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

Progressing to study Radspherin® in the first-line treatment setting for ovarian cancer

IND clearance is now obtained for both lead indications for Radspherin®

Oslo, October 31, 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 2 study for Radspherin® in patients with peritoneal carcinomatosis from ovarian cancer. This represents the second U.S. FDA IND clearance for Radspherin®, as last week, the company also announced an IND acceptance for Radspherin® in patients with peritoneal carcinomatosis from colorectal cancer.

"We are thrilled to announce the IND clearance for this phase 2b study of Radspherin®, allowing for inclusion of patients in the first-line treatment setting of ovarian cancer," said Anders Månsson, Chief Executive Officer of Oncoinvent. "This IND clearance comes in succession to the IND clearance of Radspherin® in colorectal cancer patients, announced recently. With the initiation of two U.S. clinical trials, we look forward to broadening the clinical reach of Radspherin® to include both U.S. and Europe. With compelling data supporting Radspherin® from both clinical programs, we remain steadfast in our mission and eagerly anticipate moving forward to the next stages of development."

In the phase 1 clinical trial of Radspherin® in recurrent ovarian cancer patients, a recommended dose of 7MBq was selected following the completion of dose escalation. Oncoinvent recently presented initial safety data from the ongoing RAD-18-001 study evaluating the dose, safety and tolerability of Radspherin® in patients with recurrent ovarian cancer at the 24th Congress of the European Society of Gynaecological Oncology (ESGO). The trial's safety interim analysis demonstrated that Radspherin® was well tolerated with no dose-limiting toxicity observed.

The trial, for which we have now received U.S. FDA clearance, is planned to start in Q2 of 2024. It is a randomized controlled phase 2b trial, assessing efficacy and safety of Radspherin® in patients with peritoneal metastasis from ovarian cancer. The primary objective is to compare progression-free survival (PFS) between patients who receive Radspherin® after complete surgical resection following pre-operative chemotherapy and patients who only undergo pre-operative chemotherapy and surgery.

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 clinical studies to treat peritoneal carcinomatosis from both ovarian cancer and colorectal cancer.

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