that VitroGro[®] ECM offers the opportunity for substantially more cost effective treatment of wounds compared to the current standard of care.

[1] Widgeow AD . Deconstructing the stalled wound. Wounds 2012

[2] Schultz GS. Extracellular Matrix: review of its roles in acute and chronic wounds. World Wide Wounds. 2005

[3] Moor AN. et al. Proteolytic activity in wound fluids and tissues derived from chronic venous leg ulcers. Wound Rep Reg. 2009

[4] International consensus, Acellular matrices for treatment of wounds. Wounds Int. 2010

About Tissue Therapies Limited

Tissue Therapies Limited is a biomedical technology company that is developing significantly more effective treatments for acute and chronic wound healing applications, including chronic skin ulcers and burns. Tissue Therapies Limited is commercialising VitroGro[®] ECM, a technology created by cell biology, tissue engineering and protein engineering experts at the Institute of Health and Biomedical Innovation at the Queensland University of Technology. The company is also developing treatments for psoriasis, scar prevention and various cancers including those of the breast, colon and prostate. Tissue Therapies Limited's shares are traded on the Australian, Berlin and Frankfurt stock exchanges.

More information: www.tissuetherapies.com



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