TISSUE THERAPIES

ASX ANNOUNCEMENT

25 October 2013

VitroGro® ECM Clinical Trial Application Lodged with the FDA

Biomedical company, Tissue Therapies Limited (**ASX: TIS**) has announced today that the application to conduct the pivotal venous ulcer trial has been lodged with the FDA.

It is expected that this clinical trial will provide the data suitable for approval for sale of VitroGro® ECM in the United States for the treatment of venous ulcers.

This clinical trial will be performed over 12 months and is planned as a double blinded, prospective, randomised control trial, which is an exceptional scientific standard for a wound healing human trial.

Following completion of the trial, analysis of the results and submission of an application for approval for sale is planned. It is expected that this will allow sales of VitroGro® ECM to start in the USA for the treatment of venous ulcers 26 months from the start of the pivotal trial, or 14 months after the clinical trial is complete.

The submission of the clinical trial application was delayed by the recent US Government shutdown and furlough of FDA employees.

The usual time for this type of application to be approved is 30 calendar days but the backlog of applications resulting from the furlough of FDA staff may cause this to be extended. Despite this, it is expect that approval for the clinical trial will be received before the end of December 2013

The total budget for this pivotal venous ulcer trial is A$10.2 million. The clinical trial will be start when funding is available.

Tissue Therapies Limited ABN 45 101 955 088 www.tissuetherapies.com
Level 19, 179 Turbot Street, Brisbane QLD 4000 Australia
GPO Box 1596 Brisbane QLD 4001
telephone +61 7 3334 3900 facsimile +61 7 3334 3999

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