

Adding FAP-Targeting Candidates to Theranostic Pipeline

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> 3D rendering of cancer associated fibroblast layer of tumour microenvironment.

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Telix's lead imaging product, gallium-68 (⁶⁸Ga) gozetotide injection (also known as ⁶⁸Ga PSMA-11 and marketed under the brand name Illuccix®), has been approved by the U.S. Food and Drug Administration (FDA), by the Australian Therapeutic Goods Administration (TGA), and by Health Canada. No other Telix product has received a marketing authorisation in any jurisdiction.

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Transaction to add clinically-validated FAP assets to pipeline

A promising pan-cancer target with initial focus on bladder cancer

Next generation of FAP-targeting theranostics

- Fibroblast Activation Protein (FAP) is one of the most exciting targets in nuclear medicine – expressed in over 90% of epithelial cancers¹
- Next-generation assets have potential for imaging, and both alpha and beta therapy applications
- Demonstrated safety and efficacy profile in extensive preclinical and clinical validation
- Developed by renowned radiochemist Professor Frank Roesch and team

Strategic acquisition bolsters Telix's focus in urology

- Bolsters pipeline with a pan-cancer program complementing Telix's CAIX portfolio
- Initial development program to focus on bladder cancer, which rounds out urology franchise

Deal summary

- €7M cash (upfront) (AU\$11M)
- €3M cash (12 months' time) (AU\$5M)
- Up to €132M subject to clinical milestones (AU\$215M)
- Up to €20M subject to commercial milestones (AU\$33M)²



I. Rettig et al. Proc Natl Acad Sci USA. 1988.

2. Conversion to AUD\$ is at an average exchange rate of AU\$1 = EUR € 0.61

FAP: The Achilles' heel of cancer?

Targeting key players in the tumour microenvironment (TME)

Fibroblasts are cells which help to form connective tissue and promote the body's normal healing process

In cancer this forms part of a protective wall around the tumour called **stroma** protecting it from immune response

Stroma makes up >70% of solid tumour mass¹ Cancer cells can 'manipulate' normal fibroblasts to promote tumour growth

Permanently activated fibroblasts are known as Cancer Associated Fibroblasts (CAF) CAFs are marked by significantly increased levels of Fibroblast Activation Protein (FAP)

FAP is expressed in CAFs as well as on some tumour cells, creating a potential double-hit to the tumour

FAP is a druggable target and therefore a potential Achilles' heel of cancer





The theranostic potential of FAP

Using radiation to image, damage or destroy cancer cells

Overexpressed in cancer

FAP is highly expressed in the TME of epithelial cancers, and on the surface of some specific cancer types, including sarcomas and mesotheliomas¹

Combined treatment options

Weakening of the cancer stroma may also improve the effectiveness of other therapies

Demonstrated evidence

in bladder cancer

FAP targeting for imaging

patients^{2,3} - superior to FDG highlights its potential to

address a significant unmet

need through a theranostic

approach

FAP Imaging in bladder cancer exemplifies potential for therapeutic approach





FAPI-PET-MIP

⁶⁸Ga-FAPI PET in 65-y-old patient with bladder cancer²

Patient representative scans - individual results may vary.

Powerful therapy potential

By delivering radiation to CAFs, targeted radionuclide therapy has the potential to damage or destroy the cancer stroma and cancer cells



1. Zboralski et al., *EJNMMI*. 2022.

Novruzov et al. Molecular Imaging and Biology. 2022.

3. Koshkin et al. JNM. 2024.

Cracking therapeutics: A new way to target FAP

New assets have potential to overcome key challenges

First-generation FAP-targeting candidates limited by short tumour residence

Telix's next generation candidates have a novel design enabling:

- Extended tumour retention
- Improved clearance
- Minimal off-target uptake
- Significant radiotherapeutic dose to tumour
- Labelling with either ¹⁷⁷Lu (beta) or ²²⁵Ac (alpha)

Potential for beta and alpha therapy

Clinically validated for safety profile and efficacy in several cancer types, under an extensive compassionate use program¹⁻⁴



1. Yadav et al. *EJNMMI.* 2024.

- . Ballal et al. Pharmaceuticals (Basel). 2021.
- 8. Martin et al. Cancers. 2023.
- 4. AIIMS, New Delhi, India.

Clinical evidence for acquired next-gen compounds

Proof-of-concept in-human study and extensive compassionate use

Extensive clinical data

Successful proof of concept across diagnostic, therapeutic, for multiple indications

Pan-cancer uses

Used as therapy in >120 patients across sarcoma, breast, thyroid and medullary thyroid cancers to date¹

Safety profile established

FAP-targeting diagnostic has been used in >400 patients, establishing safety profile²

Peer-reviewed data

Builds on extensive preclinical data, published in several peer-reviewed papers³

Published data demonstrates therapeutic potential¹

⁶⁸Ga-DOTA.SA.FAPi PET/CT



Intense accumulation of radiotracer in tumour mass (arrows) and multiple skeletal sites (right femurarrow head).

