ASX ANNOUNCEMENT
October 1st, 2025

Radiopharm Theranostics Receives Positive Recommendation from Data Safety and Monitoring Committee (DSMC) to Accelerate 177Lu-RAD202 Phase 1 'HEAT' Dose Escalation Clinical Trial

Phase 1 study to progress to the next dose level of 75mCi in patients with HER2+ advanced solid tumors, instead of the protocol-planned dose of 40mCi

Sydney, Australia – 1 October 2025 – Radiopharm Theranostics (ASX: RAD, Nasdaq: RADX, "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 received a positive recommendation from the Data Safety and Monitoring Committee (DSMC) to advance its clinical-stage radiotherapeutic asset, 177Lu-RAD202 (RAD202), to the next dose level of 75mCi in the Phase 1 'HEAT' clinical trial in patients with Human Epidermal Growth Factor Receptor 2 (HER2)-positive advanced solid tumors. The DSMC is a multidisciplinary committee that conducts detailed reviews of study data, discusses potential safety events and provides recommendations regarding trial continuation.

"We are encouraged by the rapid progress of the Phase 1 'HEAT' trial of RAD202 as it underscores the strong interest in new, effective therapeutic options to treat HER2-positive advanced and metastatic cancers an area of high unmet medical need" said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. "With initial dosing in June and the swift completion of the first cohort, the DSMC's recommendation to advance to a higher dose level marks an important step toward identifying the optimal Phase 2 dose and the recognition of very encouraging initial safety signals. Each cohort brings us closer to confirming RAD202's safety profile and to demonstrating its potential to offer a new treatment option for patients with HER2-positive advanced solid tumors. We remain on track to share data from the first two cohorts by year-end 2025."

The DSMC reviewed the first cohort of patients treated with 30mCi of Lu177-RAD202 and confirmed there was positive safety, pharmacokinetic, and biodistribution data and agreed that the study may continue without modifications and accelerate to the second cohort of patients at 75mCi of Lu177-RAD202. The second cohort of patients is expected to be enrolled by Q4 2025.

The Phase 1 'HEAT' study is currently being conducted at clinical centers across Australia.

About 177Lu-RAD202:

RAD202 is a proprietary single domain monoclonal antibody (sdAb) that targets the Human Epidermal Growth Factor Receptor 2 (HER2)-positive expression in advanced solid tumors. HER2 is overexpressed in breast cancer and several other solid tumors and represents a validated target in oncology. In a previous diagnostic study of ten HER2-positive breast cancer patients, RAD202 demonstrated clinical proof-of-concept and had positive safety and biodistribution.

About Radiopharm Theranostics

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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. Learn more at radiopharmtheranostics.com.

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

For more information:

Investors:
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

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

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