ASX ANNOUNCEMENT
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New RAD202 data confirms positive tumor uptake and favorable biodistribution

- *Data presented at European Molecular Imaging Meeting (EMIM 2025) for imaging with 68Ga-RAD202 confirms specific accumulation in the tumor, favorable biodistribution and low uptake in non-target organs, except for the bladder and kidney as expected*
- *Treatment with 177Lu-RAD202 results in a relevant tumor volume reduction and survival benefit, further pronounced with fractionated therapy vs single-dose treatment.*
- *These data further support the rationale for the ongoing Phase I therapeutic trial with 177Lu-RAD202 in HER2-positive solid tumors.*

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, is pleased to announce a poster presentation at EMIM 2025[1], with findings that support the clinical utility of imaging and therapy with 68Ga-RAD202 and 177Lu-RAD202 respectively, and validate an optimized therapeutic dosing regimen in murine models.

The poster presentation is by Drs. Felix Mottaghy, Betul Altunay and colleagues, from the University Hospital RWTH Aachen in Germany.

The imaging data reported that 68Ga-RAD202 binds specifically to the Human Epidermal growth factor Receptor 2 (HER2) in HER2-positive xenografts, with a high tumor-to-background ratio. The removal of a His-tag from the RAD202 nanobody, a modification which impacts biodistribution and tumor targeting, was shown to be superior for PET imaging due to the higher tumor-to-organ ratio.

Furthermore, therapy with 177Lu-RAD202 was well-tolerated, demonstrating significantly prolonged survival time. Fractionated dosing proved more effective in inhibiting tumor growth compared to single-dose therapy.

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. Previous data[2] demonstrated the safety and biodistribution of 99mTc-RAD202 in humans. 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-Human (FIH) dose finding studies.

A FIH open-label dose escalation Phase 1 study of 177Lu-RAD202 is currently recruiting in Australia[4]. The trial is designed to evaluate the safety and preliminary activity of this novel radiotherapeutic in eligible individuals with advanced HER2-positive solid tumors.

[1] Altunay B. et al, Poster # IGT-015, PW-36, March 14th, EMIM 2025.
[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
[4] ACTRN12625000191493

"These data support the potential for RAD202 to address an unmet need for HER2-positive metastatic patients that are progressing on current standard of care, or unable to tolerate current treatment options," said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. "The current comprehensive data with RAD202 further support our rationale for the Phase 1 FIH therapeutic dose escalating trial with 177Lu-RAD202, currently recruiting in HER2-positive advanced solid tumors."

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 has been listed on ASX (RAD) since November 2021. The company has a pipeline of six distinct and highly differentiated platform technologies spanning peptides, small molecules and monoclonal antibodies for use in cancer, in pre-clinical and clinical stages of development from some of the world's leading universities and institutes. The pipeline has been built based on the potential to be first-to-market or best-in-class. The clinical program includes one Phase II and three Phase I trials in a variety of solid tumour cancers including breast, kidney and brain. Learn more at radiopharmtheranostics.com.

Authorized on behalf of the Radiopharm Theranostics Board of Directors by Executive Chairman Paul Hopper.

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