



## **Oncoinvent Announces U.S. FDA Clearance of Investigational New Drug (IND) Application for Radspherin® in Colorectal Cancer Patients**

This marks the first IND clearance for initiation of Radspherin® clinical trials in the US

Oslo, October 27, 2023

Oncoinvent AS, a clinical stage company advancing alpha emitter therapy across a variety of solid cancers, today announced that it has received clearance from the U.S. Food and Drug Administration (FDA) for its Investigational New Drug (IND) application for the phase 2b study for Radspherin® in patients with peritoneal carcinomatosis from colorectal cancer.

"We are excited to announce the IND clearance for Radspherin® for colorectal cancer patients following the promising indications of safety and efficacy from the RAD-18-002 Phase 1/2a clinical trial," said Anders Månsson, Chief Executive Officer of Oncoinvent. "This is an important corporate milestone for Oncoinvent, allowing us to clinically advance Radspherin® and expand to the U.S. landscape. Today's announcement, in conjunction with the positive clinical data supporting Radspherin®, continues to reinforce our belief in its transformative potential, and we look forward to advancing its clinical development."

In the ongoing phase 1/2a clinical trials with Radspherin®, all dose levels have to date been well tolerated and 7MBq was selected as the recommended dose. Oncoinvent recently presented preliminary 18-month safety and efficacy data from the ongoing RAD-18-002 study in patients with peritoneal carcinomatosis from colorectal cancer at the 13th International Congress on Peritoneal Surface Malignancies (PSOGI). At 18 months, none of the 12 patients who received the recommended dose of 7 MBq experienced peritoneal recurrences.

Only 2.6% of all adverse events reported were considered to be related to Radspherin®, all of which were grade 1-2.

The planned trial, for which we have now received FDA clearance, is a randomized controlled phase 2b trial, assessing efficacy and safety of Radspherin® in patients with peritoneal carcinomatosis from colorectal carcinoma following cytoreductive surgery (CRS) and hyperthermic intraperitoneal chemotherapy (HIPEC). The primary objective for the trial, planned to start in Q2 of 2024, is to compare progression-free survival (PFS) between patients following CRS and HIPEC and Radspherin® versus CRS and HIPEC.



## About Oncoinvent

Oncoinvent AS is a clinical stage company developing innovative radiopharmaceutical technology that delivers precise, alpha-emitting particles across solid cancers. By leveraging internal manufacturing and supply chain capabilities to enable a clinical supply of radioisotopes, the company is advancing a pipeline of novel products that use alpha particles, a higher Linear Energy Transfer (LET) form of radiation, that can potentially eradicate cancer cells. Oncoinvent's lead candidate, Radspherin<sup>®</sup>, 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<sup>®</sup> is in two ongoing clinical studies to treat peritoneal carcinomatosis from both ovarian cancer and colorectal cancer.

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