ASX ANNOUNCEMENT
18 NOVEMBER 2024

68Ga-RAD 301 (68Ga-Trivehexin) Demonstrates Strong Potential for Imaging of αvβ6-Integrin Expression in Pancreatic Cancer Patients

- **Clinical study of 44 patients published in 'Frontiers in Nuclear Medicine' by Dr Jana Rehm and colleagues demonstrated that Ga68-labelled RAD 301 is a safe and suitable agent for imaging in pancreatic cancer.**
- **Results indicate that the primary tumor and metastases were well-visualized with a high tumor-to-background ratio.**
- **A Phase I imaging trial (NCT05799274) with 68Ga-RAD 301 in pancreatic cancer patients to assess the safety and imaging characteristics of RAD 301 is currently ongoing.**

Sydney, Australia – 18 November 2024 – Radiopharm Theranostics (ASX:RAD, "Radiopharm" or the "Company"), a clinical-stage biopharmaceutical company focused on developing innovative oncology radiopharmaceuticals for areas of high unmet medical need, is pleased to announce that a clinical study featuring 68Ga-Trivehexin (68Ga-RAD 301), conducted by Dr. Rehm and colleagues from the Technische Universität Dresden, has now been published in Frontiers in Nuclear Medicine.

The paper, entitled "αvβ6-integrin targeted PET/CT imaging in pancreatic cancer patients using 68Ga-Trivehexin"[1], describes the clinical results of a retrospective study of the biokinetics of 68Ga-RAD 301 in pancreatic cancer patients. This 44-patient study is reported as the largest cohort of individuals imaged with RAD 301 with any tracer.

The primary tumor, as well as metastases in the liver, lymph nodes, peritoneum, lung, bone, spleen, pleural cavity, and soft tissues, were visualized with a high tumor-to-background ratio. With no adverse events recorded, the findings indicate that RAD 301 is a suitable and safe diagnostic agent for imaging αvβ6-integrin expression in pancreatic cancer.

RAD 301 is a peptide that targets αvβ6-integrin, a cellular marker for tumor invasion and metastatic growth, the expression of which correlates with decreased survival in several carcinomas, particularly pancreatic. The αvβ6-integrin receptor is found in high density on most pancreatic carcinoma and head and neck squamous carcinoma cells, making it an attractive potential diagnostic and therapeutic target in Pancreatic Ductal Adenocarcinoma (PDAC) and Head-and-Neck Squamous Cell Carcinoma[2].

A Phase I imaging trial (NCT05799274) with 68Ga-RAD 301 in PDAC patients is currently being conducted at the Montefiore Medical Center, Albert Eistein College of Medicine, NY, USA. The study will assess the safety, radiation dosimetry and imaging characteristics of RAD 301 in patients with advanced PDAC[3]. In May 2023, the FDA granted Radiopharm with an Orphan Drug Designation (ODD) for RAD 301 in pancreatic cancer.

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[1] Rehm J, Winzer R, Pretze M, Müller J, Notni J, Hempel S, Distler M, Folprecht G and Kotzerke J (2024) αvβ6-integrin targeted PET/CT imaging in pancreatic cancer patients using 68Ga-Trivehexin. Front. Nucl. Med. 4:1487602. doi: 10.3389/fnume.2024.1487602

[2] Das SS, Ahlawat S, Thakral P, Malik D, Simecek J, Cb V, Koley M, Gupta J, Sen I. Potential Efficacy of 68 Ga-Trivehexin PET/CT and Immunohistochemical Validation of αvβ6 Integrin Expression in Patients With Head and Neck Squamous Cell Carcinoma and Pancreatic Ductal Adenocarcinoma. Clin Nucl Med. 2024 Aug 1;49(8):733-740. doi: 10.1097/RLU.0000000000005278. Epub 2024 May 14. PMID: 38768077.

[3] clinicaltrials.gov/study/NCT05799274

"Current imaging standards of care for the detection of PDAC have significant limitations, making this one of the highest areas of unmet medical need and posing a major challenge for healthcare providers in imaging PDAC patients," said Riccardo Canevari, CEO and Managing Director of Radiopharm Theranostics. "These findings reinforce the clinical potential of RAD 301 as an imaging agent for the more sensitive and selective detection of pancreatic cancer and its metastases, ultimately advancing PDAC patient management."

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.

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

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