

Radiopharm Theranostics announces novel data presentation of RAD 202 at 2024 European Association of Nuclear Medicine (EANM) Annual Meeting

- **New imaging data presented at EANM 2024 for Ga68-RAD 202 confirms rapid tumor uptake, favorable biodistribution and low uptake in non-specific organs.**
- **Comprehensive preclinical data package demonstrates tumor growth inhibition and significantly prolonged survival time, supporting readiness for Phase I therapeutic trial with 177Lu-RAD 202.**

Sydney, Australia – 23 October 2024 – 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 EANM 2024¹, by Drs. Felix Mottaghy, Betul Altunay and colleagues, from the University Hospital RWTH Aachen in Germany. Collectively, the recently reported findings demonstrate the clinical feasibility of imaging and therapy with RAD 202, independent of the polyhistidine tag (His-tag), a modification which impacts biodistribution and tumor targeting.

The Human Epidermal growth factor Receptor 2 (HER2) is overexpressed in breast cancer as well as several other solid tumors and represents a validated target in oncology. RAD 202 is a proprietary nanobody that targets HER2. The PET/CT data reported here demonstrate that in HER2-positive murine models, there is low uptake of 68Ga-RAD 202 in nonspecific organs, except for the bladder and kidney as expected. The findings indicated a rapid tumor uptake and high tumor-to-background ratio with or without the His-tag modification.

Previous data² demonstrated the safety and biodistribution of 99mTc-labeled RAD 202 in humans. Additional preclinical findings³ examining the therapeutic effect in HER2-positive xenografts were also recently reported with 177Lu-labeled RAD 202. These data demonstrated tumor growth inhibition, significantly prolonged survival time, and further justify First-In-Human (FIH) dose finding studies.

A FIH open-label dose escalation Phase 1 study of 177Lu-RAD 202 will commence in Q4 2024 and is designed to evaluate the safety and preliminary activity of this novel radiotherapeutic in eligible individuals with advanced HER2-positive solid tumors. The study will be conducted in Australia.

“These data strongly support the clinical development of Radiopharm’s proprietary nanobody RAD 202 as a noninvasive approach in detecting, monitoring and treating HER2-positive solid tumors,” said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics Ltd. “Importantly,

¹ 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

² Zhao et al, Molecular Pharmaceutics 2021 18 (9), 3616-3622

³ Altunay B. et al, Sept 19-20 2024, “Radiolabeling of HER2 targeting single domain antibody with 68Ga and 177Lu” Poster Presentation, CIO ABCD MSSO Science Day, Cologne, Germany

RAD 202 has the potential to address an unmet treatment gap in HER2-positive metastatic patients that are refractory to or unable to tolerate current standard of care treatments.”

“Our current data demonstrate the excellent features of RAD 202 as a theranostic compound,” said Dr Felix Mottaghy, Nuclear Medicine Head and Principal Investigator at the University Hospital RWTH Aachen in Germany. “My group is convinced that this nanobody has the potential to positively impact personalized clinical treatments of HER2-positive 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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