

Phase 1 Therapeutic Non-Small Cell Lung Cancer Trial Opens 4th January 2024

- ***Successful Site Initiation at Princess Alexandra Hospital, Brisbane for RAD 204 (PDL-1 nanobody) therapeutic Phase 1 trial***
- ***Phase 1 First-In-Human study in 21 patients designed to evaluate safety and efficacy of ¹⁷⁷Lu-RAD 204 in PD-L1-positive NSCLC***
- ***Phase 1 imaging study has been completed in 16 patients confirming safety & biodistribution****
- ***Key milestone achieved for RAD 204 clinical trial preparation with patient pre-screening started***

Sydney, Australia – 22 December 2023 – Radiopharm Theranostics (ASX:RAD, “Radiopharm” or the “Company”), a clinical-stage biopharmaceutical company focused on developing innovative radiopharmaceuticals for areas of high unmet medical need, announced today that the Site Initiation Visit (SIV) was successfully completed for the RAD 204 Phase 1 study, entitled “Study of the Safety and Tolerability of ¹⁷⁷Lu-RAD 204, a Lutetium-177 Radiolabelled Single Domain Antibody Against Programmed Cell Death-Ligand 1 in Patients with Metastatic Non-small Cell Lung Cancer.”

The First-In-Human dose escalation trial of ¹⁷⁷Lu-RAD 204 is designed to evaluate the safety and efficacy of this novel radiotherapeutic in eligible individuals with advanced Non-Small Cell Lung Cancer (NSCLC), the most common type of lung cancer. The technology underpinning the trial is Radiopharm’s proprietary nanobody from its NanoMabs platform, which targets Programmed death-ligand 1 (PD-L1)-positive expression in NSCLC.

The study will be conducted at Princess Alexandra Hospital in Brisbane, Australia, with the support of leading oncology care provider GenesisCare. The clinical site, currently pre-screening eligible NSCLC patients, confirms its readiness and commitment to dose patients with ¹⁷⁷Lu-RAD 204 and will be formally activated on 4th January 2024. The first patient is expected to be dosed in January 2024.

“Approximately 300,000 new lung cancer cases will be diagnosed in the US by the end of 2023, 81% of which are estimated to be NSCLC patients¹,” said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. “Despite the major progress in advancing anti-PD1/PD-L1 immunotherapy agents for eligible NSCLC patients, we are still struggling to understand how to treat them once they become refractory to these agents. We are highly encouraged by the initial findings from the preclinical studies and Phase I imaging data in humans for ¹⁷⁷Lu-RAD 204, and as such, we believe this radiotherapeutic agent may be a game changer, as monotherapy or in combination, for the treatment of advanced NSCLC. We look forward to continuing our progress and conducting this study, with results expected in early 2025.”

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

¹ American Cancer Society. *Cancer Facts and Figures 2023*. Atlanta; American Cancer Society: 2023.

*J Nucl Med 2019 Sep;60(9):1213-1220. doi: 10.2967/jnumed.118.224170. Epub 2019 Feb 22.

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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).

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

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