

Radiopharm Theranostics Granted U.S. Food and Drug Administration Fast Track Designation for RAD101 Imaging in Brain Metastases

RAD101 in U.S. Phase 2 clinical trial to distinguish between recurrent disease and treatment effect of brain metastases originating from solid tumors of different origin

Sydney, Australia – 11 June 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 that the U.S. Food and Drug Administration (FDA) has granted Fast Track Designation for RAD101 to distinguish between recurrent disease and treatment effect of brain metastases originating from solid tumors of different origin including leptomeningeal disease.

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 metastases.

“The FDA’s Fast Track Designation for RAD101 highlights the seriousness of recurrent brain metastases as a condition and the unmet medical need for innovative products that can differentiate between tumor recurrence and radiation necrosis or pseudoprogression,” said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. “RAD101 represents a promising advancement in improving diagnostic precision for brain metastases, offering hope for more effective clinical decision-making in the over 300,000 patients diagnosed annually in the U.S. We are excited to advance our Phase 2 clinical trial and anticipate sharing topline results in the second half of 2025.”

The FDA’s Fast Track designation is designed to facilitate the development and expedite the review of drugs that are intended to treat serious or life-threatening conditions and demonstrate the potential to address an unmet medical need. A Sponsor that receives Fast Track designation may be eligible for more frequent meetings and communications with the FDA and rolling review of any application for marketing approval. A Sponsor’s drug receiving Fast Track designation also may be eligible for Priority Review if relevant criteria are met.

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

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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 three 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.

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