ASX ANNOUNCEMENT
12 May 2025

Radiopharm Theranostics Accelerates 177Lu-RAD204 Phase 1 Dose Escalation Clinical Trial Based on Positive Recommendation from Data Safety and Monitoring Committee (DSMC)

DSMC concluded that Phase 1 study may continue as planned without any modifications

On track to complete the enrollment of the first two cohorts by mid-2025

Sydney, Australia – 12 May 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, announced today that it has achieved a key milestone in its ongoing clinical development program for its clinical-stage radiotherapeutic asset, 177Lu-RAD204, as the Data and Safety Monitoring Committee (DSMC) has approved to proceed to the next dose in its Phase 1 clinical trial in patients with PD-L1 positive advanced cancers[1]. The DSMC is an independent multidisciplinary group that conducts detailed reviews of unblinded study data, discusses potential safety concerns and provides recommendations regarding trial continuation.

"We greatly appreciate the DSMC's judicious review of our first cohort of patients in the Phase 1 study of Lu177-RAD204, which allows us to advance to the higher dose cohort in a variety of PD-L1-driven cancers," said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. "With this clearance from the DSMC, the increased number of active centers and expansion to multiple tumor types beyond Non-Small Cell Lung Cancer (NSCLC), we expect to accelerate our timelines for complete enrolment of the next cohort by mid-2025. We believe that RAD204 has the potential to strongly improve clinical outcomes for patients with PD-L1 positive advanced cancers and we look forward to seeing data from the first two cohorts of patients later this year."

The DSMC reviewed the first cohort of four patients treated with 30mCi of Lu177-RAD204 and confirmed that there was positive safety, pharmacokinetic and biodistribution data and agreed that the study may continue without modifications. The second cohort of patients will start at 60mCi of Lu177 rather than 40mCi previously assumed in the protocol. The second cohort of patients is expected to be enrolled by mid-year 2025 and will include expansion to multiple tumor types including NSCLC, Small-Cell Lung Cancer (SCLC), Triple-negative Breast Cancer (TNBC), Cutaneous Melanoma, head and neck squamous cell carcinoma (HNSCC) and Endometrial Cancer.

There are currently four clinical trial sites actively screening and recruiting patients in Australia.

About 177Lu-RAD204:

RAD204 is a single-domain monoclonal antibody (sdAb) that targets PD-L1, a protein that helps control the immune system and is overexpressed in many solid cancers, making it an attractive therapeutic target in multiple tumor types, including NSCLC, SCLC, TNBC, Cutaneous Melanoma, HNSCC, and Endometrial Cancer. Previously published Phase I imaging data of 16 NSCLC patients

[1] **ClinicalTrials.gov ID:** NCT06305962

with 99Tc-RAD204 demonstrated that the diagnostic compound is safe and is associated with acceptable dosimetry[2].

Tumor targeting with radioimmunotherapies such as 177Lu-RAD204 has the potential to address resistance mechanisms to current standard-of-care treatment options.

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. 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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Website – https://radiopharmtheranostics.com/
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[2] Xing Y, et al. J Nucl Med. 2019 Sep;60(9):1213-1220.