¹⁷⁷Lu-DOTA.(SA.FAPi)₂ post-therapy serial whole-body scans





1. Ballal et al. Pharmaceuticals. 2021; Ballal et al. JNM. 2022; Ballal et al. JNM. 2023; Bal et al. JNM. 2024.

2. AIIMS, New Delhi, India. Data on file.

3. Laeppchen et al. *Molecules.* 2024.

Compelling responses seen in late-stage cancer patients

Significant tumour mass reduction following treatment with therapeutic candidate



Clinical effect of ¹⁷⁷Lu-based, FAP-targeted therapeutic candidate in-licensed by Telix, in a patient with breast cancer. Response verified by FAP-targeted PET (above) and FDG-PET (right) using the diagnostic in-licensed by Telix.

Patient representative scans - individual results may vary.

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Clinical development led by renowned KOLs

Broad community of supporters leading investigations

Frank Roesch, PhD Mainz, DE

- Renowned radiochemist in nuclear medicine
- Invented the ⁶⁸Ga generator
- Chairs World Theranostics Conference

Ken Herrmann, MD, MBA Essen, DE

- Chair of Dept of Nuclear Medicine at University Hospital Essen
- Chair of EANM Oncology & Theranostics Committee
- Prolific commentator in nuclear medicine community

Chandrasekhar Bal, MD & Sanjana Ballal, PhD New Delhi, IN

- Extensive clinical experience with all Roesch compounds
- Widely published in both JNM and other nuclear medicine publications

Frederik L. Giesel, MD, MBA Düsseldorf, DE

- Chair of Dept of Nuclear Medicine at Uni Düsseldorf
- Global leader in application of PSMA and FAP targeting in nuclear medicine

"FAP-targeting is very exciting. In the past, we have been successful in treating primarily one cancer type with a certain asset or therapeutic agent. Here we have opened a new door to treat a variety of cancer subtypes – **a pan tumour target and even beyond!**"

- Prof. Dr. Frederik L. Giesel

Unmet need in bladder cancer

6th most common cancer in the U.S., significant unmet need

Large market opportunity

BaskProvide the stateNew cases and 16K+ deaths
per year in the U.S.1Of patients develop
metastatic disease2 with
5-year survival rate of 8%3White space opportunity for TRT5,
including FAP-targeting agents
No approved systemic radionuclide therapy
Studies suggest FAP expressed in over 67%
of cases6

\$5.6B

in 2024

→ \$13.7B

Global market for bladder cancer therapies estimated to grow by over 20% per annum over next 5 years⁴

- 1. American Cancer Society, Key Statistics for Bladder Cancer, accessed October 2024.
- 2. Mason. Eur Urol Open Sci. 2021.
- 3. National Cancer Institute, Bladder Cancer Prognosis and Survival Rates, accessed October 2024.
- 4. National Cancer Institute, Bladder Cancer Prognosis and Survival Rates, accessed October 2024.
- 5. Targeted radionuclide therapy.
- 6. Hemida et al. J Immunoassay Immunochem. 2022.
- 7. NCCN Guidelines Version 4.2024, Bladder Cancer.

Adding to the bladder cancer therapy toolbox

Complements Telix's CAIX program, options for localised and disseminated disease

Trials of TLX250-CDx in bladder cancer



3D representation with superimposed bladder based on TLX250-CDx Pelvis PET/CT Fusion images

PERTINENCE (IIT)

Alpha candidate in non-muscle invasive bladder cancer

Phase I feasibility study of TLX250-CDx complete

Moving to first-inhuman therapeutic studies with ²¹¹At (alpha) via Telix partner ATONCO

ZiP-UP (IIT)

Exploring indication expansion for TLX250 in urothelial carcinoma or bladder cancer Phase I study of TLX250-CDx complete – awaiting readout





Comparison of TLX250-CDx PET-CT with FDG-PET CT. Patient representative scans - individual results may vary.



Pan-cancer: "Double hit" at TME – targeting hypoxia and fibrosis

A complementary approach – and a "shot in the arm" to immuno-oncology

Two well validated targets with pan-cancer potential^{1, 2}





Literature reports of CAIX expression.
Giesel et al. *J Nucl Med.* 2019.

In summary: An exciting asset with big potential

Adds to urology pipeline with ability to expand to other cancer types

- Clinically validated theranostic drug candidates targeting FAP – a highly promising target
- Next-generation compounds with longer tumour retention than earlier versions
- Adds to Telix's urology development pipeline with novel candidates for bladder cancer, a major market opportunity
- Potential to generate further value from pancancer targeting
- **Clinical data** (safety profile and efficacy) reduce development risk, guide target indications and may expedite development
- Visit our website for more: <u>Attack on Stroma</u>

felix

Kratochwil et al. 2019. Journal of Nuclear Medicine June 2019, 60 (6) 801-805; DOI: https://doi.org/10.2967/jnumed.119.227967



Patient representative scans - individual results may vary.

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A confocal microscopy image of a fibroblast. Credit: National Cancer Institute.