ASX ANNOUNCEMENT
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Radiopharm Theranostics Presents Interim Analysis from Phase 2b Imaging Study of RAD101 in Suspected Recurrent Brain Metastases Following Radiotherapy at the Society for Neuro-Oncology Annual Meeting

Concordance between ^{18}F-RAD101 PET and contrast-enhanced MRI (93.5% patient-level agreement); preliminary sensitivity of 85.7% against the reference standard

Favourable safety profile with no serious treatment-emergent adverse events observed in any of the 32 participants dosed
Final analyses including specificity and complete diagnostic performance on follow-up planned to be reported in Q1 2027

Recently announced alignment with the U.S. FDA for a single, multicenter Phase 3 imaging trial evaluating RAD101 in patients with indeterminate brain metastases following radiotherapy

Sydney, Australia– 16 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 that data from the Phase 2b imaging study of RAD101 in suspected recurrent brain metastases following radiotherapy were presented at the 31st Society for Neuro-Oncology (SNO) Annual Meeting, which took place from November 12-15, 2026 in Philadelphia, PA.

"We were honored to present these encouraging interim Phase 2b results at SNO before an audience of neuro-oncology experts who confront the challenge of distinguishing recurrent disease from treatment-related effects on a daily basis," said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. "For clinicians caring for patients with brain metastases, uncertainty in imaging can have profound implications for treatment decisions, making the need for more accurate diagnostic tools increasingly urgent. We believe the high concordance observed between RAD101 PET/CT and MRI, together with encouraging preliminary sensitivity data and a favorable safety profile, further supports RAD101's potential to address this critical unmet need. Following our recent alignment with the U.S. FDA on a pivotal Phase 3 imaging study, we remain focused on advancing RAD101 toward a prospective regulatory submission and are actively engaging with potential strategic partners. We look forward to reporting additional diagnostics accuracy analyses as we continue to build the evidence supporting RAD101's differentiated value."

The Phase 2b, open-label, single-dose, single-arm, multicenter imaging study enrolled 32 participants who had suspected recurrence of previously irradiated brain metastases.

The primary endpoint was concordance with MRI, which had high patient-level agreement between 18F-RAD101 PET/CT and contrast-enhanced MRI at 93.5% for all-lesion detection. For the secondary endpoint, among the 16 participants evaluable against the reference standard (histopathology or longitudinal MRI follow-up) at the interim analysis, sensitivity was 85.7%.. No treatment-emergent serious adverse events or clinically significant laboratory or ECG abnormalities were observed. The

company plans on reporting additional diagnostic accuracy data and complete diagnostic follow up in 2027.

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

RAD101 is an ^{18}F-labelled fatty acid analogue that images FASN-associated fatty acid metabolism in brain metastases. (FASN) is 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. Positive data from the Imperial College 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 provide 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.

[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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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