

# **Oncoinvent AS**

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# Safety Monitoring Committee Approves 7 MBq as Recommended Clinical Dose for Radspherin® in the Ongoing RAD-18-002 Phase 1 Trial in Colorectal Cancer Patients

7MBq dose of Radspherin® determined to be safe, and approved by the SMC as the recommended clinical dose for repeated injection and expansion cohorts of RAD-18-002 study

Oslo 9, April 2021

Oncoinvent AS, a clinical stage company advancing a pipeline of radiopharmaceutical products across a variety of solid cancers, today announced that the Safety Monitoring Committee for the RAD-18-002 clinical trial has concluded that the 7 MBq dose of Radspherin to be safe and has approved initiation of the repeated injection and expansion cohorts of the ongoing RAD-18-002 Phase 1 study in colorectal cancer patients suffering from peritoneal carcinomatosis. Radspherin an  $\alpha$ -emitting radionuclide therapy designed for treatment of metastatic cancers in body cavities, is also being evaluated in an ongoing Phase 1 study in ovarian cancer patients with peritoneal carcinomatosis.

"We are pleased that our clinical studies continue to progress on schedule and are particularly excited to move into the next phase of our ongoing RAD-18-002 study of Radspherin®," said Jan A. Alfheim, Chief Executive Officer of Oncoinvent. "The safety results seen to date in the Phase 1 trials of Radspherin® are encouraging, and we pleased to see that the sites involved in both phase 1 trials are actively recruiting patients."

The next two cohorts of the RAD-18-002 Phase 1 study including a repeated injection cohort of three subjects and an expansion cohort of six subjects will commence in the coming weeks. In the repeated injection cohort phase, patients will receive 2 injections of a split dose of of 50% of 7 MBq. The expansion cohort phase will evaluate a single dose of 7 MBq Radspherin® in 6 patients.



## About RAD-18-002

The Phase 1 open-label, dose-escalation clinical trial is designed to assess the dose, safety and tolerability of Radspherin®, an  $\alpha$ -emitting radionuclide therapy, administered into the intraperitoneal cavity in subjects with peritoneal carcinomatosis from colorectal carcinoma following complete cytoreductive surgery and HIPEC. The trial includes a dose escalation phase followed by repeated injection and expansion cohort phases at the recommended clinical dose. 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 Radspherin®

Radspherin® is a novel alpha-emitting radioactive microsphere suspension designed for treatment of metastatic cancers in body cavities. The radium-224 based therapeutic, Radspherin® has shown strong and consistent anticancer activity at doses being essentially non-toxic in preclinical studies. It is anticipated that the product can potentially be used to treat several forms of metastatic cancer.

### **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 versality 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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