TISSUE THERAPIES

ASX ANNOUNCEMENT

EMA "Final Advice Letter"

Outcome confirms a viable pathway for taking VitroGro ECM to market in Europe, however EMA requirements mean further significant delays.

Brisbane, 1 June 2015: Tissue Therapies (ASX.TIS) announces that the European Medicines Agency's (EMA) Scientific Advice Working Party (SAWP) has accepted the Company's revised plan for the pre-clinical and clinical development of VitroGro® ECM.

Following the meeting with SAWP held on 6 May 2015, SAWP has provided written confirmation that it broadly supports the Company's *pre-clinical* plan to demonstrate the therapeutic utility of the IGF-1 component and its *clinical* plan to demonstrate comparative safety.

This outcome confirms a viable pathway for VitroGro® ECM to market in Europe as a Class III Rule 13 medical device. However, it does mean there will be further delay, cost and clinical risk, given the company will need to conduct an additional clinical trial.

In order to provide greater clarity with regard to the planned studies (both non-clinical and clinical), the company will post further technical information on the Tissue Therapies website by COB today (www.tissuetherapies.com).

Nigel Johnson, Acting CEO, said: "Unfortunately, Tissue Therapies could not satisfy the CHMP's two remaining major objections with respect to safety and the utility of the IGF-1 component with the existing evidence and trial data. Thus, the company will need to undertake additional studies which inevitably means further delays. However the proposed plan is an efficient and cost effective approach that balances risk and speed in addressing the regulatory requirements".

The EMA advised that as the previous open label study revealed no severe safety concerns, the additional data from the proposed double blind randomised controlled trial, should be acceptable under the Medical Device Directive in conjunction with planned post marketing surveillance.

At completion of the required work and subject to positive results, TIS will then need to apply to the EMA (through the Notified Body) again and proceed through the 210 day consultation process. Importantly, the studies will be supportive for the Company's application for FDA approval in the United States.

Tissue Therapies estimates it will take five months to complete the required pre-clinical program. The clinical trial, which would be conducted primarily in Europe, will be scaled to target completion in 12-18 months, subject to satisfactory patient recruitment and interim analysis. These two studies will be undertaken sequentially as the results of the pre-clinical study may influence the conduct of the trial.

As previously reported, the Board and senior management of the Company have been engaged in an intensive review of regulatory requirements and consequent operational planning. We are fully cognisant that this further delay in obtaining European and also US approval is a source of

significant concern to shareholders and other stakeholders. The Company has restructured its operational arrangements in order to conserve working capital and focus its activities on achieving approval in Europe. However, further funds will be required to fully execute the aforementioned activities necessary for approval.

In order to accelerate VitroGro® ECM deployment and thus re-create value for shareholders TIS will commence the additional work as soon as we are able and will actively pursue appropriate financing alternatives. Given the regulatory demands and being mindful of the need to minimise dilution TIS is considering strategic options including partnering or other arrangements. Consistent with our recently announced communication approach we will keep shareholders informed of progress including the estimates of costs associated with the delay and additional work.

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For more information

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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 also has a licence for commercialisation of various patent families related to wound healing and other therapeutic uses. Tissue Therapies Limited's shares are traded on the Australia, Berlin and Frankfurt stock exchanges. For more information, please visit www.tissuetherapies.com.