



AtomVie Global Radiopharma Supplies First Patient Dose in Radiopharm Theranosticsâ?? Phase 1/2a Clinical Study of ¹⁷⁷Lu-BetaBart (RV-01)

Descrizione

COMUNICATO STAMPA â?? CONTENUTO PROMOZIONALE

HAMILTON, ON, Feb. 24, 2026 /PRNewswire/ â?? AtomVie Global Radiopharma (AtomVie), a global leading radiopharmaceutical CDMO, announced that it has supplied the successful dosing of the first patient in Radiopharm Theranosticsâ?? First-in-Human Phase 1/2a clinical study of ¹⁷⁷Luâ??BetaBart (RVâ??01) by providing GMP manufacturing and distribution services for the radiotherapeutic drug product, after successfully developing and qualifying the radiolabeling process and analytical methods using a phase-appropriate approach that expedited IND filing.

The Phase 1/2a clinical study is designed as a dose-escalation and expansion trial evaluating the safety, biodistribution, radiation dosimetry, and preliminary anti-tumor activity of ¹⁷⁷Luâ??BetaBart, while also determining the recommended dose for future studies. ¹⁷⁷Lu-BetaBart (RVâ??01) is a ¹⁷⁷Lutetiumâ??conjugated monoclonal antibody engineered to target the 4Ig isoform of B7â??H3, an immune checkpoint molecule overexpressed across multiple solid tumor types.

â??Enabling the first patient dose of ¹⁷⁷Lu-BetaBart reflects what matters most to us, ensuring that highâ??quality radiopharmaceuticals are manufactured, released, and delivered on time so patients can access innovative therapies without delay,â? said Bruno Paquin, Chief Executive Officer of AtomVie. â??Our team is deeply focused on operational excellence and reliability, supporting our partners from early clinical development through global supply.â?

â??Dosing the first patient in the Phase 1/2a clinical study of ¹⁷⁷Luâ??BetaBart represents an important milestone for Radiopharm Theranostics,â? said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. â??We appreciate AtomVieâ??s manufacturing expertise and commitment to quality as we advance BetaBart for patients with aggressive and difficultâ??toâ??treat solid tumors.â?

About BetaBart (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. ¹⁷⁷Lu-BetaBart is a ¹⁷⁷Lutetium-conjugated therapeutic that targets B7-H3, an immune checkpoint molecule that is overexpressed in several tumor types. Multiple preclinical studies with BetaBart 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. 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 Theranostics 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.

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About AtomVie(AtomVie)

AtomVie is a global leading CDMO for the GMP manufacturing and worldwide distribution of clinical and commercial radiopharmaceuticals. AtomVie offers the full range of scientific, technical, regulatory, quality and logistics services combined with a specialized infrastructure for the development of radiopharmaceuticals from clinical studies, phases I to III, to commercial markets. AtomVie currently serves international clients conducting clinical studies in over 28 countries worldwide. AtomVie is currently building and commissioning a new state-of-art, purpose-built 72,300 sq ft facility, set for operational readiness in H2 2026. For additional details visit our website <https://www.atomvie.com/>

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