Oncoinvent Announces Positive Final Data from Phase 1/2a Trial of Radspherin® in Patients with Colorectal Peritoneal Metastases

Data demonstrate sustained peritoneal disease control and reinforce the potential of Oncoinvent's novel radiopharmaceutical therapy to target peritoneal disease in colorectal cancer

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Oncoinvent ASA, a clinical-stage radiopharmaceutical company developing innovative treatments for solid cancers, is thrilled to announce positive topline data from the Phase 1/2a clinical trial (RAD-18-002) evaluating Radspherin® in patients with peritoneal metastases originating from colorectal cancer.

Reducing peritoneal recurrence in colorectal cancer is critically important because peritoneal metastases are associated with a particularly poor prognosis and significantly lower overall survival compared to other forms of recurrence[1]. The development of peritoneal metastases is not only linked to worse survival, but also to distressing symptoms, making disease management more challenging and often resulting in treatment interruptions and repeated hospitalizations.

Standard therapies for peritoneal metastases are limited, and the only treatment option with curative intent is surgery, which aims to remove as much tumor as possible in the peritoneal cavity. However, surgical resection leaves behind microscopic deposits of cancer cells, giving rise to new peritoneal metastases and disease progression. Radspherin®, direct intraperitoneal targeting with the alpha-emitter radium-224, aims to eliminate these post-surgery micro-metastases and thereby prevent or delay peritoneal recurrence.

In this single-arm trial of 47 patients, 36 received Radspherin® at a 7 MBq dose. The primary endpoint—peritoneal recurrence-free survival (pRFS)—yielded remarkable results:

- Only **27.8%** (10 of 36) experienced peritoneal disease recurrence at 18 months, a marked reduction compared to published data for standard of care, where approximately **50%** of patients typically see peritoneal recurrence at this stage[2]
- At 18 months, **61.1%** (22 of 36) of patients had experienced any recurrence, but notably, just **22.7%** (5 of 22) had peritoneum as the first site of recurrence
- Final data from all 47 treated patients across dose levels further reinforce the favorable safety profile of Radspherin®

[1] Frøysnes et al. J Surg Oncol. 2016 Aug;114(2):222-7
[2] Quenet et al. Lancet Oncol. 2021 Feb;22(2):256-266

Additional results will be published upon completion of the full dataset analysis.

"It's highly encouraging to see patients treated with Radspherin® achieving outcomes that exceed expectations for this challenging population. As a clinician, I'm hopeful that this promising therapy will become an option I can offer to future patients in need," said Dr. Stein Gunnar Larsen, Principal Investigator at the Oslo University Hospital, Norway.

Prof. Dr. Wilhelm Graf, Principal Investigator at Uppsala University Hospital, Sweden, added: "Colorectal peritoneal metastases present a major therapeutic challenge with limited effective options, and these findings support the potential of a novel approach that demonstrates both clinical promise and a favorable safety profile."

"We are inspired and motivated by these compelling data. They reinforce our belief in Radspherin®'s potential as a novel treatment targeting peritoneal metastases and justify continued advancement of the program," said Oystein Soug, CEO of Oncoinvent. "We extend our deepest gratitude to the patients, investigators, and clinical teams who made this trial possible."

Radspherin® is currently investigated in an ongoing phase 2 trial evaluating the treatment of peritoneal carcinomatosis from ovarian cancer. A positive safety review of the lead-in cohort was announced in Q1 2025, and the trial is currently recruiting patients according to plan in European and US sites in the randomized phase.

About RAD-18-002

RAD-18-002 was an open label Phase 1/2a trial conducted in patients with colorectal peritoneal metastases. The trial was designed to evaluate dosing, safety and tolerability, and signal of efficacy of intraperitoneally administered Radspherin® following complete surgical resection and Hyperthermic Intraperitoneal Chemotherapy (HIPEC). A total of 47 patients were enrolled across sites in Norway and Sweden, with 36 patients receiving the recommended dose of 7 MBq.

About Radspherin®

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

About Oncoinvent

Oncoinvent is a clinical-stage biotechnology company developing novel radiopharmaceutical therapies against cancer. The lead product candidate, Radspherin®, uses the alpha-emitting radionuclide radium-224, directly targeting micro-metastases post-surgery, harnessing the benefits of modern radiopharmaceuticals without the complexities of biological targeting. Oncoinvent is

investigating the safety and efficacy of Radspherin® in a clinical development program in two indications. In addition to the currently finalized phase 1/2a trial in colorectal cancer, one phase 1 trial and one randomized phase 2 trial, both in ovarian cancer, are ongoing in the US, UK and Europe. Preliminary clinical efficacy data are highly encouraging, and no serious toxicity or safety concerns have been reported to date. The experienced Oncoinvent team runs a state-of-the-art manufacturing facility to produce drug products for clinical trials in Nydalen, Oslo. Oncoinvent is listed on the Euronext Growth Oslo.

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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