ASX ANNOUNCEMENT
15 December 2025

Radiopharm Theranostics Achieves Primary Endpoint in 92% of Patients at Interim Analysis of RAD 101 Phase 2b Imaging Trial in Brain Metastases

92% of evaluable patients at interim analysis treated with RAD 101 achieved concordance[1] with MRI imaging (the primary endpoint) with significant and selective tumor uptake in suspected or recurrent brain metastases

Company to host webinar on Tuesday, December 16 at 10:00 am AEDT (Australia) / Monday, December 15 at 6:00 pm EST (U.S.)

Sydney, Australia– 15 December 2025 – 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 interim data from the first twelve patients in its U.S. Phase 2b clinical imaging trial of RAD 101 in brain metastases. RAD 101 is Radiopharm's novel, small-molecule imaging agent targeting fatty acid synthase (FASN) and radiolabelled with Fluorine-18 for the diagnosis of suspected recurrent brain metastases from solid tumors of different origins, also known as the Pivalate technology.

The interim analysis showed that 92% (11/12) of the patients treated with RAD 101 achieved concordance with MRI (the primary endpoint) as assessed by PET imaging of brain metastases. The results showed significant and selective tumor uptake in the brain metastases. Images confirm metabolic activity in brain metastases compared to equivocal MRI findings.

"These compelling interim data significantly strengthen confidence in the success of our Phase II trial of RAD 101 and provide a strong foundation for initiating a pivotal study by the end of 2026," said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. "Integrating RAD 101 PET (Pivalate) with standard MRI has the potential to transform patient management and enable better treatment decisions for the more than 300,000 patients in the U.S. diagnosed with brain metastases each year. Independent commercial assessments estimate RAD 101's U.S. market opportunity at more than $500 million annually, positioning it to become one of the top three imaging agents in the market."

The Company recently achieved 50% patient enrollment in the Phase 2b trial evaluating RAD 101 imaging in brain metastases and RAD 101 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.

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.

[1] Concordance definition: "Agreement or correlation between MRI and Pivalate images"

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.[2]

WEBINAR DETAILS

AUSTRALIA
Date: Tuesday 16 December 2025
Time: 10:00am AEDT

USA
Date: Monday 15 December 2025
Time: 6.00pm EST

Presenters:

- Riccardo Canevari – CEO & Managing Director
- Dr Dimitris Voliotis – Chief Medical Officer
- Dr Harshad Kulkarni – BAMF Health, Grand Rapids, MI

Register for the webinar at the link below:
https://us02web.zoom.us/webinar/register/WN_aV5mGG4aT0embNN8JgzDOw

Please submit any questions to: matt@nwrcommunications.com.au

Upon registering attendees will receive an email containing information about joining the webinar. A recording will be available at the above link soon after the conclusion of the live session, with the replay to also be made available via Radiopharm's website and social media channels.

About the Phase 2 Clinical Trial of RAD101

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

[2] 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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About RAD101

RAD101 is the Company's novel imaging small molecule that targets fatty acid synthase (FASN), a multi-enzyme protein that catalyses fatty acid synthesis and is overexpressed in many solid tumors, including cerebral metastasis. Targeting FASN activity may allow for the more accurate detection of cancer cells, 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 four 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:

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