



POSITIVE RESULTS FROM THE SUCCESSFUL FIRST IN HUMAN INSERTION OF THE TUTELIX HYDROGEL SPACER IN AUSTRALIA & PROGRESSION TO STAGE 2 OF THE TUTELA CLINICAL STUDY

HIGHLIGHTS:

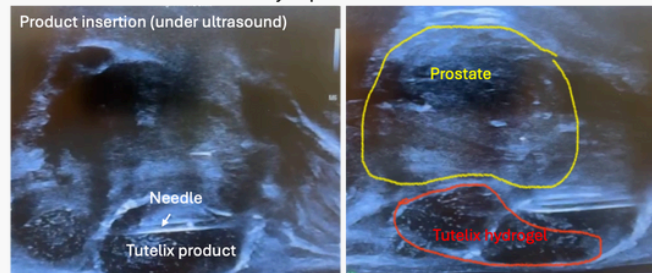
- Positive data read out from the **TUTELA trial** - the Tutelix first in human clinical investigation that has delivered results from multiple product insertions at the Gold Coast University Hospital and patients' follow up visits for the critical follow up time point of 4 weeks post operation.
- Patients in stage 1 of the clinical study were successfully implanted with the Tutelix spacer with **no product related adverse events to date**.
- The Tutelix hydrogel spacer products were successfully injected, **instantly forming a hydrogel structure at the intended site**.
- During the administration process and product gelation, high visibility of prostate via trans rectal ultrasound (**TRUS**) was maintained. This proposition of the technology minimises the risk of injury related to the procedure.
- Tutelix hydrogel spacer retained its structure in all patients and, to date, excellent product stability has been achieved post-implantation throughout the radiotherapy delivery allowing for consistent setup of patients and delivery of radiotherapy.
- Patient recruitment in stage 2 of the TUTELA clinical study has now been initiated in multiple sites across Australia.
- Activation of pathways expected to commence Q1/Q2 CY26 for large pivotal trials in Australia and the US

Tetratherix Limited (ASX:TTX) ("Tetratherix" or the "Company"), is pleased to announce that its Joint Venture partner, Tutelix Pty Ltd has completed its first Safety Review Meeting (SRM) post-completion of Stage 1 of TUTELA clinical trial. The Safety Review Committee (SRC) has met and discussed the clinical trial progress after a minimum 28 day follow up for the first patients on the TUTELA trial. The SRC noted that, to date, no procedural related adverse events have occurred. During the insertion of the Tutelix hydrogel spacer (see representative ultrasound imaging extract in Figure 1-A), the prostate remained visible via TRUS allowing for simple and safe administration of the Tutelix hydrogel spacer and minimising the risk of rectal perforation and local trauma.

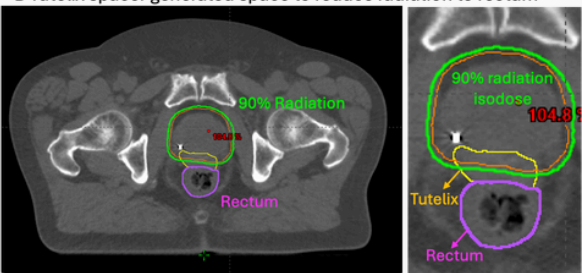
Post-Tutelix hydrogel spacer insertion and during radiotherapy delivery the presence of the Tutelix hydrogel spacer (see yellow structure in Figure 1-B) minimised the high dose received by the rectum, which is expected to reduce radiation related side effects. Importantly, the size and the structure of Tutelix hydrogel spacer remained unchanged during the treatment period which involved 20 sessions of radiation. Stability of the Tutelix hydrogel spacer from computed tomography simulation to the first treatment session (denoted #01 in Figure 1-C) and to the last treatment session (denoted #20 in Figure 1-C) was excellent, allowing for consistent setup of patients and safe delivery of radiotherapy (see Figure 1-C).

As previously planned, stage 2 of the TUTELA trial now has been initiated and patient recruitment is under way.

A Product Insertion and Visibility of prostate



B Tutelix spacer generated space to reduce radiation to rectum



C Tutelix spacer remains unchanged during radiotherapy delivery

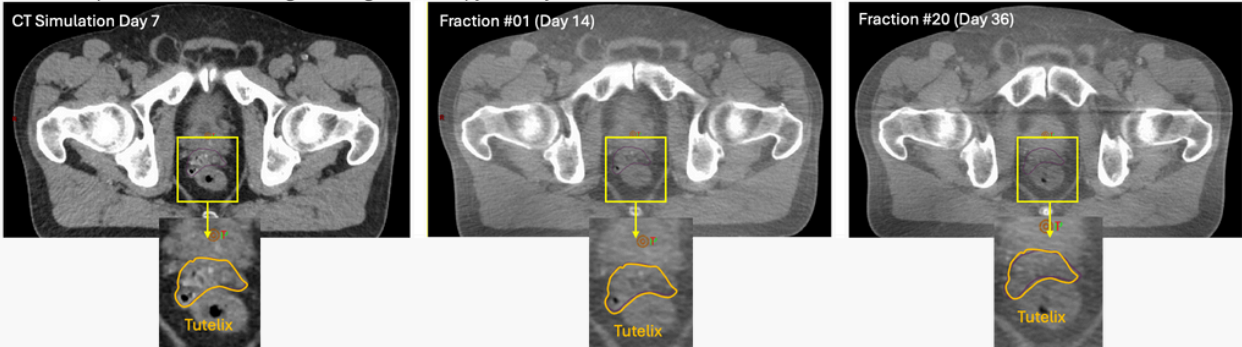


Figure 1. (A) Tutelix hydrogel spacer product insertion and the visibility of prostate under TRUS (B) space generated by the Tutelix hydrogel spacer to reduce radiation side effects; and (C) the Tutelix hydrogel spacer stability at the site.

Dr Andrew Oar - Principal Investigator Radiation Oncologist at Gold Coast University Hospital noted:

“The early results demonstrate very encouraging procedural safety in addition to excellent stability of the product during prostate radiation. The team is very excited to continue recruitment to the TUTELA trial with the aim to complete patient recruitment and product insertion over the next 3 months. Furthermore, it gives us the confidence to commence activation pathways for our pivotal trial in Australia and United States in CY26.”

Authorised for release by CEO and CTO.

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