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**ASX ANNOUNCEMENT**
**17 November 2025**

# Radiopharm Theranostics Announces 50% Enrollment in Phase 2b Clinical Trial of RAD101 Imaging in Brain Metastases

*Early patient data from Phase 2b clinical trial showed significant and selective tumor uptake in brain metastases compared to MRI*

*Phase 2b clinical trial expected to complete enrollment and have topline data in 1H26*

Sydney, Australia – 17 November 2025 – 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, today announced that the Phase 2b trial evaluating RAD101 imaging in brain metastases has achieved 50% patient enrollment threshold.

"Enrolling 50% of the patients in our Phase 2b study of RAD101 is a meaningful achievement for our RAD101 development program that brings us closer to demonstrating its clinical benefit in distinguishing between tumor recurrence and radiation necrosis in patients with brain metastasis following anticancer treatments, like SRS/radiation," said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. "Meeting this half-way milestone, along with our continuing momentum in patient enrollment, gives us further confidence in our plans to complete enrollment and share topline results in the first half of 2026."

RAD101 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 Brain metastases.

Data from the first three patients showed significant and selective tumor uptake in brain metastases. Images confirmed metabolic activity in brain metastases compared to equivocal MRI findings. These promising early results are in line with the previously published Phase 2a results and, if confirmed, will trigger the preparation of a multi-center, global Phase 3 registrational trial.

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. 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]

RAD101 has 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.

**About the Phase 2 Clinical Trial of RAD101**

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

[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

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. Secondary endpoints are accuracy, sensitivity and specificity of RAD101 in identifying tumor recurrence versus radiation necrosis in previously stereotactic radiosurgery (SRS)-treated brain metastases.

**About RAD101**

RAD101 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. Positive data from the Imperial College of London's Phase 2a imaging trial of 18F-RAD101 in patients with brain metastases (both SRS pre-treated and treatment naïve patients) showed significant tumor uptake that was independent from the tumor of origin. The study further indicated that PET-MRI may potentially represent a non-invasive prediction of overall-survival, warranting larger studies.

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

**Authorised on behalf of the Radiopharm Theranostics board of directors by Chairman Paul Hopper.**

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