ASX ANNOUNCEMENT
16 APRIL 2026

Radiopharm Theranostics Completes Enrollment in U.S. Phase 2b Imaging Trial of RAD 101 for Diagnosis of Brain Metastases

Interim data to date showed 90% concordance with MRI (the primary endpoint)

Clinical trial readout (Primary endpoint) expected in June 2026

Plans to advance RAD 101 into U.S. Phase 3 pivotal trial

Sydney, Australia – 16 April 2026 – 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 needs, today announced that the final patient has been dosed in the U.S. Phase 2b imaging trial (NCT06777433) evaluating RAD 101 in individuals with confirmed recurrent brain metastases from solid tumors of different origins.

"Dosing the final patient in our most advanced diagnostic program represents an important milestone for Radiopharm and underscores the continued momentum of our radiopharmaceutical pipeline," said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. "The interim results we have seen to date, demonstrating a high level of concordance with MRI, reinforce our confidence in RAD 101's potential to address a critical unmet need in the accurate detection of recurrent brain metastases. As we look ahead to the full data readout in June, we are focused on advancing this important program into U.S. pivotal trial and initiating constructive dialogue with the FDA to define the optimal regulatory pathway. We believe RAD 101 has the potential to meaningfully improve clinical decision-making for patients and physicians navigating this challenging disease."

"I would like to take the opportunity to thank all the patients, families, and caregivers for their trust in our clinical trial. The investigators and the Clinical Center did an amazing job in the recruitment process, and our congratulations go to BAMF HEALTH for leading the table of the top recruiters," added Mr. Canevari.

RAD 101 is the Company's 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. Targeting FASN activity may allow for the more accurate detection of cancer cells, representing a clinically relevant method for the imaging of brain metastases.

The U.S. multicenter, open-label, single arm Phase 2b clinical trial 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. RAD 101 received U.S. Food and Drug Administration (FDA) Fast Track Designation to distinguish between recurrent disease and treatment effect of brain metastases originating from solid tumors of different origin, including leptomeningeal disease.

In the U.S. alone, there are more than 300,000 patients diagnosed annually with cerebral metastases. The incidence of Intracranial Metastatic Disease (IMD) continues to increase, in part, due to improvements in systemic therapy resulting in a more durable control of the primary tumor.

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Contrast-enhanced Magnetic Resonance Imaging (CE-MRI) is the preferred method for imaging IMD, but has limitations, particularly in follow-up surveillance scans to optimise patient care.[1]

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 five Phase 1 trials in a variety of solid tumor cancers, including lung, breast, and brain metastases. Learn more at radiopharmtheranostics.com.

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

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[1] A hybrid [18F]fluoropivalate PET-multiparametric MRI to detect and characterise brain tumour metastases based on a permissive environment for monocarboxylate transport | European Journal of Nuclear Medicine and Molecular Imaging