

## **Radiopharm Completes Productive End-of-Phase 2 Meeting with U.S. Food and Drug Administration for Pivotal Development Program of RAD101**

*Constructive FDA interaction provides clear framework for RAD101 pivotal clinical development plan in brain metastases imaging*

*Currently executing Phase 3 readiness activities in anticipation of FDA meeting minutes in next 30 days*

Sydney, Australia – October 5, 2026 – Radiopharm Theranostics Limited (ASX: RAD, Nasdaq: RADX, “Radiopharm” or the “Company”), a clinical-stage radiopharmaceutical company, today announced the successful completion of an End-of-Phase 2 (EOP2) meeting with the U.S. Food and Drug Administration (FDA or the Agency) regarding RAD101, the Company's investigational radiopharmaceutical imaging agent for the detection of brain metastases.

RAD101 is the Company's novel Fluorine-18-labeled small-molecule imaging agent that targets fatty acid synthase (FASN) and is being developed to diagnose suspected recurrent brain metastases arising from a range of solid tumors. Previously reported data from the Phase 2b clinical trial showed that RAD101 demonstrated 93% concordance with MRI across all evaluable lesions, meeting the Phase 2 trial's primary endpoint.

The Company expects to receive the FDA's official meeting minutes within approximately 30 days. The minutes will provide the formal record of the meeting and the Agency's feedback on the proposed pivotal clinical development program. RAD intends to provide a further update following receipt and review of the official minutes.

“The successful completion of our End-of-Phase 2 meeting with the FDA marks a pivotal milestone for RAD101 and an important inflection point in the evolution of our company,” said Riccardo Canevari, Chief Executive Officer of Radiopharm. “The discussion was highly constructive and provided meaningful clarity on the regulatory pathway for RAD101, reinforcing our confidence in the program's potential to address a significant unmet need in brain metastases imaging. We are encouraged by the collaborative dialogue with the Agency and believe this interaction positions us well as we finalize our pivotal development strategy and take the next critical steps toward a potential registration program.”

Building on the momentum from the meeting, RAD is moving immediately to advance Phase 3 readiness activities, including clinical and operational planning, in order that the program is positioned to progress efficiently once the Agency's formal feedback is received.

“RAD101 represents a differentiated imaging approach targeting fatty acid synthase, a compelling biological mechanism that has demonstrated promising clinical potential in brain metastases,” continued Mr. Canevari. “As we prepare for pivotal development, we are also evaluating opportunities to engage with potential strategic partners who recognize the value of this program and share our vision for bringing this innovation to patients and clinicians worldwide. Given the scale of the opportunity and the maturity of the asset, we believe now is the appropriate time to explore pathways that could maximize both clinical impact and long-term value creation.”

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 also recently announced a partnership with Siemens Healthineers, who will manufacture and distribute doses of 18F-labeled RAD101 to support Radiopharm's upcoming Phase 3 registrational trial in the U.S.

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 optimize patient care.<sup>1</sup>

#### **About RAD101**

RAD101 is the Company's novel imaging small molecule that selectively binds to fatty acid synthase (FASN), a multi-enzyme protein that catalyses de-novo fatty acid synthesis and is overexpressed in cerebral metastasis 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 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 five Phase 1 trials in a variety of solid tumor cancers including lung, breast, prostate and brain. Learn more at [radiopharmtheranostics.com](http://radiopharmtheranostics.com).

#### **Forward-Looking Statements**

This announcement contains forward-looking statements, including statements regarding the planned development of RAD101, potential future clinical trials, regulatory interactions, Phase 3 readiness activities, a potential NDA submission, and potential strategic partnering opportunities. These statements are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied. RAD101 is an investigational product and has not been approved for commercial use by the FDA or any other regulatory authority.

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<sup>1</sup> [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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**Authorized on behalf of the Radiopharm Theranostics Board of Directors by Executive Chairman Paul Hopper.**

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