TISSUE THERAPIES

ASX ANNOUNCEMENT

5 December 2013

Update on VitroGro® ECM FDA Clinical Trial Approval

Biomedical company, Tissue Therapies Limited (**ASX: TIS**) has received formal notification from the United States FDA that the application for a clinical trial of VitroGro® ECM for the treatment of venous ulcers will be approved. The only request from the FDA for final approval to be granted is for the Company to submit a plan that is acceptable to the FDA for an additional test of VitroGro® ECM.

The FDA has requested Tissue Therapies to provide a plan to develop an additional quality control test for manufacturing and stability. The scientific and clinical results demonstrate that VitroGro® ECM is stable and effective in use but the FDA has requested this additional final test and the Company has agreed.

The additional test requested by the FDA is to detect a theoretically possible change in stability that the company has not observed with extensive testing to date.

It is not a requirement for this new testing to be complete for the Company to obtain approval for the venous ulcer clinical trial to proceed. The FDA only requires a commitment from Tissue Therapies for approval to be granted.

The relevant contractor is currently actioning the plan for submission to the FDA.

There are no other issues that the FDA requires the Company to resolve for approval of the VitroGro® clinical trial.

The immediate focus of the Company remains the start of sales in the UK and Europe but it is valuable to know that the US venous ulcer clinical trial will be able to proceed as soon as funding is available.

The final CE Mark review required by the EMA is progressing as expected and should allow the start of sales of VitroGro® ECM in the UK and Europe in 2nd Q 2014

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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