ASX ANNOUNCEMENT
4 November 2026

Radiopharm Theranostics Announces Alignment with U.S. FDA on Single Pivotal Phase 3 Trial for RAD101 in Diagnosis of Brain Metastases

Single, multicenter Phase 3 imaging trial of approximately 280 patients with brain metastases designed to demonstrate sensitivity and specificity above prespecified performance thresholds.

Radiopharm Theranostics advancing preparations for Phase 3 study with clinical supply of 18F-labeled RAD101 from partnership with Siemens Healthineers

Company expects to complete CRO selection in the fourth quarter 2026, initiate site activations and begin dosing patients in first half 2027

Sydney, Australia– 4 November 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 receipt of the final meeting minutes following its End-of-Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA), at which the Company reached alignment with the FDA on the design of a pivotal Phase 3 trial to evaluate RAD101 in patients with indeterminate brain metastases following radiotherapy. The pivotal, multicenter single Phase 3 imaging clinical trial is expected to enroll approximately 280 patients with indeterminate brain metastases from various solid tumor types after previous radiotherapy. The co-primary endpoints of the study will be sensitivity and specificity of RAD101 PET against a defined reference standard.

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 brain metastases 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.

Regulators reviewed the data from the Company's Phase 2b trial of RAD101, which demonstrated 93% concordance between MRI and PET imaging of brain metastases in a patient population with suspected recurrence. The results showed substantial and selective tumor uptake of RAD101, with PET demonstrating tracer uptake in lesions that were equivocal on MRI.

"Accurately distinguishing recurrent tumor from treatment-related necrosis is one of the most important challenges physicians face when managing patients with brain metastases. This determination has profound implications for patient care, helping clinicians decide whether a patient requires additional intervention and treatment or can be managed with continued observation and surveillance. Existing imaging modalities often leave uncertainty, creating difficult clinical decisions for both physicians and patients. RAD101 has shown the potential to resolve diagnostic uncertainty in lesions that are equivocal on MRI, potentially offering a clearer assessment of active disease," said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. "We are grateful to the FDA for its constructive review of our clinical data and for aligning with us on a single, multicenter pivotal study design. Importantly, the approximately 280-patient trial is substantially smaller than many historical registrational imaging studies (i.e. prostate cancer imaging

agents required two Phase 3 trials and more than 700 patients combined.) We believe this reflects the significant unmet medical need faced by patients with brain metastases from solid tumors. We look forward to advancing RAD101 into this pivotal study as we work to provide physicians and patients with a more reliable tool to guide critical treatment decisions."

RAD101 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 has also announced a partnership with Siemens Healthineers, who will manufacture and distribute doses of 18F-labeled RAD101 to support the upcoming Phase 3 registrational trial in the U.S.

In the U.S. alone, there are more than 300,000 patients diagnosed annually with brain 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]

About RAD101

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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

[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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