ASX ANNOUNCEMENT

17 December 2015

FDA Regulatory Progress Update

Brisbane, 17 December 2015: Tissue Therapies Limited (the "Company") yesterday received formal notification from the US Food and Drug Administration (FDA) in relation to its Phase II Investigational New Drug (IND) application for VF-001 (previously referred to as VitroGro® ECM). On 21 October 2015, the Company conducted a Type A meeting with the FDA, at which time the parties reviewed a substantial submission by the Company regarding additional manufacturing process development activity that the Company has conducted since December 2013. This additional activity was undertaken to meet specific FDA clinical material manufacturing requirements for a biologic drug product.

Following a review of Type A meeting minutes, requests for additional supporting documentation and a further telephone briefing on 8 December 2015, the FDA has indicated to the Company that there is no additional process development required for Phase II material manufacturing at this time. This outcome paves the way for the Company to prepare final materials and lot certification for Phase II clinical studies, currently planned for the first half of 2016 (as previously disclosed).

At this time, the Company remains on Clinical Hold (21 CFR § 312.42) by the FDA. In order to lift the Clinical Hold and be permitted to commence clinical studies in the United States, the Company will be required to provide the following items:

1) A complete lot release data and/or a Certificate of Analysis (CoA) for the proposed clinical lot(s) for the Phase II study that incorporate the new manufacturing assays that have been developed by the Company. This item pertains to the standard material release documentation requirements for an IND approval process.

2) Demonstration that the materials that will be used in the proposed Phase II study have a comparable profile to the materials used in the previous clinical study. These assays have already been developed and validated by the Company and will be run as part of the material release as standard.

These two items had not been prepared before now because the Company elected to first receive FDA agreement that the revised manufacturing process was adequate before risking shareholder capital on a final production run (approximately $500,000). This scope of work represents approximately a three-month period of activity that the company intends to run concurrently with site qualification for the US multi-centre Phase II clinical trial planned by the Company.

Nigel Johnson, CEO of Tissue Therapies commented, "The FDA has raised no further technical issues with Tissue Therapies' revised manufacturing and characterisation process at this time, which in turn defines the pathway for the company to prepare final material and release documentation for the US Phase II study planned for next year."

"The team, led by Nigel Johnson, has undertaken a huge amount of work over the past 12 months to address the additional biopharmaceutical manufacturing requirements of the FDA. This has involved developing sophisticated assays and techniques that takes us a significant step further towards the manufacturing of our lead wound care product as a biologic drug", commented Dr. Christian Behrenbruch, Executive Director. "This is a positive step forward for the Company and its revised regulatory strategy, and is consistent with recent shareholder communication."

The FDA has also provided useful guidance for technical development activities that the Company will need to conduct in parallel to Phase II clinical studies in order to prepare for Phase III readiness.

Review of the above enumerated items and formal notification from FDA of hold removal is required before conducting clinical studies in the United States.

The Company will be scheduling a shareholder call to discuss the content of the release. Communication details to follow.

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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 owns various patent families related to wound healing and other therapeutic uses. Tissue Therapies Limited's shares are traded on the Australian, Berlin and Frankfurt stock exchanges. For more information, please visit www.tissuetherapies.com.