

## Radiopharm Theranostics Doses First Patient with 18F-RAD101 in U.S. Phase 2b Imaging Study of Brain Metastasis

*Phase 2b study evaluating diagnostic performance of 18F-RAD101 for suspected recurrent brain metastases from solid tumors of different origins*

*Underscores Radiopharm's commitment to developing transformative oncology radiopharmaceuticals*

Sydney, Australia – 28 April 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 the dosing of the first patient in its U.S. Phase 2b imaging study of 18F-RAD101 in suspected recurrent brain metastasis.

The U.S. multicenter, open-label, single arm Phase 2b clinical trial<sup>1</sup> is evaluating the diagnostic performance of 18F-RAD101 in 30 individuals with confirmed recurrent brain metastases from solid tumors of different origins. The primary objective of the study is concordance between 18F-RAD101 positive lesions and those seen in conventional imaging (MRI with gadolinium) in participants with suspected recurrent brain metastases.

RAD101 is a novel imaging small molecule that targets fatty acid synthase (FASN), a multi-enzyme protein that catalyses fatty acid synthesis and is overexpressed in many solid tumors, including cerebral metastasis. Disruption of FASN activity allows for the accurate detection of cancer cells, representing a strongly viable target for the imaging of brain metastasis. Positive data from the Imperial College of London’s Phase 2a imaging trial of 18F-RAD101 in patients with brain metastases showed significant tumor uptake that was consistent with and independent from the tumor of origin.<sup>2</sup>

“We are proud to pioneer the first U.S. clinical trial of RAD101,” said Harshad R. Kulkarni, MD, Chief Medical Advisor at [BAMF Health](#) and Principal Investigator of this Phase 2b study. “This marks an important step toward improving diagnostic precision and enabling more evidence-based, individualized treatment decisions for patients with brain metastases following stereotactic radiosurgery.”

“This trial is an excellent illustration of BAMF Health’s clinical trials platform in action,” added BAMF Health’s Director of Clinical Trials. “Our Radiopharmacy is producing the imaging agent on-site, our clinic team is caring for the patient and providing the best image in the world, and our clinical trials team expertly coordinates it all. BAMF’s facility and team were built to do trials just like this.”

“Current standard of care imaging is less sensitive in discriminating between tumor recurrence and radiation necrosis in patients with brain metastasis who have received anticancer treatments, including radiation,” said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics

<sup>1</sup> <https://www.clinicaltrials.gov/study/NCT06777433>

<sup>2</sup> S. Islam et. Al., EJNMMI; 07 February 2025. <https://doi.org/10.1007/s00259-025-07118-0>

Ltd. “18F-RAD101 has the strong potential to improve diagnostic accuracy of brain metastases, and holds promise for discriminating between treatment effect and true progression in the more than 300,000 patients diagnosed with brain metastasis each year in the U.S. alone. We look forward to advancing this clinical trial and to reporting topline data 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](https://radiopharmtheranostics.com).

### **About BAMF Health**

BAMF Health is the world’s first vertically integrated platform for intelligence-based precision medicine. Headquartered in Grand Rapids, Michigan, BAMF Health employs the most advanced theranostic imaging technology to detect and treat cancer and other diseases and conduct advanced clinical trials. Our overriding mission is to empower patients to become people again. With a team of data scientists, researchers, software engineers, and clinicians —all working in lockstep—we’re making good on it. To learn more about BAMF Health, visit [www.bamfhealth.com](https://www.bamfhealth.com).

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

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