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Radiopharm Theranostics Doses First Patient in Phase 1/2a Clinical Study of BetaBart (RV-01)

First radiotherapeutic agent developed by Radiopharm Ventures, the joint venture between Radiopharm Theranostics and MD Anderson Cancer Center

Preclinical animal studies of BetaBart (RV-01) have demonstrated tumor shrinkage and prolonged survival [1]

Sydney, Australia – 24 February 2026 – Radiopharm Theranostics (ASX:RAD, "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 dosing of the first patient in its First-In-Human (FIH) Phase 1/2a clinical trial of 177Lu-Betabart (RV-01).[2]

The Phase 1/2a clinical trial is a dose escalation and expansion trial of 177Lu-BetaBart, designed to evaluate its safety, biodistribution and radiation dosimetry of 177Lu-BetaBart, along with its preliminary anti-tumor activity. The trial will also determine the recommended dose of 177Lu-BetaBart for future studies. This agent was developed by Radiopharm Ventures, a joint venture between Radiopharm and The University of Texas MD Anderson Cancer Center. RAD previously announced on 28 July 2025 that the U.S. Food and Drug Administration (FDA) has provided Investigational New Drug (IND) clearance for Betabart (RV-01).

177Lu-Betabart is a Lu^{177}-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.

"Dosing of the first patient in the Phase 1/2a trial of 177Lu-BetaBart marks an important milestone for Radiopharm, as this is the first radiotherapeutic agent from our joint venture to enter the clinic," said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. "177Lu-BetaBart has the potential to become a highly differentiated radiotherapeutic for patients with aggressive advanced solid tumors, and we are grateful to our collaborators and participants in this Phase 1/2a trial."

"We are honored to administer the first dose of 177Lu-BetaBart in this Phase 1/2a clinical trial," noted Brandon Mancini, MD, MBA, FACRO, Medical Director at BAMF Health. "As a leading center for radiopharmaceutical therapeutic trials, we appreciate the opportunity to provide this novel, first-in-class radiotherapeutic for the treatment of a variety of advanced refractory solid tumors, while offering exceptional care to our clinical trial participants."

In preclinical studies, 177Lu-BetaBart has shown evidence of efficacy and targeting of the specific 4Ig isoform of B7-H3, supporting its potential use in multiple indications, including prostate, pancreatic, breast and other solid tumors.[3]

1 https://pubmed.ncbi.nlm.nih.gov/38182652/
2 https://clinicaltrials.gov/study/NCT07189871
3 https://pubmed.ncbi.nlm.nih.gov/38182652/

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 four 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.

For more information:
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

Paul Hopper
Executive Chairman
P: +61 406 671 515
E: paulhopper@lifescienceportfolio.com

Media
Matt Wright
NWR Communications
P: +61 451 896 420
E: matt@nwrcommunications.com.au