VitroGro® ECM Medical Device Classification Confirmed

ASX Announcement 30 October 2012
Tissue Therapies Limited ABN 45 101 955 088

Announcement

Biomedical company, Tissue Therapies Limited (ASX: TIS) has been notified that the Medicines and Healthcare products Regulatory Agency (MHRA) review of VitroGro® ECM has confirmed classification of VitroGro® ECM as a Medical Device Class 3, but under Device Rule 13 instead of Device Rule 8, as was agreed earlier with the Notified Body.

As a result, the MHRA has decided that a European Medicines Agency (EMA) review of manufacturing and quality data is required and this will take up to 210 calendar days. The review start date will be advised to Tissue Therapies by the EMA. The EMA review is a desk audit; no on-site inspections are required.

The management of the Company is confident in the VitroGro® ECM quality and manufacturing data that will be submitted to the EMA, particularly because Eurogentec (protein manufacturer) and Catalent (fill and finish/packaging) are ISO, EU and FDA certified and licensed.

While this further delay in the start of sales in the EU is frustrating, there are some powerful advantages and compensating factors that will result from the EMA review, including:

- The approval to sell in the EU will be final; no further potential regulatory examination will remain after the EMA review is complete.
- The EMA examination will provide Tissue Therapies with a definitive regulatory approval for sale, signed off by all 27 EU member states.
- This stronger, more comprehensive VitroGro® ECM regulatory package will be used to apply for approvals in other jurisdictions that recognise or give weight to CE Mark, eg. Turkey, the Middle East, Russia, Taiwan, Latin America, Canada and Australia.
- The Company will use the time of the EMA review to prepare for earlier sales launches than were initially planned in the Nordic countries, the Middle East, Turkey, Latin America and Russia, while we continue with the preparations to lodge the applications for venous and diabetic ulcer trials with the FDA.

The EMA submission is already substantially complete. Preparation work on this has been ongoing since early August, in case the EMA review was required.

The required format of the EMA dossier is an international standard called the Common Technical Document (CTD). This format is well understood by the Company. This was the template for the submission to Health Canada to gain approval for the first clinical trial of VitroGro® ECM and is the same format that will be required for FDA approval for sale.

The Company remains ready to start sales in the EU immediately CE Mark is granted. The EMA review will strengthen the VitroGro® ECM regulatory approval position in other international jurisdictions and should allow sales to start earlier in those other territories than was previously planned.

ENDS

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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] Widgerow 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

TISSUE THERAPIES

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