Friday 1st July 2022
ASX Announcement

LODGEMENT OF TYPE C MEETING REQUEST WITH US FOOD AND DRUG ADMINISTRATION (FDA)

Tissue Repair Limited (the Company) is pleased to announce that it has submitted a Type C Meeting request with the FDA which, if endorsed, will provide clarity on the substantive matters for the company to progress into a Phase III clinical program for its lead drug candidate TR-987.

At the meeting the Company aims seeks to clarify a broad set of matters required to facilitate progression into the trial program. This should allow recommendations and responses to be tabled by the FDA in August 2022.

The content included in the expanded type C meeting request to the FDA is based on input from a range of experts covering regulatory, clinical and pre-clinical aspects. Key plans and proposals to be submitted to the FDA for approval or guidance include matters relate to:

- Chemistry Manufacturing and Controls – where the Company seeks endorsement of its proposed manufacturing and analytical plans including the proposed 20+ specification tests.
- Raw material – that the FDA endorse the Company's yeast supply arrangements and characterisation and supports the creation of a master cell bank facilitating long term supply.
- Toxicology – endorsement of the Company's proposed toxicology program consisting of additional tests including in vitro analysis, mini-pig toxicology studies and maximal clinical use human studies, with these to be conducted in conjunction with the Phase III clinical trial program.
- Clinical trial – that the FDA provide guidance on certain elements related to a Phase III clinical trial protocol

Should the FDA endorse the plans, program and recommendations contained in this meeting request, the Company should have sufficient clarity on the substantive items required to obtain Phase III clinical trial approval early in 2023.

The Company believes the program of work detailed in the FDA submission can be fully funded from its current cash reserves to deliver a Phase III outcome.

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.

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