ASX ANNOUNCEMENT
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Radiopharm Theranostics Selected for Late-Breaking Oral Presentation of Positive Data from Interim Analysis of U.S. Phase 2b Imaging Trial of RAD101 at 2026 Society of Neuro-Oncology Annual Meeting

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

Meeting with FDA planned on October 1st to align on RAD101Phase 3 pivotal trial protocol

Brain Metastases Imaging has ~$600 million total addressable market, and there are no currently approved PET products

Sydney, Australia – 14 September 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 positive data from an interim analysis of the Company's Phase 2b imaging clinical trial (NCT06777433) of 18F-RAD101 (RAD101) in participants with suspected recurrent brain metastases from solid tumors has been selected for a late-breaking oral presentation at the 31st Annual Meeting of the Society of Neuro-Oncology (SNO26), taking place from November 12-15, 2026 in Philadelphia.

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.

"Having these data selected for a late-breaking oral presentation at SNO26 is a meaningful recognition of the potential clinical importance of RAD101," said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. "The neuro-oncology community understands better than anyone the challenges associated with distinguishing active brain metastases from treatment effects using current imaging approaches. Knowing whether metastatic disease is present can fundamentally alter a patient's treatment path and prognosis. We believe these data underscore RAD101's potential to address a significant unmet need by helping physicians make more informed decisions and potentially changing the course of disease management for patients with suspected recurrent brain metastases."

Previously reported results from the Phase 2b imaging trial of RAD101 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.

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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. multi-center, 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 2 and five Phase 1 trials in a variety of solid tumor cancers including lung, breast, prostate and brain. Learn more at radiopharmtheranostics.com.

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

For more information:

Investors:
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

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Website – https://radiopharmtheranostics.com/
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