ASX ANNOUNCEMENT
12 November 2025

Radiopharm Theranostics starts enrollment of the Third Cohort of Phase 1 Dose Escalation Clinical Trial of 177Lu-RAD204

*Data Safety Monitoring Committee approves advancing to a higher dose of **90mCi***

The first two Cohorts' patients show tumor uptake and a favourable safety profile

Sydney, Australia – 12 November 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 the completion of enrollment for the second cohort of patients in the Phase 1 dose escalation trial of 177Lu-RAD204 in PD-L1 positive advanced cancers, including non-small cell lung cancer (NSCLC), small cell lung cancer (SCLC), triple-negative breast cancer (TNBC), cutaneous melanoma, head and neck squamous cell carcinoma (HNSCC) and endometrial cancer.

"We continue to execute to plan and are pleased to have completed enrollment of the second cohort of patients in the Phase 1 study of RAD204," said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. "This represents a major milestone for Radiopharm Theranostics, as we can now proceed in dosing patients in the Third Cohort with a dose of **90mCi** of Lu177, as approved by the Data and Safety Monitoring Committee. Our basket trial is targeting multiple tumor types including NSCLC, SCLC, TNBC, Cutaneous Melanoma, HNSCC and endometrial cancer. We look forward to continuing to collect more patient data, as we believe RAD204 could significantly improve clinical outcomes for patients with PD-L1 positive advanced cancers who face a life-limiting disease with limited effective treatment options."

The open-label Phase 1 trial, entitled "Phase 0/1 Study of the Safety and Tolerability of 177Lu-RAD204, a Lutetium-177 Radiolabelled Single Domain Antibody Against Programmed Cell Death-Ligand 1 in Patients with Metastatic Solid Tumors," is a first-in-human study to evaluate the safety, tolerability, biodistribution, radiation dosimetry and preliminary anti-tumour activities of 177Lu-RAD204[1] in eligible individuals with PD-L1 expressing advanced cancers.

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 1 imaging data of 16 NSCLC patients with 19Tc-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.

[1] ClinicalTrials.gov ID: NCT06305962
[2] Xing Y, et al. J Nucl Med. 2019 Sep;60(9):1213-1220.

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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 four 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.

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