Press Release 4.2022

Data from the ongoing Radspherin® RAD-18-002 phase 1 trial in colorectal cancer patients to be presented at the 2022 ASCO Annual Meeting

All dose levels of Radspherin® were well tolerated with a maximum dose level toxicity not reached in the RAD-18-002 study.

Radspherin® is currently being evaluated in two ongoing Phase 1 trials for the treatment of peritoneal carcinomatosis from ovarian cancer and colorectal cancer

Oslo 26, May 2022

Oncoinvent AS, a clinical stage company advancing a pipeline of radiopharmaceutical products across a variety of solid cancers, today announced that interim safety data from its ongoing Phase 1 RAD-18-002 clinical trial assessing the dose, safety, and tolerability of Radspherin®, in patients with peritoneal carcinomatosis from colorectal carcinoma will be presented at the 2022 American Society of Clinical Oncology (ASCO) Annual Meeting, which will take place in Chicago, IL (both in-person and virtually) from June 3 to 7, 2022. The poster, titled "First experience with ^{224}Radium-labelled microparticles (Radspherin®) after CRS-HIPEC for peritoneal metastasis in colorectal cancer (a phase 1 study)" will be presented by Principle Investigator Stein Gunnar Larsen, MD during the "Gastrointestinal Cancer – Colorectal and Anal" session at 9:00 a.m. EDT on June 4, 2022.

"We are excited to share these compelling and important interim safety data at ASCO, which continues to demonstrate that all dose levels of Radspherin® are well tolerated with no dose limiting toxicities due to the Radspherin® treatment observed to date," said Jan A. Alfheim, Chief Executive Officer of Oncoinvent. "The data to be presented provides strong support as we progress Radspherin® through clinical development. In particular, the observed biodistribution of Radspherin® in this study is highly encouraging. We look forward to reporting longer-term safety, dosimetry, and first efficacy results of Radspherin® later this year."

Details of the poster presentation are as follows:

Poster Presentation Title: First experience with ^{224}Radium-labelled microparticles (radspherin) after CRS-HIPEC for peritoneal metastasis in colorectal cancer (a phase 1 study).
Session Title: Gastrointestinal Cancer – Colorectal and Anal
Date/Time: June 4, 2022 at 9:00 a.m. EDT
Presenting Author: Stein G Larsen
Abstract Number: 3599

This first-in-human Phase 1 study is designed to evaluate the safety and tolerability of Radspherin® after dose escalation at increasing levels of 1-2-4-7 MBq and explore the highest tolerated dose and biodistribution. In this planned safety interim analysis, conducted 21 days following administration at two specialized cytoreductive surgery-hyperthermic intraperitoneal chemotherapy (CRS-HIPEC) centers (Norwegian Radium Hospital and Uppsala University Hospital), a total of 23 patients were enrolled; 14 in the dose escalation cohort, 3 in the repeated cohort, and 6 in an expansion cohort. Radspherin® was injected in the abdominal cavity through an in-dwelling catheter 2 days after completion of CRS-HIPEC. The maximal tolerated dose and biodistribution were evaluated by single photo-emission computed tomography and computed tomography (SPECT/CT) imaging.

Key results:

- The biodistribution of Radspherin® showed a relatively even peritoneal distribution, and no patients had compartments of the abdominal cavity without radioactivity, and the number of hot spots were low.
- No serious adverse events were observed related to treatment with Radspherin®.
- The 7Mbq dose was selected as recommended dose as no dose limiting toxicity (DLT) was observed at this level.

Radspherin® is also being evaluated at the 7Mbq dose in a Phase 1 open-label, dose-escalation clinical trial in subjects with peritoneal carcinomatosis from ovarian cancer following complete cytoreductive surgery.

About the RAD-18-002 Study
The phase 1 open-label, dose-escalation clinical trial is designed to assess the dose, safety, and tolerability of Radspherin®, an α-emitting radionuclide therapy, administered into the intraperitoneal cavity in subjects with peritoneal carcinomatosis from colorectal carcinoma following complete cytoreductive surgery and HIPEC. Key objectives in the study include determining maximum tolerated dose, abdominal biodistribution, and preliminary anti-tumor activity. Please refer to www.clinicaltrials.gov for additional clinical trial details.

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®, 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 Phase 1 studies to treat peritoneal carcinomatosis from both ovarian cancer and colorectal cancer.

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