TISSUE THERAPIES

ASX ANNOUNCEMENT

18 March 2013

Regulatory Update

After market close on 13 March 2013, Biomedical company, Tissue Therapies Limited (**ASX: TIS**) was informed by the Notified Body, British Standards Institute (BSI) that a European Commission (EC) Medical Devices Group meeting voted that VitroGro® ECM should be regulated as a Medicine and not a Device.

This email from BSI was the first indication that the Company had of any further consideration of the classification of VitroGro® ECM.

During October 2012, Tissue Therapies was notified by BSI that the "final classification" of VitroGro® ECM was as a Device. This followed a thorough review by a broad range of experts, conducted by the UK Medicines and Healthcare products Regulatory Agency (MHRA). (Please see **ASX: TIS** VitroGro® ECM Medical Device Classification Confirmed 30 October, 2012.)

Until the email from BSI on 13 March 2013, the advice to the Company from BSI was that we were waiting only for a formal start date for the European Medicines Agency (EMA) Committee review of manufacturing quality data as the last step needed for the granting of CE Mark and the start of sales.

The EMA approval process excludes sponsor companies like Tissue Therapies from direct contact with the EMA. The Company has been entirely dependent on BSI to make the submissions and to keep it informed.

Following receipt of the 13 March 2013 email from BSI, Tissue Therapies arranged an independent expert review of the submission by BSI to the EMA. This assessment indicates that the submission to the EMA was poorly constructed and did not provide adequate information for the Medical Devices Group.

This independent advice also says that the MHRA remains convinced that the correct classification of VitroGro® ECM is as a Device.

While the vote of the EC Medical Devices Group has not yet resulted in a formal EMA decision, the Board of Tissue Therapies Ltd considered it material information and requested a trading halt.

If the EMA formalises the vote of the EC Medical Devices Group ie. that VitroGro® ECM should be regulated as a Medicine, appeal options are available. Advice is being taken on which of these should be used. There are no additional regulatory charges to the Company for an appeal.

In any appeal, the advantage to Tissue Therapies will be in being able to put the facts directly. Notified Bodies like BSI do not participate in appeals.

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If an appeal regarding a pharmaceutical classification becomes necessary and is successful, the final approval for sale process will revert to the maximum 210-calendar day review of manufacturing quality data, followed by the granting of CE Mark.

If an appeal is not successful, then it will be necessary for a pivotal clinical trial to be performed and the data submitted for approval before sales of VitroGro ECM can start in the EU.

The planned US FDA venous ulcer trial would then be used to satisfy simultaneously the EU and FDA requirements. Subject to funding, (approximately A$8 million) this trial could start late this year or early 2014 and could be designed to be completed in one year by adding additional clinical trial sites already identified in the USA. This should allow sales to start simultaneously in the EU and the USA during the second half of 2015, bringing forward the start of US sales by approximately two years (currently planned to start in the second half of 2017).

As a result of the current uncertainty, the Board has withdrawn the non-renounceable entitlement issue, at least until the EU classification of VitroGro® ECM is clarified.

As a matter of urgency, the Board has also commissioned an independent, expert review of the Company's regulatory affairs procedures. An experienced EU regulatory affairs consultant has been retained to perform this review. The findings will be provided to Non-Executive Director, Mr Iain Ross who being recently appointed is least involved.

The Company will announce additional information on this matter as soon as it is received.

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**