Oncoinvent Announces First Patient Dosed in its Phase 2 Clinical Trial of Radspherin® in Ovarian Cancer Patients

U.S. Food and Drug Administration (FDA) recently granted Fast Track designation for Radspherin® for the treatment of patients with peritoneal metastases from ovarian cancer

Oslo, Norway 10, October 2024

Oncoinvent, a clinical stage, radiopharmaceutical company developing innovative treatments for solid cancers, today announced that the first patient has been dosed in its Phase 2 study of Radspherin® in patients with peritoneal carcinomatosis from ovarian cancer. Radspherin® is a novel alpha-radiation therapy candidate designed for targeted, local treatment of cancers that have spread to body cavities. The Phase 2 trial is a randomized controlled study designed to assess progression-free survival (PFS) in primary advanced ovarian cancer patients treated with Radspherin® following complete surgical resection and pre-operative chemotherapy.

“We are pleased to announce the dosing of the first patient in our Phase 2 study of Radspherin® in ovarian cancer patients, representing another pivotal achievement that underscores the potential of our clinical program,” said Oystein Soug, Chief Executive Officer of Oncoinvent. “This milestone builds upon the highly encouraging data from our Phase 1/2a trials in ovarian and colorectal cancer patients, where Radspherin® demonstrated promising safety and efficacy. This follows the FDA’s recently granted Fast Track designation, bringing us closer to demonstrating the therapeutic potential of Radspherin®. We look forward to advancing this clinical study as part of our mission to improve outcomes for patients suffering from peritoneal carcinomatosis.”

The Phase 2 trial (NCT06504147) is a randomized controlled study assessing the efficacy and safety of Radspherin® in patients with peritoneal metastasis from ovarian cancer. The primary objective is to compare PFS between patients who receive Radspherin® after complete surgical resection following pre-operative chemotherapy, and patients who only undergo pre-operative chemotherapy and surgery. The study is being conducted at six centers in the US, UK, Norway, Spain and Belgium. Positive Phase 1/2a data from the safety interim analysis demonstrated that Radspherin® was well tolerated with no dose-limiting toxicity observed at the recommended dose of 7MBq.

About Oncoinvent

Oncoinvent AS is a clinical stage, radiopharmaceutical company developing innovative treatments for solid cancers. The technology platform is focused on the use of alpha-emitting radionuclides to deliver powerful radiation directly to cancer cells. The Company's lead product candidate, Radspherin®, is being advanced through clinical development by a carefully composed team with experience from all stages of radiopharmaceutical development. Internal manufacturing and supply chain capabilities have been established, which now have the capacity to supply Radspherin® for multi-center phase 2 clinical studies. For additional information, please visit www.oncoinvent.com

About Radspherin®

Radspherin® is an investigational radiopharmaceutical designed for the local treatment of cancer that has spread to body cavities. It consists of billions of tiny calcium carbonate microparticles containing the radioactive material radium-224. The mode of action is the targeted delivery of alpha-particles, a highly potent form of radiation. Radspherin® is being investigated in ongoing clinical studies to treat peritoneal metastases from ovarian and colorectal cancer; it is administered intraperitoneally after surgical resection and removal of all macroscopic tumors.

Forward-Looking Statements

All statements other than statements of historical facts contained in this press release are forward-looking statements and are not a representation that Oncoinvent's plans, estimates, or expectations will be achieved. These forward-looking statements represent Oncoinvent's expectations as of the date of this press release, and Oncoinvent disclaims any obligation to update the forward-looking statements. These forward-looking statements are subject to known and unknown risks and uncertainties that may cause actual results to differ materially, including with respect to whether the results of clinical or other studies will support the use of our product offerings, the impact of results of such studies, our expectations of the reliability, accuracy and performance of our tests, or of the benefits of our tests and product offerings to patients, providers and payers.

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