



## ASX ANNOUNCEMENT

30 September 2014

### EMA 180-Day Review Questions Received

Biomedical company, Tissue Therapies Limited (**ASX: TIS**) has announced that the EMA Review Committee 180-day questions have been received from the Notified Body, British Standards Institute (BSI).

Most of the issues raised in the 120-day questions have now been classified by the EMA as completely resolved.

The definitive answers to a number of the 180-day questions will require further analytical data from the Company's manufacturer. While answers to these queries are compiled, the maximum 210 calendar day review clock will stop.

It is anticipated that the duration of this clock stop will be much shorter than that required to respond to the 120-day questions but it is likely that the time necessary to prepare the best answers to the 180-day questions will mean that this response will be considered at the December 2014 meeting of the EMA CHMP Committee. Given this timetable, it is possible that the granting of CE Mark by BSI may not be finalised until early 2015.

The EMA review committee provided the 180-day questions to the BSI in accordance with the review procedure, as summarised in the last Company announcement. (**ASX: TIS** Response Lodged to EMA Review Questions, 28 July 2014)

A further announcement will be released when the response to the 180-day questions is lodged.

## 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 <sup>[1]</sup>.
- 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 <sup>[1,2,3,4]</sup>. Replacement of this damaged ECM is a beneficial strategy for treating hard to heal wounds <sup>[1]</sup>. 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](http://www.tissuetherapies.com)