

Radiopharm Theranostics Provides Positive Clinical Updates Across Four Programs

- *Preliminary data from first three patients in Phase 2b imaging clinical trial of RAD 101 show uptake in brain metastases from solid tumors, confirming proof-of-concept with Phase 2 topline results expected by H1 2026*
- *First cohort of patients in Phase 1 clinical trial of RAD 202 (HER2) shows higher than expected tumour uptake; Anticipates second cohort of patients to be fully enrolled with data available by year-end 2025*
- *Data from first six patients in Phase 1 clinical trial of RAD 204 (PDL-1) show promising tumor uptake, stable disease at the first dose level in two out of three patients*
- *Data from Phase 1 study with RAD 301 supports decision to advance to Phase 2 imaging trial in patients with loco-regional pancreatic cancer*

Sydney, Australia – 20 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 an update on its pipeline of clinical programs and outlined expected milestones through the end of 2025 and into 2026.

“We are highly encouraged by the consistent and positive data emerging from our four lead clinical programs, which continue to validate the potential of our differentiated radiopharmaceutical pipeline,” said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. “Our strategic execution remains strong, and we anticipate a steady stream of topline data readouts across multiple trials in the near term. As we advance these programs toward their next stages of development, we are proud of the meaningful progress being made. On behalf of our entire team, I express our gratitude to the investigators, patients, and families participating in our clinical trials—their trust and commitment are the foundation of our work.”

“Looking ahead, we are excited to initiate Phase 1 trials for RV01 and RAD402, our promising preclinical monoclonal antibody assets, by year-end. With this expansion, our clinical portfolio will include four therapeutic candidates and two imaging agents by December 2025, underscoring our commitment to transforming cancer care through potentially first-in class and best-in-class radiopharmaceuticals,” Canevari concluded.

Recent Clinical Achievements and Upcoming Milestones (additional data available in the accompanying PowerPoint presentation)

18F-RAD101 – *Small molecule targeting fatty acid synthase radiolabelled with Fluorine-18*

The Company continues to evaluate RAD 101 in a single-arm U.S. Phase 2b clinical trial evaluating the diagnostic performance of the molecule in 30 individuals with suspected recurrent brain

metastases from solid tumors of different origin. RAD 101 has received U.S. Food and Drug Administration (FDA) Fast Track Designation to expedite the review process and help bring the novel imaging small molecule to the more than 300,000 patients diagnosed annually in the U.S. with cerebral metastases. The study has currently enrolled 12 patients and the Company anticipates to complete enrollment in the first quarter of 2026.

- Data from the first three patients show significant and selective tumor uptake in brain metastases. Images confirm metabolic activity in brain metastases compared to equivocal MRI findings.
- These promising early results are in line with the previously published Phase 2a results and, if confirmed, will trigger the preparation of a multi-center, global Phase 3 registrational trial.

177Lu-RAD202 – Nanobody targeting HER2 radiolabelled with Lutetium 177

The Company continues to evaluate RAD 202 in the Phase 1 ‘HEAT’ clinical trial in patients with Human Epidermal Growth Factor Receptor 2 (HER2)-positive advanced solid tumors. HER2 is overexpressed or amplified in breast cancer and several other solid tumors and represents a validated target in oncology. RAD 202 has demonstrated clinical proof-of-concept with favourable safety and biodistribution and was recently recommended by the Data Safety and Monitoring Committee (DSMC) to progress to the next dose level of 75mCi in the ‘HEAT’ trial.

- Dosing at the 30mCi dose level of RAD202 has been completed and the study is advancing to the next dose level of 75mCi following recommendation from the DSMC.
- Data available from the first three patients in the first cohort of the study show very significant tumor uptake in HER2 positive tumors.
- The safety profile of RAD202 has been favourable with no drug-related adverse events reported.
- The Company expects to complete enrollment in the higher dose Cohort 2 and to have data from both the first and second cohorts available by year-end 2025.

177Lu-RAD204 – Nanobody targeting PD-L1 radiolabelled with Lutetium 177

The Company continues to evaluate RAD 204 in its Phase 1 study in PD-L1-positive 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. Previous Phase 1 imaging data of 16 NSCLC patients treated with RAD 204 demonstrated that the diagnostic compound is safe and is associated with acceptable dosimetry. The Company recently completed dosing in its first cohort of patients at 30mCi.

- Two out of three patients in the 30mCi cohort exhibited stable disease for 5.5 months in last-line metastatic NSCLC, compared to historical data of 3.5 months PFS with standard of care (SOC).
- Dosing is completed at the second cohort dose level of 60mCi. Meeting with the DSMC is scheduled to approve further dose escalation to the third dose level.
- Initial data from the first six patients across the first two cohorts show tumor uptake in the PD-L1-positive lesions, in line with published results of the previously conducted imaging study.

- The safety profile of RAD204 has been favourable and there have been no dose limiting toxicities reported.

Ga68-RAD301 – Peptide targeting $\alpha\beta6$ -integrin radiolabelled with Gallium 68

RAD 301 is being evaluated in a Phase 1 imaging trial in patients with Pancreatic Ductal Adenocarcinoma (PDAC). The $\alpha\beta6$ -integrin is a cellular marker for tumor invasion and metastatic growth, which correlates with decreased survival in several carcinomas, particularly pancreatic. RAD 301 has previously received Orphan Drug Designation (ODD) from the FDA and data from the Phase 1 trial are supportive of the Company's decision to move to a Phase 2 imaging trial in patients with loco-regional pancreatic cancer.

- Enrollment in the Phase 1 imaging trial in metastatic pancreatic cancer is continuing with six subjects dosed out of nine subjects in total.
- Initial data from the first six subjects confirmed safety and significant uptake in $\alpha\beta6$ positive lesions.
- The unmet medical need in the earlier stages of disease and the large disease prevalence have influenced the decision to plan a Phase 2 imaging trial to evaluate RAD 301 in the preoperative setting of loco-regional pancreatic cancer.

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 metastases. Learn more at radiopharmtheranostics.com.

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

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