ASX ANNOUNCEMENT

Radiopharm Theranostics Receives IND approval from US FDA to Initiate Phase I Therapeutic Clinical Study to target B7H3 with Betabart (RV-01)

Lu177-B7H3 monoclonal antibody is first in class targeted radiopharmaceutical in development against the 4Ig subtype of B7-H3

On track to initiate first-in-human study of RV-01 in solid tumors in 4Q25

Sydney, Australia – 28 July 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 that the U.S. Food and Drug Administration (FDA) has provided clearance of the Company's Investigational New Drug (IND) application for Betabart (RV-01), its Lu177-B7H3 monoclonal antibody designed with strong affinity for the 4Ig isoform of B7H3 that is highly expressed in tumors and not in healthy tissues.

"FDA clearance to initiate our first-in-human Phase 1 clinical trial of RV-01 represents a major milestone for Radiopharm Theranostics and our joint venture with MD Anderson Cancer Center," said Riccardo Canevari, CEO and Managing Director. "RV-01 is the first monoclonal antibody developed through this collaboration, and we believe it has the potential to become a highly differentiated radiopharmaceutical for patients with aggressive solid tumors. We are excited to advance this program into the clinic and anticipate dosing the first patients later this year."

"Recent reported preclinical studies demonstrated that RV-01 exhibits hepatic clearance, allowing the isotope sufficient time to effectively target tumors while potentially minimizing adverse effects such as hematological toxicities. Unlike peptides or small molecules, monoclonal antibodies are primarily cleared by the liver—an organ known for its radio-resistance. This characteristic, combined with the shortened half-life of RV-01 and the strong affinity for the target make this agent stand out and may offer a significant advantage not just over other monoclonal antibodies but also targeted radiotherapeutics with renal excretion pathway, the latter of which are often associated with higher risk of radiopharmaceutical-induced kidney toxicity," noted Dimitris Voliotis, M.D., Chief Medical Officer of Radiopharm Theranostics.

"The high affinity and selectivity of RV-01 for the 4Ig isoform of B7H3 allows the antibody to bypass the soluble 2Ig isoform in the blood, boost binding of the radiopharmaceutical to tumor targets and avoid the formation of immune complexes in circulation," noted David Piwnica-Worms, M.D., Ph.D., Professor, MD Anderson Cancer Center, and scientific co-founder of Radiopharm Ventures.

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. Deregulated B7-H3 expression is consistently correlated with enhanced tumor aggressiveness and poor clinical outcomes. Targeting the 4 Ig isoform of B7-H3 with a selective radioligand therapy may offer a novel strategy for treating refractory or high-risk tumors.

About RV-01

RV-01 is the first radiopharmaceutical therapeutic agent developed by Radiopharm Ventures, the Joint Venture formed between Radiopharm Theranostics and MD Anderson Cancer Center (MDACC).

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. RV-01 has received IND-clearance from the U.S. FDA and plans to initiate a first-In-human Phase 1 study in the second half of 2025.

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. Learn more at radiopharmtheranostics.com.

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

For more information:

Investors:
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

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

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Website – https://radiopharmtheranostics.com/
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