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ASX Announcement

FDA clears Tissue Repair to progress into a Phase 3 clinical program for its lead drug candidate TR-987®

The Company is pleased to announce it has held its End of Phase 2 meeting with the US FDA for its lead drug candidate TR-987®. During the meeting the Company reached broad agreement with the FDA on the core components of its proposed Phase 3 trial protocol.

The Company now expects to commence enrolment of patients for its Phase 3 trials before the end of the year.

Tissue Repair Limited (the Company or TR) is pleased to announce completion of its End of Phase 2 (EOP2) meeting with the US FDA during which it received detailed feedback and broad agreement on the proposed pivotal Phase 3 protocol and the overall clinical program towards a New Drug filing.

The FDA provided clearance for the Company to progress into a Phase 3 program, following review of its EOP2 dossier to date and the proposed Phase 3 protocols. TR will now submit its Phase 3 protocol for final review by FDA and clearance for patient enrolment.

Following this critical meeting with the FDA, TR is preparing to establish clinical operations to enrol patients suffering from venous leg ulcers (VLUs) before the end of the year. US and Australian sites have already been canvassed with some 15 sites approached – demonstrating a strong level of engagement and commitment to participate in the trial.

TR co-founder Tony Charara said, “It is a big milestone to enter Phase 3 and to be fully funded to complete it, a milestone achieved by a super talented and driven team. TR has a genuine shot at delivering the first drug to be approved for treatment of chronic venous leg ulcers in almost two decades. This is a debilitating condition with significant unmet needs. Achieving an FDA-approved new drug label is a very valuable prize”.

The Company plans to conduct two trials, each with 300 patients, in Australia and the US. Overall, the Phase 3 clinical program will enrol 600 patients. TR is also pleased to confirm the acceptance and appointment of pre-eminent lead investigators for the Phase 3 trials being Professor Robert Kirsner from the University of Miami for the US trial and Professor Michael Woodward from Austin Health in Melbourne for the Australian trial. Professor Kirsner was the lead investigator on the Smith and Nephew drug candidate for VLUS, HP802-247 product in 2016 and Professor Woodward was the original lead investigator in the Company’s Phase 2A trial.

The primary endpoint of these trials will be incidence of complete closure over a 16-week treatment period. The two main secondary endpoints will be reduction on ulcer size and amelioration of pain in affected patients.

As previously announced TR believes it has sufficient funding on hand, including Australian government R&D rebates, to complete its Phase 3 trials.

For further information in relation to this release please contact Darryl Reed at darryl.reed@trtherapeutics.com 0419 557 663.

This announcement has been approved for release by TRP's board.

About Tissue Repair
Tissue Repair Limited (ASX:TRP) is an advanced biotechnology company developing second generation wound healing agents. The Company is a Phase 3 asset and is focussing on commencing phase 3 trials 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, skin and aesthetic conditions.