TISSUE THERAPIES

ASX ANNOUNCEMENT

01 June 2012

CE Marking Progress

Biomedical company, **Tissue Therapies Limited** (**ASX: TIS**) advises that it will provide additional information to the Notified Body assessing the Company's application for CE Marking of its initial product, VitroGro® ECM.

Tissue Therapies CEO, Dr Steven Mercer said that the Company had planned for requests for additional data in a range of critical areas, particularly manufacturing and compliance with the essential requirements for devices sold in the EU.

"After making recent enquiries of the Notified Body assessing the application for CE Marking of VitroGro® ECM, we have been informed that the reviewers will request additional information" he said.

"Additional requests for information during the CE Mark review process are considered routine and are not surprising to us or our regulatory advisors.

"In anticipation of this type of request we have completed additional work to ensure we could promptly respond to likely enquiries during the examination process."

"We remain confident that CE Mark will be granted in time for the planned start of sales in the UK and Europe at the end of June 2012."

Dr Mercer said that the CE Mark submission was based on the strong clinical results of the pivotal EU study in hard-to-heal wounds, primarily venous leg ulcers, as well as validation of manufacturing processes.

He also said that the nature of the additional information required indicated that significant progress had been made to bring VitroGro® ECM to market and that the review was moving to the final phase.

A pallet of VitroGro® ECM in the warehouse ready for sale. This pallet contains 4,000 treatments. The recommended course of treatment for a hard-to-heal wound is once per week for 10 weeks.

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What is VitroGro® ECM?

- VitroGro® ECM is a biomimetic scaffold that is sterile, acellular and flowable (designed to be applied to the surface of wounds).
- It is an artificially created matrix protein designed from polypeptide sequences that normally provide attachment sites in healthy skin that guide cells during normal wound healing.
- In chronic (non-healing) wounds, skin cells are deprived of these attachment sites because the extracellular matrix (ECM) is degraded.
- VitroGro® ECM restores normal wound healing by replacing the degraded ECM with a scaffold containing the attachment sites that guide skin cell attachment, proliferation and migration (the essential processes of normal wound healing).
- VitroGro® ECM is a temporary matrix that is designed to be replaced through the normal process of tissue restoration and turnover.
- VitroGro® ECM consistently and conveniently restores healing in chronic ulcers that have failed to respond to current expert care.
- 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.

About Tissue Therapies Limited

Tissue Therapies Limited is an Australian, ASX-listed company developing biomedical technologies for wound healing, tissue repair, cell culture and other applications.

The Company has worldwide exclusive rights to commercialise VitroGro®, a technology developed to enhance cell growth and migration by cell biology, tissue engineering and protein engineering experts at the Institute of Health and Biomedical Innovation (IHBI) at the Queensland University of Technology (QUT). VitroGro® has particular commercial applications in wound healing, tissue regeneration, cell-based therapies and cell culture.

Based on its VitroGro® technology, Tissue Therapies is developing more effective treatments for acute and chronic wound healing applications including chronic skin ulcers and burns.

Tissue Therapies is also proceeding with the development of other commercial applications of various VitroGro® and other technologies for the treatment of psoriasis, scar prevention and potential treatments for various cancers including those of the breast, colon and prostate.

VitroGro® also provides a fundamental, transforming technology for completely defined cell culture reagents (ie. containing no purified animal or human proteins) to sustain and enhance the growth of live cells for emerging cell-based therapies, along with research and industrial cell culture markets internationally.

More information: **www.tissuetherapies.com**