

## ASX ANNOUNCEMENT

13 May 2015

## **Shareholder Update**

**Brisbane, 13 May 2015**: Tissue Therapies (ASX.TIS) is providing this update on the status of the European Medicines Agency's (EMA) response to the company's request for advice through the Scientific Advice Working Party (SAWP) process.

The SAWP is comprised of scientific experts from Member States of the European Union and coordinates the provision of scientific advice and protocol assistance from the EMA.

Tissue Therapies submitted a comprehensive written response to a list of questions provided by SAWP ahead of a constructive discussion meeting in London on 6 May 2015. An additional question was received from SAWP after the meeting and the company filed a written response on 12 May 2015.

As previously reported, the primary purpose of the meeting was to discuss and agree upon:

- 1. An appropriate disease model and further *in vitro* studies that will provide pre-clinical data that demonstrates the utility of IGF-1 in a chronic disease setting and supplement further clinical trial data;
- 2. An appropriate clinical study designed to assess comparative safety.

The next step is for the SAWP to put an integrated view forward to the Committee for Medicinal Products for Human Use (CHMP) regarding the outcomes of the 6<sup>th</sup> May meeting. The matter is expected to be tabled at the next meeting of the CHMP, scheduled 18 -21 May 2015.

In the weeks following the CHMP meeting, Tissue Therapies expects to receive either a written confirmation that the company's proposed changes are acceptable, recommendations for further changes to the plan, or alternatively another list of questions for the company to address.

The company has filed a submission with SAWP to obtain advice on whether the proposed changes are effective, compliant and able to provide adequate data that is more likely to support a favourable benefit-risk assessment, however it is important to note that the CHMP will not be bound by scientific advice recommendations when forming an opinion for the purpose of CE marking. Tissue Therapies will need to implement the changes to the development plan, and subsequently undergo another "210 day" ancillary medicinal product consultation for the IGF-1 component of VitroGro® ECM.



Tissue Therapies' remains committed to keeping shareholders fully informed during the process and an announcement will be made when further information becomes available or the regulatory procedure has completed.

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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 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 Australia, Berlin and Frankfurt stock exchanges. For more information, please visit www.tissuetherapies.com.