Oncoinvent Receives FDA Fast Track Designation for Radspherin® as Treatment for Peritoneal Carcinomatosis from Ovarian Cancer

Phase 2b trial of Radspherin® to treat ovarian cancer patients expected to initiate imminently

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Oncoinvent ASA, a clinical stage radiopharmaceutical company advancing alpha emitter therapy across a variety of peritoneal metastases, today announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation to Radspherin® for the treatment of patients with peritoneal metastases from ovarian cancer.

"Fast Track designation for Radspherin® is a key milestone for Oncoinvent, particularly as we are on the verge of initiating a Phase 2b trial to evaluate Radspherin® in peritoneal metastases from ovarian cancer, and later also in peritoneal metastases stemming from colorectal cancer patients," said Anders Månsson, Chief Executive Officer of Oncoinvent. "Importantly, this designation reinforces the urgent need for safe and effective therapies for patients suffering from peritoneal metastases. These metastases have a particularly negative impact on life expectancy and effective treatment therefore has a significant chance of affecting overall survival in these patients. We believe we are well positioned to execute the clinical development of Radspherin® in our upcoming trial and look forward to advancing this innovative product candidate to benefit patients battling this type of cancer, for whom there are limited treatment options."

The randomized, controlled Phase 2b trial will assess the efficacy and safety of Radspherin® in patients with peritoneal metastases 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. Positive data from the Phase 1/2a safety interim analysis demonstrated that Radspherin® was well tolerated with no dose-limiting toxicity observed with the administration of the recommended dose of 7MBq.

Fast Track designation is a process that is designed to facilitate the development and expedite the review of therapies intended to treat serious conditions and address unmet medical needs to potentially bring important new medicines to patients earlier. Companies whose programs are granted Fast Track designation are eligible for more frequent interactions with the FDA during clinical development. Provided relevant criteria are met, programs with Fast Track designation are eligible for accelerated approval and priority review as well.

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 have been shown to eliminate 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.

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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