

Radiopharm Theranostics Achieves Primary Endpoint In 90% of Patients At Second Interim Analysis of RAD 101 Phase 2b Imaging Trial in Brain Metastases

90% of patients dosed with RAD 101 and evaluable at interim analysis achieved concordance with MRI imaging (the primary endpoint)

First five patients with available data from six-month follow-up and biopsy show encouraging trend for Sensitivity and Specificity (secondary objective)

Company to host webinar on March 25 at 9:00 am AEDT (Sydney, Melbourne) / Tuesday, March 24 at 6:00 pm EST (U.S.)

Sydney, Australia—24 March 2026 – 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 the second interim data from twenty 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.

The second interim analysis showed that 90% (18/20) of the patients dosed with RAD101 achieved concordance between PET imaging and MRI (the primary endpoint). The results showed significant and selective tumor uptake in the brain metastases. Images confirm metabolic activity in brain metastases compared to equivocal MRI findings.

In addition, the first five patients with evaluable six-month follow-up and/or biopsy data show a positive trend for sensitivity and specificity (the secondary objectives). Sensitivity and specificity are two of the fundamental hallmarks of any diagnostic test including in imaging. They measure an imaging test's ability to correctly identify patients with a disease (sensitivity, true positive rate), as well as patients without the disease (specificity, true negative rate).

“The strength and consistency of these interim results further validate the potential of RAD 101 to address one of the most challenging diagnostic gaps in neuro-oncology,” said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. “With 90% concordance demonstrated to date and encouraging early signals in sensitivity and specificity, we are increasingly confident in RAD 101’s ability to support more accurate and timely treatment decisions for patients with brain metastases. We look forward to the final data readout from the full 30-patient study by June, which will guide our path toward a pivotal trial and, ultimately, toward bringing this important imaging agent to the clinicians and patients who need it.”

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. 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

WEBINAR DETAILS

AUSTRALIA

Date: Wednesday 25 March 2026

Time: 9:00am AEDT

USA

Date: Tuesday 24 March 2026

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_Uy9zCUEhQUaMqC1rYG5Zhw

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. multicenter, 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.

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

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](#)

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:

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

Paul Hopper
Executive Chairman
P: +61 406 671 515
E: paulhopper@lifescienceportfolio.com

Media

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