RAD 202 receives approval to start Phase 1 therapeutic trial

- **Ethics approval received in Australia for the initiation of RAD's Phase 1 therapeutic trial of ^{177}Lu-RAD202 in Breast and Gastric Cancers.**
- **The Phase 1 First-In-Human study is designed to assess the safety, tolerability & preliminary clinical activity of ^{177}Lu-RAD202 in individuals with HER2-positive metastatic solid tumors.**
- **Ten HER2-positive breast cancer patients previously dosed in a Phase 1 diagnostic study demonstrated the safety and biodistribution of ^{177}Lu-RAD202, validating its potential for the treatment of advanced HER2-expressing cancers.**

Sydney, Australia – 20 December 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 it has been granted Belberry Human Research Ethics Committee (HREC) approval in Australia to initiate its First-In-Human (FIH) Phase 1 therapeutic clinical study of 177Lu-labelled RAD 202 for the treatment of HER2-expressing solid tumors.

The open-label Phase 1 trial, entitled 'HEAT' (HER2 Antibody Therapy with Lutetium-^{177}), is a dose escalation trial of ^{177}Lu-RAD202, and is designed to evaluate the safety and preliminary clinical activity of this novel radiotherapeutic in individuals with HER2-expressing advanced cancers. RAD 202 is a single-domain monoclonal antibody (sdAb) that targets the Human Epidermal growth factor Receptor 2 (HER2), which is overexpressed in breast cancer as well as several other solid tumors, and represents a validated target in oncology. The multicenter study is planned to recruit across Australia, with the support of leading oncology care provider GenesisCare CRO.

Previous data[1] demonstrated the safety and biodistribution of 99mTc-labeled RAD 202 in humans. Additional preclinical findings examining the therapeutic effect in HER2-positive xenografts were also recently reported with 177Lu-labeled RAD 202[2]. These data demonstrated tumor growth inhibition, significantly prolonged survival time, and further justify FIH dose finding studies.

"We are thrilled to receive approval to proceed with our Phase 1 FIH basket trial in Australia," said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. "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. With RAD 202, we hope to provide an alternative strategy that can improve clinical outcomes for patients with HER2-positive advanced cancers, while potentially preserving their quality of life."

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.

[1] Zhao et al, Molecular Pharmaceutics 2021 18 (9), 3616-3622

[2] 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

The company has a deep pipeline of highly differentiated molecules spanning peptides, small molecules and monoclonal antibodies for use in cancer, in pre-clinical and clinical stages of development. 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 two Phase I trials in a variety of solid tumour cancers including brain, lung, breast and pancreas. Learn more at radiopharmtheranostics.com.

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

For more information:

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

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

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