# QUARTERLY REPORT 1st QUARTER 2021







### Highlights

- 7 MBq of Radspherin® is approved as Recommended Clinical Dose for in the ongoing RAD-18-002 Phase 1 trial in Colorectal Cancer Patients
- The Phase 1 Trial treating peritoneal carcinomatosis in platinum sensitive recurrent ovarian cancer patients with Radspherin® progresses to the third dose level

#### **Operational review**

During first quarter of 2021 Oncoinvent both initiated and completed the recruitment of patients in the final dose level of the ongoing RAD-18-002 Phase 1 trial, in which colorectal cancer patients suffering from peritoneal carcinomatosis were treated with Radspherin®. The Safety and Monitoring Committee (SMC) concluded that the 7 MBq dose of Radspherin® to be safe and it was recommended as the clinically relevant dose. The SMC has approved initiation of the repeated injection and expansion cohorts.

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, has commenced. In the repeated injection cohort phase, patients will receive 2 injections of a split dose of 50% of 7 MBq. The expansion cohort phase will evaluate a single dose of 7 MBq Radspherin® in 6 patients. The recruitment of patients for these two cohorts has be initiated.

During the first quarter of 2021 the company also advanced the RAD-18-001 Phase 1 trial in platinum sensitive recurrent ovarian cancer patients suffering from peritoneal carcinomatosis to the third dose level. In this cohort, patients will receive 4MBq of Radspherin®. Enrollment has begun.



The primary objective of the two ongoing studies is to identify the optimal dose of Radspherin® for treatment of peritoneal carcinomatosis. In addition to determining the safety parameters of the drug, the Phase 1 trials will enable the company to obtain key biodistribution information and, potentially, initial indication of treatment efficacy.

Radspherin®, an  $\alpha$ -emitting radionuclide therapy designed for treatment of metastatic cancers in body cavities, is a 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.

#### **Financial review**

Oncoinvent had an EBITDA of minus NOK 16.8 mill. in the 1st quarter of 2021, compared to minus NOK 13.0 in the 1st quarter of 2020. Total operating expenses during the quarter was NOK 17.1 mill an increase from NOK 13.1 mill the same period in 2020. The increase is according to plans as the company continues to grow and advance ongoing projects preparing for the next clinical trials.



KEY FIGURES	1st QUARTER		YTD		FULL YEAR
AMOUNTS IN NOK	2021	2020	2021	2020	2020
TOTAL REVENUES AND OTHER INCOME	321 544	50 000	321 544	50 000	10 377 166
Payroll and related expenses	8 194 953	6 564 801	8 194 953	6 564 801	31 401 987
Other operating expenses	8 884 942	6 492 313	8 884 942	6 492 313	34 395 890
TOTAL OPERATING EXPENSES	17 079 895	13 057 114	17 079 895	13 057 114	65 797 877
EBITDA	- 16 758 351	- 13 007 114	- 16 758 351 -	13 007 114	- 55 420 711
Depreciation and amortization	- 1 155 135	1 137 556	- 1155135	1 137 556	- 4 830 452
EBIT	- 17 913 486	- 14 144 670	- 17 913 486 -	14 144 670	- 60 251 163
Finance cost and other income	- 24 215	57 536	- 24 215	57 536	- 1 031 396
NET PROFIT(LOSS) FOR THE PERIOD	- 17 889 271	- 14 202 206	- 17 889 271 -	14 202 206	- 59 219 767
Net Proceeds from equity issue		-		-	49 568 974
Cash and cash equivalents, end of period	98 366 332	107 952 443	98 366 332	107 952 443	113 297 444
Total number of shares, beginning of period	14 314 639	13 190 411	14 314 639	13 190 411	13 190 411
Total number of shares, end of period	14 314 639	13 190 411	14 314 639	13 190 411	14 314 639

The company had NOK 98.4 mill. in cash and cash equivalents at the end of the quarter and expect to have sufficient funds to complete and present the phase I safety data as previously guided. The company is currently planning for a private placement in the second quarter to fund the upcoming Radspherin® phase 2 clinical trials.

Oslo, 10. May 2021

The Board of Directors Oncoinvent AS

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## Glossary

Cytoreductive surgery	Cytoreductive surgery is an approach to cancer treatment that aims to reduce the number of cancer cells via resection of primary tumours or metastatic deposits.
GMP	Good manufacturing practices (GMP) are the practices and quality system procedures required by regulatory agencies to ensure that the pharmaceutical products manufactured are of the quality required for their intended use.
HIPEC	Hyperthermic Intraperitoneal Chemotherapy
Intraperitoneal injection	Intraperitoneal injection or IP injection is the injection of a substance into the peritoneal cavity. The method is widely used to administer chemotherapy drugs to treat some cancers, particularly ovarian cancer.
Metastases	Metastasis is the medical term for cancer that spreads to a different part of the body from where it started.
Microparticles	Microparticles are particles between 0.1 and 100 micrometers in size. Commercially available microparticles are manufactured in a wide variety of materials, including ceramics, glass, polymers, and metals. Microparticles have been found to have widespread applications in medicine, biochemistry, colloid chemistry, and aerosol research.
Peritoneal carcinomatosis	Peritoneal carcinomatosis is a type of cancer that occurs in the peritoneum, the thin layer of tissue that covers the peritoneal cavity. The disease develops when cancers of the appendix, colon, ovaries or other organs spread to the peritoneum and cause tumors to grow.
Peritoneal cavity	The space within the abdomen that surrounds the intestines, the stomach, and the liver. It is covered by thin membranes (peritoneum).
Radspherin®	Oncoinvent's lead product candidate currently being developed to treat peritoneal carcinomatosis
Radioisotope	A radioisotope (radioactive nuclide, radionuclide, or radioactive isotope) is an atom that has excess nuclear energy, making it unstable. This excess energy can be emitted from the nucleus as gamma radiation, or create and emit from the nucleus a new particle (alpha particle or beta particle), or transfer this excess energy to one of its electrons, causing that electron to be ejected as a conversion electron. During those processes, the radionuclide is said to undergo radioactive decay and emit ionizing radiation.
Radiotherapy	The treatment of disease, especially cancer, by means of ionizing radiation.