ASX ANNOUNCEMENT

23 April 2015

Shareholder Update

Brisbane, 23 April 2015: Tissue Therapies (ASX.TIS) provides an update to shareholders regarding its recent Oral Explanation with the European Medicines Authority's Committee for Medical Products for Human Use (CHMP) held on 25 March 2015 in London.

Following recent management changes, Interim Chairman, Dr Cherrell Hirst and Mr Nigel Johnson, Acting CEO, have led an operational review. This review, involving the Board and senior management of the Company, included a comprehensive review of the chronology of events relating to the EU regulatory process.

"The Board of Tissue Therapies acknowledges that pursuing regulatory approval of VitroGro® ECM in Europe has been a complex process, into which shareholders deserve greater insight. We also recognise that the continued delay in obtaining CE Mark approval is a source of significant concern to shareholders," said Dr Hirst.

In order to provide greater clarity with regard to the current regulatory status and the complex issues involved, and to address a number of questions raised by shareholders, the company has issued this shareholder update and posted a detailed Q&A document on the Tissue Therapies website (www.tissuetherapies.com).

Outcomes of the CHMP Oral Explanation

The Notified Body was satisfied that VitroGro® ECM fulfilled the essential requirements to be placed on the market as a medical device in Europe, however the EMA was required to conduct an additional assessment of the usefulness of the ancillary medicinal ingredient.

At the Oral Explanation with the Committee for Medicinal Products for Human Use (CHMP) in March 2015, the Company presented an overview of VitroGro® ECM, its proposed indications and pre-clinical and clinical data that support the product's overall safety, usefulness and performance.

Tissues Therapies has addressed more than 30 matters raised by European Medicines Authority (EMA) assessors throughout the course of the regulatory procedure to date. The vast majority of these issues have been resolved in the Company's favour.

Following the completion of the Oral Explanation, two key objections remain which require the Company to provide additional data. While Tissue Therapies intends to continue to pursue CE Mark

approval of VitroGro® ECM it has elected to withdraw its application for scientific opinion from EMA so that these objections can be resolved.

The VitroGro® ECM protein comprises two components: vitronectin, which is responsible for the physical action, and IGF-1, which is responsible for the medicinal activity. The EMA has asked the Company to address two key issues, which relate to the safety and utility of the IGF-1 component:

1. The EMA has made a request *for additional preclinical work in order to assess the utility or additional benefit of the medicinal component (IGF-1) of VitroGro® ECM, in a therapeutic setting;*
2. The EMA has stated that the Company's clinical study design (previously conducted) *does not permit an adequate and reliable interpretation of the clinical benefit risk profile of the incorporation of the ancillary substance (the IGF-1 component) into the device.*

During the conformity assessment to the Medical Devices Directive, which occurred prior to the EMA's involvement, the Notified Body (British Standards Institute), accepted the clinical study. There was no signal of any problem with the quality, safety or usefulness of the IGF-1 component. In fact, upon referring the matter to the EMA (once the product was required to be classified under Rule 13), the Notified Body reported to the EMA that the usefulness of the IGF-1 component was demonstrated. Hence, from the Company's perspective there was no reason to change the development plan or obtain advice from the EMA Scientific Advisory Working Party (SAWP) regarding changes to the development plan.

More detailed information on the product, oral explanation outcomes and regulatory process to date is provided via the Q&A documentation which can be accessed on the Company website (www.tissuetherapies.com).

Next steps

To address the concerns raised at the Oral Explanation the company is meeting with SAWP 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 meeting is expected to take place in May 2015. It is possible that additional meetings may be required to reach final agreement on the study designs.

Mr Johnson, Acting CEO, said: "Tissue Therapies has a lot of compelling data that supports an effect of the VitroGro protein and the IGF-1 component. I genuinely believe in VitroGro and now that we

are changing our development plan, we have an opportunity to take advice from SAWP. The issues that CHMP have raised are legitimate and we will address the remaining issues."

Dr Hirst added: "Following completion of the comprehensive business review at Tissue Therapies, and in response to the temporary approval delay in Europe, the Company has taken measures to conserve the Company's cash position by reducing all non-essential spending.

"Our highly experienced internal team is working closely with external consultants who have significant experience as US and EU regulators to prepare for a comprehensive discussion with SAWP at the forthcoming meeting in May 2015. Until we know the outcome of that meeting, which may not be definitive, we cannot finalise our future plans.

"I would like to highlight that Tissue Therapies' application to the notified body for CE Marking in Europe remains viable, and every effort is being made to ensure the VitroGro® ECM's potential to improve wound management and healing is recognised."

"Finally, I would like to confirm that Tissues Therapies is committed to keeping shareholders fully informed during the process, providing further insights wherever possible."

- ENDS -

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.