ASX Announcement

Wednesday 28 September 2022

Tissue Repair ("TRP") receives response from the US Food and Drug Administration (FDA) which clarifies path to phase 3 trials

The FDA has broadly accepted as reasonable the Company's intended program of works for TR-987®. Based on the FDA recommendations TRP is now planning to file for a meeting with the FDA to review a phase 3 protocol and formally seek approval to commence a phase 3 clinical program for TR-987®.

The Company believes that it will be able to obtain approval to commence its phase 3 clinical trials in 2023.

Tissue Repair Limited (**'TRP'** or **'the Company'**) (**ASX:TRP**) is pleased to announce that it has received responses to the matters raised in the Type C meeting that the Company submitted to the FDA on June 29, 2022.

The Type C meeting sought clarity on substantive matters for the Company to prepare to progress into a phase 3 clinical program for its lead drug candidate TR-987®. In its response, the FDA has broadly accepted as reasonable the Company's intended approach to:

- Chemistry Manufacturing and Controls - including release specifications for Glucoprime®
- Raw material - including the Company's yeast supply arrangements, characterisation and creation of a master cell bank facilitating long-term supply of this raw material
- Toxicology - including the Company's proposed abridged toxicology program consisting of an *in vitro* degradation analysis, a 28-day mini-pig toxicology study, and a maximal clinical use human study.

The Company also sought advice from the FDA on Fast Track Designation and/or Breakthrough Therapy Designation (FTD/BTD).

The FDA did not accept that TR-987® was eligible for Fast Track Designation and/or Breakthrough Therapy Designation (FTD/BTD), based on results from the Company's phase

2B study alone, stating that for this to be considered a further phase 2 trial would be required. The FDA did however note that if the Company adopted this route, it may only have to conduct a single confirmatory (phase 3) trial, rather the two phase 3 trials it has been planning and budgeting for. The FDA indicated that if results showed that TR-987® had the potential to address an unmet medical need in the treatment of venous stasis (leg) ulcers over the existing therapies, it could then submit a formal request for FTD/BTD status.

Based on the recommendations within the Type C meeting response, the Company is pleased to have greater clarity on key matters to progress into a phase 3 program, which was the main purpose of the meeting.

The Company will continue to consult with its regulatory advisers and then seek further discussions with the FDA on the outstanding matters, with a view to holding a meeting with the FDA to close out its phase 2 studies and confirm protocols for its planned phase 3 trials.

At this stage, the Company still believes that it is on track to commence its phase 3 clinical trials in 2023.

The Company remains confident that the costs of the adjusted program of work required by the FDA following resolution of the outstanding items above can be fully funded from its current cash reserves to deliver a phase 3 outcome.

For further information in relation to this release please contact Darryl Reed at
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This announcement has been approved for release by TRP's board.

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About Tissue Repair

Tissue Repair Limited (ASX:TRP) is an advanced biotechnology company developing second generation wound healing agents. The Company's core focus is entering a phase 3 program in chronic wounds for its lead drug candidate TR-987®, with a secondary focus on commercialising TR Pro+™ a post procedure topical gel to accelerate healing and improve skin quality post any cosmetic procedure. The Company's longer-term strategy is to commercialise its propriety Glucoprime® API to treat a variety of wounds and skin conditions.