ASX ANNOUNCEMENT
17 August 2026

Radiopharm Theranostics To Meet with U.S. FDA to Align on Pivotal Phase 3 Trial Design for RAD 101 in Diagnosis of Brain Metastases

RAD 101 Phase 2b trial demonstrated 93% concordance with MRI across all evaluable lesions, meeting the Phase 2 trial's primary endpoint

End-of-Phase 2 meeting with the U.S. FDA scheduled for October 1st , 2026; on track to be Phase 3 ready by year-end 2026

Sydney, Australia and MALVERN, Pa. – 17 August 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 it has scheduled an End-of-Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA) for October 1st , 2026, to align on the design of a pivotal Phase 3 trial to evaluate RAD101 in patients with suspected recurrence of brain metastases following radiotherapy. RAD101 is the Company's novel Fluorine-18-labeled small-molecule imaging agent that targets fatty acid synthase (FASN) and is being developed to diagnose suspected recurrent brain metastases arising from a range of solid tumors.

The focus of the meeting will be to align on the pivotal Phase 3 clinical trial design criteria, including the number of patients to be enrolled along with primary and secondary endpoints. The regulators will also be reviewing the data from the Phase 2b trial of RAD 101, which demonstrated 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, with images confirming metabolic activity in PET compared to equivocal MRI findings.

"We are pleased to have secured an End-of-Phase 2 meeting with the FDA for RAD101, an important milestone that brings us closer to advancing this promising imaging agent into a pivotal Phase 3 program," said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. "We believe the upcoming discussion will provide important alignment on the clinical and regulatory pathway forward, enabling us to finalize plans for a registrational study and remain on track to be Phase 3-ready by year-end. Supported by the strong Phase 2b data demonstrating 93% concordance with MRI, we believe RAD101 has the potential to address a meaningful unmet need in the diagnosis of recurrent brain metastases and create significant value for patients, clinicians, and shareholders."

RAD 101 has received 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 registrational trial in the U.S.

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]

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 2 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.

For more information:
Riccardo Canevari
CEO & Managing Director
P: +1 862 309 0293
E: rc@radiopharmtheranostics.com

Anne Marie Fields
Precision AQ (Formerly Stern IR)
E: annemarie.fields@precisionaq.com

Media
Matt Wright
NWR Communications
P: +61 451 896 420
E: matt@nwrcommunications.com.au

[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