



ASX ANNOUNCEMENT

28 July 2014

Response Lodged to EMA Review Questions

Biomedical company, Tissue Therapies Limited (**ASX: TIS**) has announced that a comprehensive response to the EMA Committee review questions was submitted to the EMA after market close on Friday 25 July 2014 (Australian Eastern Standard Time). A positive response from the EMA review is the last step in the process for CE Mark to be granted to allow the sale of VitroGro® ECM in the EU (including the UK).

The response provided by Tissue Therapies to the EMA provides detailed answers to the review questions and is expected to result in a favourable EMA opinion during the second half of 2014, as previously announced (**TIS: ASX** Appendix 4D and CE Mark Update, 26 February 2014).

This submission by the Company provides answers to the 120 calendar day questions received from the EMA reviewers earlier this year, as part of the maximum 210 calendar day review. The review clock stops while answers are being prepared. Lodging this response with the EMA restarts the clock on the review from the 120 calendar day stop point.

The EMA is required by the rules of this review to provide any further questions and comments to the Notified Body, (BSI) by 180 calendar days i.e. on or before Wednesday 24 September 2014

It was evident from the detailed analysis of EMA questions when these were received earlier in 2014 that the most definitive response from Tissue Therapies would involve the development of additional test methods for stability and release for sale of VitroGro® ECM and that this would take a few months of work.

A detailed project plan for the development of this additional testing was reviewed and agreed in onsite meetings in Belgium with the Company's key manufacturers, Eurogentec and Catalent during February 2014 and this has generated the data for the Company's response to the EMA.

In parallel with the preparation of the response to the EMA, the Company has continued detailed health economics analyses in preparation for reimbursement applications and comprehensive sales, marketing, logistics and publication preparation to optimise the sales launch of VitroGro® ECM in the UK and Europe shortly after CE Mark is granted.

A further announcement will be made by Tissue Therapies Ltd once the EMA assesses the Company's response and provides feedback.

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