

## **Positive guidance from FDA Pre-IND meeting supports an IND application for a Phase 2b/3 clinical trial Imaging Brain Metastasis**

Sydney, Australia – 29 May 2023 – Radiopharm Theranostics (ASX:RAD, “Radiopharm” or the “Company”), a developer of a world-class platform of radiopharmaceutical products for both diagnostic and therapeutic uses, is pleased to announce that it has completed a positive pre-Investigational New Drug (IND) meeting with the U.S. Food and Drug Administration (FDA) for F18-pivalate (RAD 101).

This is a significant milestone towards our IND application for our late stage clinical trials. Based on positive guidance received from the U.S. FDA, the Company will file an IND application to initiate a multi-center trial for imaging brain metastasis during the third quarter of 2023 and anticipates having the first patient dosed by the end of the year.

RAD 101 is a proprietary imaging agent composed of F18 radioisotope and pivalate, a small molecule that targets fatty acid synthetase. In October 2022, positive data from the Imperial College of London’s Phase IIa imaging trial of RAD 101 in patients with brain metastases showed significant tumour uptake that was consistent with and independent from the tumour of origin. This supports the potential use of pivalate to monitor cerebral metastasis.

“Pivalate represents a new class of targeted radiopharmaceuticals with RAD 101 data demonstrating very positive performance in brain metastasis,” said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. “We are engaging with the FDA to expedite clinical development of RAD 101, considering the high unmet medical need in around 300,000 patients that are diagnosed with brain mets in the U.S. every year. Being so close to late stage development is highly exciting for us and for the medical community.”

Radiopharm holds an exclusive global license for the pivalate platform technology and also has a collaboration in place with Imperial College of London to develop a therapeutic candidate leveraging the same mechanism of action.

### **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. The company has a pipeline of six distinct and highly differentiated platform technologies spanning peptides, small molecules and monoclonal antibodies for use in cancer, in pre-clinical and clinical stages of development from some of the world’s leading universities and institutes. 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 breast, kidney and brain. Learn more at [RadiopharmTheranostics.com](https://RadiopharmTheranostics.com).

**Authorised on behalf of the Radiopharm Theranostics board of directors by Executive Chairman Paul Hopper.**

**ASX ANNOUNCEMENT  
29 MAY 2023**



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