ASX ANNOUNCEMENT
22 July 2026

Radiopharm Theranostics Announces Positive Phase 2b Trial Results of RAD 101 for Diagnosis of Brain Metastases

RAD101 PET demonstrated 93% concordance with MRI across all evaluable lesions, meeting the trial's primary endpoint.

14 patients with available data from six-month follow-up and biopsy show preliminary 86% (12/14) Sensitivity (secondary objective). Specificity data will be available in Q4 2026.

The Company plans to advance RAD101 into a U.S. Phase 3 pivotal trial in Q4 2026

The imaging Brain Metastases total addressable market is ~$600+m for which there is no currently approved PET product

Sydney, Australia – 22 July 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 need, today announced positive data from all thirty evaluable patients in the Phase 2b trial of RAD101 in participants with suspected recurrence of brain metastases after radiotherapy. RAD101 is Radiopharm's novel imaging small molecule targeting fatty acid synthase (FASN) radiolabelled with Fluorine-18 for the diagnosis of suspected recurrent brain metastases from solid tumors of different origins. The data from these findings will be used to support the initiation of a pivotal multi-center, global Phase 3 imaging trial.

The analysis of the imaging data for all assessed lesions showed 93% concordance between MRI and PET imaging of brain metastases in this patient population with suspected recurrence. The results showed substantial and selective tumor uptake of RAD101. Images confirm metabolic activity in PET compared to equivocal MRI findings.

Additionally, 14 patients with evaluable six-month follow-up and/or biopsy data show preliminary 86% sensitivity, representing a strong positive trend (a secondary objective). Sensitivity measures an imaging test's ability to correctly identify patients with disease.

"The entirety of this dataset captures the strength and potential of RAD101 to address a difficult diagnostic challenge in neuro-oncology," said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. "Achieving the primary endpoint provides strong validation of our approach and supports the advancement of RAD101 into an intended registrational Phase 3 program. We look forward to continuing our discussions with the U.S. FDA as we finalize the study design and work toward bringing a more precise diagnostic tool to patients and clinicians. With this positive data in hand, we have a strong foundation from which to launch our pivotal 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 tumors outside of the central nervous system. 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. The company also recently announced a partnership with Siemens Healthineers, who will manufacture and distribute doses of 18F-labeled RAD101 to support Radiopharm's upcoming Phase 3 pivotal trial in the U.S.

About the Phase 2b Clinical Trial of RAD101

The U.S. multicenter, open-label, single arm Phase 2b clinical trial is assessing the diagnostic performance of 18F-RAD101 in 30 evaluable individuals with suspected recurrent brain metastases from solid tumors of different origins. The primary objective of the study is concordance between 18F-RAD101 PET-positive lesions and those equivocal lesions seen in conventional imaging (MRI with gadolinium) in participants with known brain metastases and suspected relapse after stereotactic radiosurgery (SRS). Secondary endpoints are sensitivity and specificity of RAD101 in identifying tumor recurrence versus radiation-associated changes in previously SRS-treated brain metastases.

About RAD101

RAD101 is the Company's novel imaging small molecule that selectively binds to fatty acid synthase (FASN), a multi-enzyme protein that catalyses de-novo fatty acid synthesis and is overexpressed in cerebral metastasis from solid tumors. Targeting FASN activity may allow for the more accurate detection of cancer cells in the CNS, 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 2b and five 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.

[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

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