ASX RELEASE

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FAST TRACK ETHICS APPROVAL & TUTELIX PLATFORM EXPANSION

Highlights

- Ethics approval granted in Australia for the Tutelix™ international pivotal clinical trial (n=~240) targeting TGA and FDA 510(k) clearances.
- Tutela pilot clinical study has completed enrolment (n=15) across multiple Australian sites, zero product-related adverse events recorded.
- Closing the gap – potential Tutelix™ platform expansion to gynaecological cancers.

Tetratherix Limited (ASX:TTX) (**Tetratherix**) is pleased to announce that its joint venture Tutelix™ has secured the necessary ethical approval to formally initiate its international pivotal clinical trial for the Tutelix™ hydrogel spacer in Australia.

Dr Ali Fathi, CTO of Tetratherix, said:

"The positive six-month follow-up data confirms an exciting opportunity beyond the prostate program. Tutelix™ maintaining its structure and holding space under sustained anatomical pressure gives us a technical basis to pursue a gynaecological indication where no commercially approved product has existed."

Ethics Approvals: Pivotal Trial

The Human Research Ethics Committee (**HREC**) at St Vincent's has granted its approval in Australia for the Tutelix™ pivotal clinical trial (n=~240). The pivotal trial has been designed to support both a TGA and FDA 510(k) regulatory submissions and is structured with 50% of patients to be enrolled in Australia and the remaining 50% in the United States. The timeline communicated in the Tetratherix prospectus has accelerated; Australian enrolment is expected to commence in Q1 FY27 with US enrolment to follow subject to IDE approval.

Tutela Study Implantations Completed

The Tutelix™ Tutela clinical study has completed enrolment of all 15 patients across multiple Australian sites, each of whom has been implanted with the Tutelix™ spacer. Throughout the study, Tutelix™ continues to demonstrate a strong safety profile with zero product-related adverse events recorded at any follow-up time point. The study has consistently confirmed that the Tutelix™ spacer maintains its structure, does not migrate from the injection site, facilitates simple and safe administration under trans-rectal ultrasound (**TRUS**), and effectively creates and maintains space between the prostate and rectum to optimise radiation delivery and reduce rectal radiation dose.

Potential Platform Expansion

Six-month follow-up data has been collected for a third of patients enrolled in the Tutela study. These results successfully demonstrate the structural stability and spacing capability of the Tutelix™ spacer for at least six months post-implantation. Structural stability combined with the strength of separation in combination with ultrasound visibility provides a unique technical differentiation of the Tutelix™ spacer technology to possibly expand its utility across an additional radiation opportunity - gynaecological cancer. The results suggest the Tutelix™ spacer technology may uniquely generate space for gynaecological cancer radiation, as it can withstand the increased pressure from the abdominal anatomy for the sustained period of time. This would address an unmet need to reduce the radiation side effects in gynaecological cancers, advancing women's health and servicing a currently neglected oncology market.

Tetratherix™

Why This Matters: Closing The Gap

Women receiving radiotherapy for cervical, uterine and vaginal cancers face a similar anatomical problem to men treated for prostate cancer: the tumour may be in proximity other organs, which limits the radiation dose that can be safely delivered and may cause injury during and after treatment. The solution, an injectable spacer that temporarily separates healthy tissue from cancerous tissue, has been standard care for men for more than a decade, with multiple products regulatory cleared for the prostate indication.

Conversely, no spacer has ever been approved for use with gynaecological cancer treatment anywhere in the world.

The patient impact of this chasm caused by the neglected need is measurable due to the greater radiation toxicities in gynaecological cancers.

Across the Tutelix™ initial target markets, over twenty thousand women per year receive radiotherapy treatment taking longer than 75-days, detrimentally affecting the survival rate of patients. At that threshold, published data shows three-year survival falling from ~88% to ~42%. Protective spacing created using Tutelix™, by enabling more effective dose delivery within the critical window and reducing toxicity, has the potential to directly influence patient outcomes.

The gynaecological site poses a different technical challenge to the prostate. The weight of the abdominal mass places greater sustained pressure on a spacer at the gynaecological site than at the prostate. The Tutela six-month follow-up data, which confirms that the Tutelix™ spacer maintains its structure and holds space for at least six months post-implantation, is significant not just as a prostate milestone, but as a platform proof point. Extrapolating the benefits of the Tutelix™ spacer, the study data confirms that the spacer could possibly sustain separation under the greater anatomical pressures present at the gynaecological site.

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For any questions regarding this announcement, to receive regular Tetratherix announcements & updates and to engage with management join the TTX Investor Hub or for more information visit:

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This announcement was authorised for ASX release by the CEO.

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