

Radiopharm Theranostics Receives FDA Orphan Drug Designation for Trivehexin (RAD 301) in Pancreatic Cancer

- *Trivehexin radiopharmaceuticals being developed for imaging and treatment of cancers expressing $\alpha\beta6$ -integrin*
- *Pancreatic ductal adenocarcinoma is primary indication due to high unmet need*
- *Potential follow-on indications include non-small cell lung cancer, head and neck, and colorectal cancer*

Sydney, Australia – 9 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 the US Food and Drug Administration (FDA) has granted Orphan Drug Designation to Ga68-Trivehexin (RAD 301) radiopharmaceutical technology for imaging of patients with pancreatic ductal adenocarcinoma (PDAC).

Radiopharm is developing Trivehexin as a novel radiopharmaceutical for imaging and treatment of pancreatic cancer. Trivehexin is a proprietary peptide-based molecule that targets $\alpha\beta6$ -integrin, a cellular marker for tumor invasion and metastatic growth, the expression of which correlates with decreased survival in several carcinomas. The $\alpha\beta6$ -integrin receptor is found in high density on most pancreatic carcinoma cells, making it an attractive diagnostic and therapeutic target.

“Orphan Drug Designation for RAD 301 comes on top of FDA IND approval for a Phase I clinical trial in pancreatic cancer, which is planned to start in the next few weeks in the United States,” said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. “This important designation further reinforces the excitement of investigators conducting the study. The FDA’s decision highlights the significant demand for effective imaging agents for improved and earlier diagnosis of pancreatic cancer, which has one of the highest levels of unmet needs among all cancer types.”

The Company now holds two FDA Orphan Drug Designations, along with the LRRC15 antibody DUNP19 for the treatment of patients with osteosarcoma. Designation is granted for a drug or biologic product with the potential to diagnose, prevent or treat rare diseases and conditions. Recipients of the designation receive benefits and incentives including tax credits for qualified clinical trials, exemption from user fees and a potential seven years of market exclusivity if the drug is approved.

Radiopharm signed an exclusive licensing agreement with TRIMT GmbH for development and commercialization of RAD 301 in USA, Australia, China, Hong Kong, and Japan.

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

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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.

For more information:

Riccardo Canevari
CEO & Managing Director
P: +1 862 309 0293
E: rc@radiopharmtheranostics.com

Paul Hopper
Executive Chairman
P: +61 406 671 515
E: paulhopper@lifescienceportfolio.com

Timothy McCarthy
Investor Relations
LifeSci Advisors, LLC
P: +1 917 679 9282
E: tim@lifesciadvisors.com

Matt Wright
NWR Communications
P: +61 451 896 420
E: matt@nwrcommunications.com.au

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