

Radiopharm Theranostics Doses First Patient in Second Cohort of Phase 1/2a Clinical Trial of BetaBart (RV-01) in B7-H3 Expressing Solid Tumors

Doses first patient at 70 mCi dose of RV-01, the first radiopharmaceutical therapeutic developed in Company's joint venture with MD Anderson Cancer Center

Sydney, Australia – 26 August 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 that it has dosed the first patient in the second cohort of its First-In-Human (FIH) Phase 1/2a clinical trial of RV-01 (177Lu-Betabart) in patients with B7-H3 expressing tumors. This follows a positive recommendation from the Safety and Monitoring Committee (SMC), an independent multidisciplinary committee, to advance to the 70 mCi dose of RV-01.

RV-01 is a 177Lutetium-tagged engineered monoclonal antibody, designed with a strong affinity for the 4Ig isoform of B7-H3. B7-H3 is an immune checkpoint molecule that is overexpressed across several tumor types and has emerged as a compelling target for antibody-based cancer immunotherapy. Multiple preclinical studies with RV-01 have shown tumor shrinkage and prolonged survival in animals treated with the radiotherapeutic agent.

The Phase 1/2a clinical trial is a dose escalation and expansion trial designed to evaluate the safety, biodistribution, radiation dosimetry and preliminary anti-tumor activity of RV-01 in B7-H3 expressing tumors. The trial will determine the recommended dose of RV-01 to move forward in future studies. The Phase 1/2a study is currently being conducted at clinical centers across the U.S.

"Dosing the first patient in the second dose cohort of our Phase 1/2a RV-01 study marks an important clinical and operational milestone for Radiopharm and reflects the continued advancement of this first therapeutic radiopharmaceutical program from our joint venture with MD Anderson Cancer Center," said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. "The recommendation to proceed to the 70 mCi dose level provides an important early indication of the program's progression through dose escalation and reinforces our confidence in RV-01's development pathway."

"B7-H3 remains one of the most compelling targets in oncology due to its broad expression across multiple solid tumor types, and we believe RV-01 has the potential to emerge as a differentiated therapeutic approach for patients with significant unmet needs. We remain focused on enrolling patients in the current cohort and look forward to reporting initial clinical data later this year," commented Dimitris Voliotis, M.D., Chief Medical Officer of Radiopharm Theranostics.

About RV-01

RV-01 is the first radiopharmaceutical therapeutic agent developed by Radiopharm Ventures, the Joint Venture formed between Radiopharm Theranostics and The University of Texas MD Anderson Cancer Center. RV-01 is a 177Lutetium-conjugated therapeutic that targets B7-H3, an immune

checkpoint molecule that is overexpressed in several tumor types. Multiple preclinical studies with RV-01 have shown tumor shrinkage and prolonged survival in animals treated with the radiotherapeutic agent.

About the Phase 1/2a Clinical Trial

The FIH Phase 1/2a study (NCT07189871) is designed to establish the safety profile, biodistribution, pharmacokinetics, and radiation dosimetry of ¹⁷⁷Lu-Betabart (RV-01). The study aims to enroll 61 eligible participants who have a documented history of histopathologically confirmed castrate resistant prostate cancer, colorectal cancer, non-small cell lung cancer, small cell lung cancer, head and neck squamous cell cancer, ovarian cancer, cervical cancer, endometrial cancer, triple negative breast cancer, or esophageal squamous cell carcinoma.

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, prostate 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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