ASX ANNOUNCEMENT
18 NOVEMBER 2025

Radiopharm Theranostics Receives Approval to Initiate Phase 1 Therapeutic Trial of RAD 402 (KLK3-mAb with Tb161) in Advanced Prostate Cancer

RAD 402 is a humanized IgG1 internalized by prostate cells, binding KLK3 with high affinity

Tb-161 antitumor activity driven by the dual emission of beta particles and Auger electrons

Sydney, Australia – 18 November 2025 – Radiopharm Theranostics (ASX:RAD, "Radiopharm" or the "Company"), a clinical-stage biopharmaceutical company focused on developing innovative oncology radiopharmaceuticals for areas of high unmet medical need, today announced that it has been granted Bellberry Human Research Ethics Committee (HREC) approval in Australia to initiate its First-In-Human (FIH) Phase 1 clinical trial of its Kallikrein Related Peptidase 3 (KLK3)-targeting radiotherapeutic, RAD 402, for the treatment of metastatic or locally advanced prostate cancer.

RAD 402 is an anti-KLK3 monoclonal antibody radiolabelled with the radionuclide 161Tb for the treatment of prostate cancer. Prostate Specific Antigen (PSA) is a widely used biomarker to detect prostate cancer and is encoded by the KLK3 gene. KLK3 is expressed in the prostate along with most adenocarcinomas of the prostate including their metastases.

Previous comprehensive preclinical proof-of-concept Biodistribution studies of RAD 402 in mouse xenografts showed strong tumour targeting, limited bone and marrow uptake, and a hepatic excretion profile consistent with expectations for a monoclonal antibody. Radiopharm has signed in 2022 a supply agreement with Terthera for the production of Tb161 and in 2025 with Cyclotek for radiolabeling RAD402 with 161Tb, supporting the initiation of the Phase 1 FiH trial of RAD 402.

"Receiving HREC approval marks a key milestone for Radiopharm and for patients in need of safer, more effective new treatments for prostate cancer," said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. "This clearance enables us to advance RAD 402 into our first-in-human Phase 1 clinical trial, which, to my knowledge, is the first company-sponsored therapeutic trial using 161Tb. We are highly encouraged by RAD 402's potential antitumor activity, driven by the dual emission of beta particles and Auger electrons from Tb-161. Targeting KLK3 in advanced prostate cancer represents a novel and promising mechanism of action. The strength of our preclinical data, combined with regulatory endorsement, underscores RAD 402's first-in-class potential".

About Radiopharm Theranostics
Radiopharm Theranostics is a clinical stage radiotherapeutics company developing a world-class platform of innovative radiopharmaceutical products for diagnostic and therapeutic applications in areas of high unmet medical need. Radiopharm is listed on ASX (RAD) and on NASDAQ (RADX). The company has a pipeline of distinct and highly differentiated platform technologies spanning peptides, small molecules and monoclonal antibodies for use in cancer. The clinical program includes one Phase 2 and four Phase 1 trials in a variety of solid tumor cancers, including lung, breast, and brain metastases. Learn more at radiopharmtheranostics.com.

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Authorised on behalf of the Radiopharm Theranostics board of directors by Chairman Paul Hopper.

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