

Radiopharm Theranostics Presents Initial Findings from Phase 1 First-in-Human HEAT Clinical Trial for 177Lu-RAD202 in HER2+ Solid Tumors at American Association for Cancer Research 2026

177Lu-RAD202 demonstrated encouraging tumor uptake and a favorable safety profile in the lowest dose cohort

Data Safety and Monitoring Committee Recently Approved Advancing 177Lu-RAD202 to Next Highest Dose at 130 mCi

Sydney, Australia – 20 April 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 new data from the ongoing Phase 0/1 HEAT trial ([NCT06824155](https://clinicaltrials.gov/ct2/show/study/NCT06824155)), evaluating 177Lu-RAD202, a first-in-class HER2-targeted radiopharmaceutical therapy, will be presented as a poster at the American Association for Cancer Research (AACR) Annual Meeting 2026, being held April 17–22, 2026 in San Diego, California.

“These first-in-human results represent an important early milestone for our HER2-targeted radiopharmaceutical program,” said Dr. Dimitris Voliotis, Chief Medical Officer of Radiopharm Theranostics. “In a heavily pre-treated patient population with significant unmet need, 177Lu-RAD202 demonstrated encouraging tumor uptake and a favorable safety profile at the lowest dose level. Importantly, the observed dosimetry supports continued dose escalation, which was recently approved by the Data Safety and Monitoring Committee (DSMC) to advance to the third cohort at 130 mCi dosing. We look forward to further evaluating the therapeutic potential of this novel approach and expect to see signs of antitumor activity at higher, more therapeutic dose levels.”

The AACR poster highlights first-in-human safety, biodistribution, dosimetry and tumor uptake clinical findings from the initial lowest dose cohort of three patients with advanced HER2-positive breast and urothelial cancers who had received multiple prior metastatic therapies and were dosed at 30 mCi.

Key Findings from the AACR Abstract and Poster

- **Meaningful tumor uptake** of 177Lu-RAD202 was observed at the initial and lowest dose level of 30 mCi, particularly in breast cancer lesions
- **177Lu-RAD202 was generally well tolerated** in the first three treated patients, with predominantly Grade 1–2 treatment-emergent adverse events
- **No dose-limiting toxicities** or treatment discontinuations due to adverse events were observed
- **Organ-level absorbed radiation doses** were within expected and clinically acceptable ranges, supporting continued dose escalation

Poster Presentation Details

- **Title:** A First-in-Class HER2-Targeted Radiopharmaceutical Therapy: Initial Findings from the Phase 0/1 HEAT Trial of 177Lu-RAD202 in HER2+ Advanced Solid Tumors
- **Abstract Number:** CT046
- **Presenter:** Dimitris Voliotis, M.D., Chief Medical Officer of Radiopharm Theranostics
- **Session:** Poster Session
- **Dates:** April 20, 2026 at 9:00 AM PT

The complete poster can be found on the Company's website [here](#).

On April 8, 2026, Radiopharm Theranostics announced the positive recommendation from the Data Safety and Monitoring Committee (DSMC) to advance 177Lu-RAD202 to the third cohort at a dose level of 130mCi in the Phase 1 'HEAT' clinical trial in patients with HER2-positive advanced solid tumors¹. The DSMC is a multidisciplinary committee that conducts detailed reviews of study data, discusses potential safety events and provides recommendations regarding trial continuation.

About the HEAT Trial

177Lu-RAD202 is a Lutetium-177-labeled single-domain antibody (sdAb) designed to target HER2-expressing tumors. The sdAb format enables deep tumor penetration and rapid systemic clearance, while the beta-emitting isotope 177Lu delivers cytotoxic radiation with potential bystander effects independent of HER2 receptor density.

The HEAT trial (HER2-Antibody Therapy with Lutetium-177; ([NCT06824155](#)) is a first-in-human, open-label, multicenter integrated Phase 0/1 study evaluating 177Lu-RAD202 in patients with HER2-positive locally-advanced or metastatic solid tumors.

- **Phase 0** evaluates biodistribution, pharmacokinetics, and radiation dosimetry using an imaging dose
- **Phase 1** consists of multiple-dose escalation to assess safety, tolerability, tumor targeting, and to determine the recommended Phase 2 dose

About RAD202:

RAD202 is a proprietary single-domain monoclonal antibody (sdAb) that targets the Human Epidermal Growth Factor Receptor 2 (HER2)-positive expression in advanced solid tumors. HER2 is overexpressed in breast cancer and several other solid tumors and represents a validated target in oncology. In a previous diagnostic study of ten HER2-positive breast cancer patients, RAD202 demonstrated clinical proof-of-concept and had positive safety and biodistribution^{2,3}.

About Radiopharm Theranostics

¹ clinicaltrials.gov/study/NCT06824155

² Zhao et al, *Br Canc Res* (2024)

³ Zhao et al, *Mol Pharmaceut* (2021)

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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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