

Radiopharm Theranostics Achieves Confirmed Durable Partial Response in Ongoing Phase 1 Trial of RAD204 in Patients with Advanced Solid Tumors Post-Immunotherapy

First RECIST-confirmed durable Partial Response at current highest dose level #3 (90mCi) with the patient remaining progression free beyond seven months

Second patient dosed remains progression free on treatment with RAD204 with early tumor shrinkage observed after first treatment

RAD204 is generally well-tolerated with no dose-limiting toxicities observed in any of the dosing cohorts thus far

Sydney, Australia and MALVERN, Pa. – 22 July 2026 – 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 updated clinical results from the first two patients in the third cohort of RAD204, the Company’s investigational PD-L1-targeted lutetium-177 nanobody radiotherapeutic being evaluated in a Phase 1 clinical trial in patients with advanced solid tumors in a post-immunotherapy setting.

Radiopharm previously received positive recommendations from the Data and Safety Monitoring Committee, allowing the Company to proceed with enrolling patients in the Phase 1 treatment study after completion of cohorts # 1 and #2 to the current highest dose level #3 (90 mCi). Initial data from all cohorts of the Phase 1 treatment study demonstrated tumor uptake in the PD-L1-positive lesions, which is in line with published results from the previously completed imaging study.

“We are excited to announce positive initial data from the first two patients treated with RAD204 in the third dosing cohort, which showed favorable tolerability and tumor reduction in target lesions, with both patients remaining on treatment,” said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. “Importantly, the first patient has achieved a durable confirmed RECIST Partial Response lasting through four treatment cycles and has remained progression-free beyond seven months. The combined preliminary results indicate the broad therapeutic potential of RAD204 in PD-L1-associated malignancies. Additionally, the data demonstrated that RAD204 was generally well-tolerated, reinforcing the safety profile of RAD204 at the highest dose level evaluated and supporting continued dose escalation.”

“We remain laser-focused on advancing the Phase 1 study and anticipate releasing additional data that will support the therapeutic potential of RAD204 to treat PD-L1 associated malignancies. The totality of data across our multiple dose cohorts supports our confidence in this program and are expected to inform the recommended dose for our planned Phase 2 clinical trial,” concluded Mr. Canevari.

Initial Clinical Results from Cohort 3 of the Phase 1 Trial of RAD204

Thus far, two patients have been dosed with RAD204 in the third cohort of the Phase 1 treatment study, with the third patient under screening evaluation. Both patients remain on treatment, and initial clinical observations from the ongoing study support the potential of repeated administration of RAD204.

Patient 1

- Patient 1 has achieved a RECIST-confirmed Partial Response after the second treatment cycle, which has been maintained during continued therapy:
 - 19% reduction in target lesions from baseline, observed after Dose 1.
 - 43% reduction after Dose 2, which meets the RECIST criteria for a Partial Response.
 - 43% reduction maintained after Dose 3, i.e., a confirmed Partial response per RECIST
 - 35% reduction after Dose 4, while continuing to meet RECIST criteria for a Partial Response.
- The patient remains progression-free beyond seven months with continued follow-up.

Patient 2

- Patient 2 has demonstrated an early 7% reduction in target lesions following the first treatment cycle. The patient remains on treatment and is progression-free with continued follow up for additional efficacy and safety assessments.

Safety and Tolerability

- In all patients dosed to date across dose levels 1 to 3, RAD204 has continued to demonstrate a favorable safety and tolerability profile. There have been no dose-limiting toxicities observed in any of the cohorts thus far. Kidney uptake has been limited (cumulative 8.1 Gy across the four cycles, in Patient 1) and does not represent a potential obstacle for escalation to the next higher dose level (Dose level #4).

About the Phase 1 Study

The ongoing first-in-human Phase 1 study is evaluating the safety, tolerability, dosimetry, pharmacokinetics and preliminary anti-tumor activity of RAD204 in patients with advanced solid tumors following progression on standard therapies. The primary objectives are to establish the recommended Phase 2 dose and characterize safety, while secondary endpoints include anti-tumor activity, eg., tumor responses and duration of responses.

About RAD204

RAD204 is a single-domain monoclonal antibody (sdAb) that targets PD-L1, a protein that regulates the immune system's response to malignant tumors and is overexpressed in many 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 with 99Tc-RAD204 demonstrated positive tumor targeting, favorable biodistribution and image characteristics correlating with PD-L1 immunohistochemistry results in cancer patients². Tumor targeting with radioimmunotherapies such as 177Lu-RAD204 has the potential to address resistance mechanisms to current standard-of-care treatment options. The platform is designed to

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provide hidden epitope access, exceptional stability, rapid tumor penetration, favorable pharmacokinetics and the potential for repeat dosing.

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 five Phase 1 trials in a variety of solid tumor cancers including lung, breast, and brain metastases. Learn more at radiopharmtheranostics.com

Authorised on behalf of the Radiopharm Theranostics board of directors by Chairman Paul Hopper.

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