

VitroGro® ECM Meets CE Mark Requirements

ASX Announcement 16 July 2012
Tissue Therapies Limited ABN 45 101 955 088

Announcement

Biomedical company, Tissue Therapies Limited (ASX: TIS) is very pleased to announce that the requirements for CE Mark approval of its initial product, VitroGro® ECM, have been satisfied and that formal approval is expected shortly.

The Notified Body, the British Standards Institute (BSI) has advised the Company that under its CE Mark application, VitroGro® ECM conforms to the essential requirements of the EU Medical Devices Directive.

Tissue Therapies CEO Dr Steven Mercer said that sales will commence immediately the final Certificate is issued.

He said “VitroGro® ECM will be approved in the EU for broad applications in wound care which will open up a series of significant market segments for the Company’s initial product.”

“Importantly, VitroGro® ECM will be approved for the treatment of all ‘hard to heal’ wounds, primarily venous ulcers. This includes burns and acute injuries in patients who have compromised healing, as well as diabetic, venous and pressure ulcers.”

Dr Mercer said BSI confirmed that the examination of the Design Dossier was complete and that all examiner questions were answered to its satisfaction.

He also said that two of the senior BSI staff had commented that the high quality of the Tissue Therapies’ CE Mark submission had impressed the examiners.

“We are advised by BSI that the remaining process for issuing the final Certificate is a routine matter.”

Dr Mercer said the Company would receive a draft CE Mark Conformity Certificate from BSI for confirmation of details shortly. Following the confirmation of those details, the final Certificate will be issued, subject to BSI staff availability, allowing sales to commence.

“We therefore expect to receive the formal CE Mark Certificate within the coming weeks.

“Sales and distribution resources are poised for the immediate start of the VitroGro® ECM rollout campaign in the UK and initial European markets,” he said.

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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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