ASX Announcement 1 November 2011

Successful FDA Classification and EU Audit

- VitroGro® protein has been classified as a biologic product by the FDA – no change to clinical trial, approval or reimbursement plans.
- FDA biologic classification is consistent with the planned US clinical trials, manufacturing and sales launch of VitroGro® wound healing products.
- Successful compliance audit with EU Notified Body found no non-conformances.

Biomedical company, **Tissue Therapies Limited (ASX: TIS)** has announced today that it has received formal classification of the VitroGro® synthetic protein as a biologic product from the US Food and Drug Administration (FDA). This is now the usual FDA classification for synthetic protein products used for human treatment.

On Friday 28 October the EU Notified Body, British Standards Institute, completed an audit of the quality management systems of Tissue Therapies. This audit found no non-conformances and the Company will shortly receive the certificates of compliance necessary for the sale of VitroGro® wound healing products in the EU and Canada.

The lead US regulatory consultant working with Tissue Therapies, Dr Patsy Trisler said, "Synthetic proteins are now usually classified as biologic products and the Tissue Therapies preparation for US FDA clinical trials, approval for sale and reimbursement have been designed to satisfy or exceed all of the requirements of this classification."

The CEO of Tissue Therapies, Dr Steven Mercer said, "From the start of our FDA preparation we understood that a biologic classification was possible and planned our US FDA clinical trials to satisfy either the device or biologic classification. We did this because we recognised that some wound healing products produced from purified animal proteins are currently regulated by the FDA as devices, compared to VitroGro® which uses a synthetic manufacturing process that avoids the use of human or animal derived materials.

Dr Mercer explained, "A biologic classification is much simpler, quicker and cheaper than the approval process required for a product classified as a pharmaceutical."

"We are very pleased to have achieved certainty on the classification of VitroGro® in the USA. The FDA classification and successful BSI audit are two more critical milestones we have now achieved that are essential for the commencement of sales, initially in the EU in the second quarter of 2012 and later in the United States, Canada and globally. The Company is now in a strong position for the start of key market sales in 2012."

For Further information

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- About Tissue Therapies

Tissue Therapies Limited is an Australian company developing biomedical technologies for wound healing, tissue repair, cell culture and other applications.

The Company has worldwide exclusive rights to commercialise VitroGro®, a technology developed by cell biology, tissue engineering and protein engineering experts at the Institute of Health and Biomedical Innovation (IHBI) at the Queensland University of Technology (QUT) for cell growth and migration. VitroGro® has particular commercial applications in wound healing, tissue regeneration, cell-based therapies and cell culture.

Based on its VitroGro® technology, Tissue Therapies is developing more effective treatments for acute and chronic wound healing applications including chronic skin ulcers and burns.

Tissue Therapies is also proceeding with the development of other commercial applications of various VitroGro® and other technologies for the treatment of psoriasis, scar prevention and treatment and potential treatments for various cancers including those of the breast, colon and prostate.

VitroGro® also provides a fundamental, transforming technology for completely defined cell culture reagents (ie. containing no purified animal or human proteins) to sustain and enhance the growth of live cells for emerging cell-based therapies, along with research and industrial cell culture markets internationally.

More information: www.tissuetherapies.com

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