TISSUE THERAPIES

ASX ANNOUNCEMENT

28 July 2015

Change in strategy - Development of VitroGro® as a pharmaceutical worldwide

- Strategy extends patent term and maximises commercial potential
- Revised plan offers the most attractive outcomes with a lesser level of approval risk
- Provides an opportunity to reposition VitroGro® as a broad spectrum healing promoter for ulcers of all severity
- Greater partnering opportunities

Brisbane, Australia, 28 July 2015: Tissue Therapies (ASX:TIS), a biomedical technology company developing effective treatments for wound healing, today announces its intention to develop VitroGro® ECM as a pharmaceutical worldwide for wound healing, and approval will be concurrently sought from the United States Food and Drug Administration (FDA) and the European Medicines Agency (EMA).

In recent months Tissue Therapies' Board and management have been reviewing the Company's strategic and operational plan. Central to the review has been an assessment of the previous strategy of seeking CE Mark approval following receipt of a final advice letter from the EMA when a viable pathway for development and review as a Class III Rule 13 medical device was established in Europe.

After a detailed assessment of the market opportunity and regulatory risk, the Board has concluded a pharmaceutical pathway offers the most attractive outcomes for VitroGro® and TIS with a lesser level of approval risk.

The first step in this process is a meeting with FDA for guidance on development and review and this is being sought as a priority.

The following statements underpin this decision:

- The US is the largest market for chronic wounds.
- The FDA provides clear and specific guidance for approval pathways for products being developed for chronic cutaneous ulcer and burn wounds. VitroGro® will be repositioned as a broad spectrum healing promoter for ulcers of all severity.
- Achieving both venous leg ulcer and diabetic foot ulcer indications is the most commercially advantageous opportunity open to the company. With time being of the essence, the company expects that subject to FDA advice it can concurrently deliver for both indications in Europe and the US using this pathway.
- A pharmaceutical is more likely to realise global potential sooner and more broadly than a medical device developed specifically for Europe.
- From TIS's current position, whilst the relative time to develop a worldwide pharmaceutical is longer than for a device in Europe, it offers a far greater value outcome than a device in Europe.

- A pharmaceutical product permits a patent term extension of up to five years and potentially longer, at least another two to three years regulatory exclusivity, for trial data and market exclusivity subject to national law[1].
- The approval risk of a pharmaceutical is less because the development and review will focus on the whole protein rather than the IGF-1 component, as is the case for a device approval with EMA. The EMA device approval pathway is considered by the Company to be technically more challenging because of the need to separate the effect of the IGF-1 component from the effect of the Vitronectin component.
- The clinical endpoints for the US will meet the requirements for approval in Europe, Asia Pacific and South America and a number of other jurisdictions.
- The pre-clinical and clinical work that has been completed for CE marking remains relevant and will continue to form part of the Company's submissions as it recommences engagement with the FDA.
- Subject to FDA guidance, the Company anticipates this development and approval process is not likely to be much more than one year longer than the approval pathway Tissue Therapies established with the EMA for a device.

Tissue Therapies, Acting CEO, Mr Nigel Johnson, said: "Along with meeting with the FDA, seeking a development partner is a critical priority in Tissue Therapies focus. Partnering may also provide an opportunity to develop other valuable opportunities for example, pressure ulcers, burns, skin tears such as pre-tibial lacerations, and possibly in ophthalmology and veterinary indications as well as other areas."

Interim Chairman, Dr Cherrell Hirst added: "The Board and management are determined to have the Company deliver on each of the milestones necessary to achieve approval. Acquiring the IP was a critical first step. These goals can be best achieved if we have the continuing support of our shareholders."

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

Additional Background

Subject to FDA guidance, the next steps after the regulatory meeting are expected to include:

- Manufacturing for and execution of a human dose response study. The dose response study is anticipated to require around 12 months to complete. While this study would be commenced as soon as possible, subject to FDA guidance and manufacturing it may not commence until Q1 CY2016.
- A subsequent meeting with the regulator following the completion of the dose-response study.
- Manufacturing of VitroGro® for the selected dose and execution in parallel of two adaptive efficacy studies in the indications of venous leg ulcers and diabetic foot ulcers. The efficacy studies are expected to require 18 months to complete.

[1] The granting of a period of data exclusivity is to compensate an innovator company for the investment in developing a new pharmaceutical by restricting the marketing of a generic version during the period of data exclusivity.

- Assuming satisfactory progress, the Company would be in a position to file a New Drug Application for approval in 2H CY2018.
- In parallel with the aforementioned milestones smaller additional supporting studies will be required including biological characterisation and stability of the protein.

Further information will be provided regarding the costs of this program following the meeting with FDA and external validation of the costs.

- 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 owns 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.