

### Press Release 02.2023

# Oncoinvent Announces Two Publications in Special Edition of *Frontiers in Medicine* Focused on Alpha Radioisotopes

Publications highlight the safety and tolerability of Radspherin<sup>®</sup> for patients and those externally exposed to radiation, all dose levels were well tolerated with dose level toxicity (DLT) not reached.

Oslo 21, April 2023

Oncoinvent AS, a clinical stage company advancing alpha emitter therapy across a variety of solid cancers, today announced the online publication of two articles in the recent special edition of Frontiers in Medicine focused on alpha radioisotopes. The first article, titled "Radiation safety considerations for the use of radium-224-calciumcarbonate-microparticles in patients with peritoneal metastasis," focuses on the effective radiation dose limit for hospital workers, carers, and the public from patients receiving <sup>224</sup>Ra-CaCO<sub>3</sub>-MP. The second, titled "First experience with <sup>224</sup>Radium-labeled microparticles (Radspherin®) after CRS-HIPEC for peritoneal metastasis in colorectal cancer (a phase 1 study)," supports the favorable safety profile of Radspherin® and establishes sustained tolerability in all dose levels for patients treated to date with colorectal cancer.

"We are excited to share these compelling and important publications in this special edition of Frontiers in Medicine, which continue to demonstrate that all dose levels of Radspherin® are well tolerated with no dose limiting toxicities to date," said Jan A. Alfheim, Chief Executive Officer of Oncoinvent. "Additionally, with these publications, we have shown that no precautions related to external exposure should be required for patients treated with <sup>224</sup>Ra-CaCO<sub>3</sub>-MP – a major risk factor to consider in radiopharmaceutical development that has now been significantly reduced. We are highly encouraged by the clinical data we have obtained to date and look forward to leveraging our expertise as a leader within the radiopharmaceutical space and progressing the clinical development of Radspherin®."

In the publication titled "Radiation safety considerations for the use of radium-224-calciumcarbonate-microparticles in patients with peritoneal metastasis," six patients with colorectal cancer from the phase 1 trial were injected with 7 MBq of <sup>224</sup>Ra-CaCO<sub>3</sub>-MP. At 3, 24, and 120 hours post injection, the patients underwent measurements with an ionization chamber and a scintillator-



based iodide detector as well as whole body gamma camera imaging. Researchers also collected urine and blood samples post injection to estimate activity concentration of <sup>224</sup>Ra and <sup>212</sup>Pb. It was found that the patients' median effective whole-body half life of <sup>224</sup>Ra-CaCO<sub>3</sub>-MP ranged from 2.6 to 3.7 days, with a mean value of 3.0 days. Importantly, in the scenarios with exposure at the hospital, sporadic patient contact resulted in a range of 3.9–6.8 μSv per patient, and daily contact resulted in 4.3–31.3 μSv depending on the scenario, suggesting that a single hospital worker can treat around 200-400 patients injected with <sup>224</sup>Ra-CaCO<sub>3</sub>-MP before external exposure is exceeded. Family members and other members of the public were expected to receive well below 0.25 mSv, thereby eliminating the need for restrictions to reduce external exposure. These data demonstrate that, due to low dose rates from the patients and low amount of activity found in blood and urine, no precautions related to external exposure are required when treating patients with Radspherin®.

In the publication titled "First experience with <sup>224</sup>Radium-labeled microparticles (Radspherin®) after CRS-HIPEC for peritoneal metastasis in colorectal cancer (a phase 1 study)," 23 patients were enrolled and administered Radspherin® at increasing activity dose levels of 1-2-4-7 over a period of 30 days. A total of 68 grade 2 adverse events were reported for 17 patients during the first 30 days; most were considered related to CRS and/or HIPEC. No DLT was documented at the 7 MBq dose level that was then defined as the recommended dose. Additionally, the biodistribution of Radspherin® showed a relatively even peritoneal distribution. These results underscore that all dose levels of Radspherin® were well tolerated, and DLT was not reached. Of note, no deaths occurred, and no serious adverse events were considered related to Radspherin®. This favorable safety profile in the current study is in line with documentation from other preclinical and clinical studies with other related alpha-emitting compounds administered intraperitoneally.

#### **About Frontiers in Medicine**

Frontiers in Medicine is a broad-scope, multidisciplinary journal covering all established medical disciplines to improve clinical practice and patient care. Led by Field Chief Editor Prof Michel Goldman (Université libre de Bruxelles, Belgium), Frontiers in Medicine welcomes basic and clinical medical research that facilitate the translation of scientific advances into new therapies or diagnostic tools. In addition to papers that provide a link between basic research and clinical practice, a particular emphasis is given to studies that are directly relevant to patient care.

#### About Radspherin®

Radspherin® is a novel alpha-emitting radioactive microsphere suspension designed for treatment of metastatic cancers in body cavities. The radium-224 based therapeutic, Radspherin® has shown strong and consistent anticancer activity at doses being essentially non-toxic in preclinical studies. It is anticipated that the product can potentially be used to treat several forms of metastatic cancer.



#### **About Oncoinvent**

Oncoinvent AS is a clinical stage company developing innovative radiopharmaceutical technology that delivers precise, alpha-emitting particles across various cancers. By leveraging internal manufacturing and supply chain capabilities to enable a clinical supply of radioisotopes, the company is advancing therapy based on alpha particles, a higher Linear Energy Transfer (LET) form of radiation, that can potentially eradicate cancer cells. Oncoinvent's lead candidate, Radspherin®, is designed for treatment of metastatic cancers in body cavities, and its versatility allows it to be deployed for the treatment of a variety of cancer indications. Radspherin® is in two ongoing clinical studies to treat peritoneal carcinomatosis from both ovarian cancer and colorectal cancer.

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