

New clinical trial data highlights RAD 101 (18F-Pivalate) successfully detects Brain Metastases

- **Successful detection of brain metastases using RAD 101 (18F-Pivalate) in a novel multiparametric imaging methodology (PET-mpMRI) study across 22 patients.**
- **All brain metastases, regardless of whether they were previously treated with radiation and the tumor of origin, were detected with RAD101, demonstrating a high tumor-to-background ratio.**
- **A Phase 2b imaging study to evaluate the diagnostic performance of RAD 101 in individuals with suspected recurrent brain metastases is currently recruiting in the United States.**

Sydney, Australia – 10 February 2025 – 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, is pleased to announce the publication of a novel imaging approach demonstrating proof-of-concept for the use of RAD 101 for successful detection of brain metastases (both treatment-naïve and previously treated) from a variety of primary solid tumors.

The clinical study, recently published by Islam et al. in the prestigious *European Journal of Nuclear Medicine and Molecular Imaging*¹, reports a novel methodology of detecting brain metastases using the proprietary radiotracer 18F-RAD101 in a hybrid imaging test that combines Positron Emission Tomography and Multiparametric Magnetic Resonance Imaging (PET-mpMRI). The study investigated the imaging characteristics of brain metastases in 12 treatment-naïve (no prior brain radiotherapy) patients and 10 patients who had previously been treated with brain radiation². All brain metastases, regardless of the tumor of origin, were detected with 18F-RAD101 PET-mpMRI, with a high tumor-to-background ratio.

RAD 101 is a novel imaging small molecule that targets fatty acid metabolism, which is upregulated in many solid tumors, including cerebral metastases. Targeting the transport and metabolism of fatty acid synthase, RAD 101 enables accurate detection of cancer cells, representing a viable target for the imaging of brain metastases. In October 2022, preliminary positive data from the Imperial College of London’s Phase 2a imaging trial of RAD 101 in patients with brain metastases showed significant tumor uptake that was independent from the tumor of origin³, now confirmed in the larger study.

Radiopharm’s RAD 101 Phase 2b clinical trial, entitled “An Open-Label, Single Dose, Single Arm, Multicenter Phase 2b Study to Establish the Imaging Performance of RAD101 Positron Emission Tomography (PET) in Participants with Suspected Recurrent Brain Metastases from Solid Tumors”, is

¹ Islam, S., Inglese, M., Aravind, P. et al. A hybrid [¹⁸F]fluoropivalate PET-multiparametric MRI to detect and characterise brain tumour metastases based on a permissive environment for monocarboxylate transport. *Eur J Nucl Med Mol Imaging* (2025). <https://doi.org/10.1007/s00259-025-07118-0>

² NCT04807582

³ Poster Presentation - 34th EORTC/AACR/NCI Annual Symposium, Barcelona, Spain, 26-28th October 2022

currently open and recruiting in the United States⁴. The trial is designed to evaluate the diagnostic performance of 18F-RAD101 in individuals with suspected recurrent brain metastasis from solid tumors of different origins.

“Intracranial metastases occur with a frequency four-times higher than primary tumors of the brain,” said Dr Eric Aboagye, lead inventor of RAD 101, co-author of the publication, Professor of Cancer Pharmacology & Molecular Imaging at the Imperial College of London, and Director of the CRUK-EPSRC-MRC-NIHR Comprehensive Cancer Imaging Centre. “With a poor prognosis, there is a need for improved detection and characterization of these metastases. Our work affirms the current understanding of the way in which cancers of diverse origin utilise simple short chain fatty acids compared to glucose and other nutrients in the brain environment, and how to employ this information to improve detection of metastases in the brain. 18F-RAD101 PET also provides us with opportunities to delve deeply into therapeutic opportunities.”

“The rising incidence of brain metastases is largely attributed to improved systemic cancer treatments leading to longer patient survival,” said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. “Contrast Enhanced MRI is the current standard of care but provides limited sensitivity for distinguishing disease progression from radiotherapy versus treatment effects. This is the first clinical study with 18F-RAD101 PET-mpMRI that demonstrates potentially more sensitive detection of brain metastases compared to current standard of care, offering a strong potential to improve diagnostic accuracy of suspected recurrent brain metastases.”

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 has been listed on ASX (RAD) since November 2021 and on the Nasdaq (RADX) since November 2024. The company has a deep pipeline of highly differentiated molecules spanning peptides, small molecules and monoclonal antibodies for use in cancer, in pre-clinical and clinical stages of development. The pipeline has been built based on the potential to be first-to-market or best-in-class. The clinical program includes one Phase II and three Phase I trials in a variety of solid tumour cancers including brain, lung, breast and pancreas. Learn more at radiopharmtheranostics.com.

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

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