

Significant progress with B7-H3 targeting radio-antibody (BetaBart)

- Pre-IND meeting request with FDA submitted
- First GMP batch of antibody + chelator successfully produced

Sydney, Australia – 3 October 2024 – 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, is pleased to announce regulatory and manufacturing progress for its B7-H3 targeting radio-antibody, BetaBart.

The monoclonal antibody is the first radiopharmaceutical therapeutic agent developed by Radiopharm Ventures, the Joint Venture formed between Radiopharm Theranostics (RAD) and MD Anderson Cancer Center (MDACC).

The strong preclinical data package combined with GMP quality production, supported the pre-IND submission to the US Food and Drug Administration (FDA). Preparations are on track to prepare the IND submission with the FDA and subsequently start the Phase I/II First-In-Human (FIH) therapeutic trial with BetaBart in multiple tumour types in the US, expected for mid-2025.

B7-H3 is an immune checkpoint molecule that is overexpressed in several tumour types, and represents a highly attractive target for antibody-based cancer immunotherapy. Deregulated B7-H3 expression is linked with tumour aggressiveness and poor outcomes. BetaBart is the first and only targeted radiopharmaceutical in development against the 4lg subtype of B7-H3, which is the most common subtype expressed on human tumours.

Multiple preclinical studies with BetaBart show tumour shrinkage and prolonged survival in animals treated with this radiotherapeutic agent. The monoclonal antibody, invented at MDACC, has been specifically engineered with a shorter blood circulation time and reduced affinity for on-target off-tissue toxicity, leading to a final molecule that is highly promising for human use in clinical settings.

BetaBart will be used in the planned FIH clinical trial as a 177 Lutetium-conjugated therapeutic. The supply chain of the isotope Lu177 has been secured by multiple contracts.

Radiopharm’s Managing Director and CEO Riccardo Canevari said: "We are extremely pleased with the strong collaboration with MD Anderson and the early results we saw with BetaBart (RV-01) are impressive, so we’re looking forward to developing this further."

Dr David Piwnica-Worms of the MDACC Department of Cancer Systems Imaging said: "It has been an exciting and rewarding journey for our research team to be working with our strong partners at RAD to bring this antibody through the regulatory steps required for human testing."

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 has been listed on ASX (RAD) since November 2021. The company has a pipeline of distinct and highly differentiated platform technologies spanning

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peptides, small molecules and monoclonal antibodies for use in cancer, in pre-clinical and clinical stages of development from some of the world's leading universities and institutes. The pipeline has been built based on the potential to be first-to-market or best-in-class. Learn more at [Radiopharmtheranostics.com](https://radiopharmtheranostics.com).

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

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