

α V β 6 Integrin (RAD301) IND approval for Phase 1 trial

Sydney, Australia – 30 December 2022 – Radiopharm Theranostics (ASX:RAD), a developer of a world-class platform of radiopharmaceutical products for both diagnostic and therapeutic uses, is pleased to announce it has received US Food and Drug Administration (FDA) Investigational New Drug Application (IND) approval for its α V β 6 Integrin (RAD301) technology.

The approval allows Radiopharm to begin a Phase 1 imaging trial in ambulatory patients with pancreatic cancer, targeting commencement at the end of Q1 CY23 with an estimated close by Q3 CY23.

Radiopharm is now proceeding with clinical site preparation for the trial, with the first subject expected to be dosed at Montefiore Einstein Cancer Center (MECC) in New York.

Pancreatic cancer presents a high unmet medical need with current imaging options having several limitations. RAD301 technology has already generated significant clinical data from 88 patients dosed to date in various geographies.

Radiopharm Theranostic Chief Executive Officer & Managing Director, Riccardo Canevari, said: “We’re looking forward to working further with this peptide to prove its ability to deliver high quality imaging results in diagnosing pancreatic cancer.”

“We’re very confident we can drive the speed of recruitment for the trial and that the technology will generate a positive outcome we can push toward commercialisation,” Canevari added.

Dr Lionel S. Zuckier, MD, MBA, Principal Investigator of this clinical trial, Professor of Radiology and Division Head of Nuclear Medicine at Albert Einstein College of Medicine at Montefiore Medical Center, and a member of MECC said: “Patients with pancreatic cancer have limited therapeutic options, and on top of that face challenges in their initial diagnosis and follow up. The medical community needs improved imaging agents to facilitate optimized patient diagnosis and management.”

Early-phase clinical trials are a high priority for MECC in its drive to address the needs of its diverse Bronx community as well as patients with cancer around the nation and the world, said MECC Director Edward Chu, M.D., MMS. “For 50 years, our basic scientists have been making paradigm-shifting discoveries in the laboratory that have laid the groundwork for drug discovery and development and in particular, for translation of these discoveries into early-phase clinical trials.”

Radiopharm Theranostics and TRIMT GmbH entered into an exclusive license agreement in August 2021 to develop radiopharmaceuticals including Ga68-Integrin (RAD301).

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

For more information:

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