ASX ANNOUNCEMENT
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Radiopharm Theranostics Doses First Patient in Phase 1 'HEAT' Trial of 177Lu-RAD202 for Treatment of Advanced HER2-Positive Solid Tumors

Phase 1[1] First-In-Human study designed to assess safety, tolerability, right dose for Phase 2 and early signs of efficacy of 177Lu-RAD202 in individuals with advanced HER2-positive solid tumors

Previous clinical proof-of concept data[2] for targeting HER-2 demonstrated the safety and biodistribution of 99mTc-RAD202 in humans

Sydney, Australia – 4 June 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 the dosing of the first patient in its Phase 1 'HEAT' clinical trial of RAD202, a proprietary nanobody that targets Human Epidermal Growth Factor Receptor 2 (HER2)-positive expression in a wide array of advanced solid tumors.

The open-label Phase 1 "HEAT' clinical trial is a dose escalation trial of 177Lu-RAD202 that is designed to determine the recommended Phase 2 dose and to evaluate the safety and preliminary clinical activity of this novel radiotherapeutic in individuals with HER2-expressing advanced cancers. The study is currently being conducted at clinical centers across Australia.

"Dosing patients in the HEAT clinical trial marks an important milestone in our transition to a clinical-stage company," said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. "Despite progressive improvements in the management of metastatic HER2-positive disease, the majority of patients experience disease progression on current standard of care and require further therapeutic options. The dosing of the first patient in the 'HEAT' trial represents a significant step toward achieving RAD202's potential to address an unmet need for HER2-positive metastatic patients who are progressing or unable to tolerate current treatment options. With RAD202, we hope to provide an option that can meaningfully improve clinical outcomes for HER2-positive patients, while preserving their quality of life."

HER2 is overexpressed in breast cancer as well as several other solid tumors and represents a validated target in oncology. RAD202 is a proprietary single domain antibody that targets HER2. Ten HER2-positive breast cancer patients previously dosed in a Phase 1 diagnostic study of RAD202 demonstrated clinical proof-of concept as well as the safety and biodistribution of RAD202, validating its potential for the treatment of advanced HER2-expressing cancers[2]. Preclinical findings[3] examining the therapeutic effect in HER2-positive xenografts were also recently reported with 177Lu-RAD202. Collectively, these data further justify first in humans dose finding studies.

"It is a privilege to be the first centre to administer 177Lu-RAD202, targeting HER2-positive tumors in this Phase 1 clinical trial (HEAT)." said Dr Aviral Singh, Clinical Head of Theranostics and Nuclear

[1] clinicaltrials.gov/study/NCT06824155
[2] Zhao et al, Molecular Pharmaceutics 2021 18 (9), 3616-3622
[3] Altunay B. et al, EP-0136, Eur J Nucl Med Mol Imaging (2024) 51 (Suppl 1): S1–S1026. DOI: 10.1007/s00259-024-06838-z

Medicine at St John of God Murdoch Hospital. "This opens the possibility of novel therapeutic avenues for patients with aggressive tumour types, including breast, ovarian, gastric, pancreatic, bladder, and several other cancers. With the trust put in us by Radiopharm, we look forward to a successful trial with beneficial outcomes for our patients."

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 three Phase 1 trials in a variety of solid tumor cancers including lung, breast, and brain metastases. Learn more at radiopharmtheranostics.com.

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

For more information:
Riccardo Canevari
CEO & Managing Director
P: +1 862 309 0293
E: rc@radiopharmtheranostics.com

Anne Marie Fields
Precision AQ (Formerly Stern IR)
E: annemarie.fields@precisionaq.com

Paul Hopper
Executive Chairman
P: +61 406 671 515
E: paulhopper@lifescienceportfolio.com

Media
Matt Wright
NWR Communications
P: +61 451 896 420
E: matt@nwrcommunications.com.au