

October 2023

## Developing a New Standard Therapy for Peritoneal Carcinomatosis (PC)

with local short-range alpha-radiation from Radspherin<sup>®</sup> micro-particles, with non-systemic administration.

## **Key Take Home Messages**

Radiopharmaceuticals is a hot-spot

A rapidly growing development area in oncology, and as such it has substantial Investor and Big Pharma focus.

#### **Oncoinvent Competency is solid**

Founders and key personnel at Oncoinvent have a proven track record of developing a radiopharmaceutical that successfully made it to market (Xofigo<sup>®</sup>).

#### Peritoneal Carcinomatosis has a high unmet medical need

A disease area with a large unmet medical need. Peritoneal metastases can originate from several cancer types, and patient numbers are significant.

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#### Radspherin<sup>®</sup> is a Pipeline in a Product

There is significant potential for this non-systemic, receptor-independent, alpha-radiation therapy, applicable in many different cancer types.

#### Standard of Care status is attainable

Radspherin<sup>®</sup> has the possibility to become Standard of Care for peritoneal metastases from an array of different cancer types – Blockbuster Potential!

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## Radiopharmaceuticals is an Investment hot-spot in Oncology



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"**RayzeBio** stock opens with a big gain, to push valuation up to \$1.4 billion"

Marketwatch 15 Sep 2023

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"Convergent Therapeutics Announces \$90 Million Series A Financing to Advance the Clinical Development of Radiopharmaceuticals for the Treatment of Prostate Cancer and Other Solid Tumors"

Cision 3 May 2023

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"Startup **Mariana** raises \$175M for radiopharmaceutical drug research"

Biopharma Dive 7 Sep 2023

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"Eli Lilly Jumps Into Radiopharmaceuticals via \$1.4B **Point Biopharma** Acquisition"

MedCity News 3 Oct 2023



## Oncoinvent has a solid foundation for the creation of next generation radiopharmaceuticals

#### Radiochemistry and preclinical expertise

The company features **solid competency** in radiopharmaceutical development with founders and key staff having a solid track-record in developing alpha-emitting therapy that made it successfully to market



#### Robust isotope supply chain

**Multiple supply sources** of Thorium-228 raw material ensure a continuous and uninterrupted supply of Radium-224



#### Innovative alpha-particle product

A suspension of  $CaCO_3$  micro-particles labeled with the alpha-emitting radioisotope Ra-224 uniquely delivers non-systemic, receptor-independent, radio-pharmaceutical therapy



#### GMP manufacturing & clinical operations

Internal GMP radiopharmaceutical manufacturing & supply capabilities. Pre-clinical and clinical studies demonstrate excellent safety and very promising long-term efficacy data

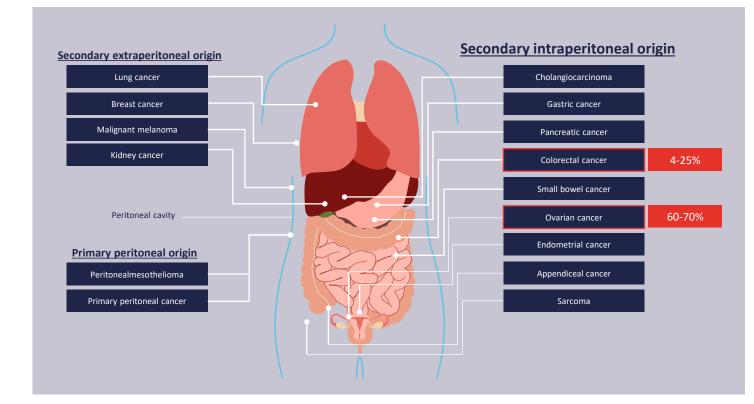


## **Peritoneal Carcinomatosis**

- A multiple cancer type disease area with a significant unmet medical need



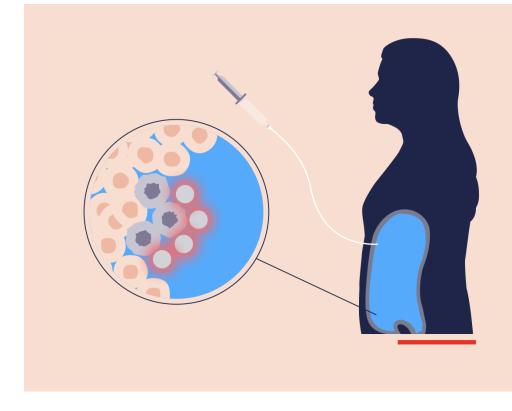
- Tumors of the peritoneum are most frequently caused by metastases from other primary cancers: ovarian and colorectal cancers are the commonest causes
- High patient burden and a dramatic impact on quality of life
- Poor prognosis and limited treatment options
- Considerable patient numbers and a significant unmet medical need!



## How Radspherin<sup>®</sup> is administered in the Clinic

- Delivering highly effective receptor-independent alpha-therapy directly to target area

- A catheter is left after Cytoreductive Surgery (CRS)
- Through that catheter a single dose of Radspherin<sup>®</sup> microparticles, dispersed in a solution, are injected directly into the peritoneum, avoiding the need for systemic administration
- The alpha-radiating microparticles spread throughout the cavity eradicating micro-metastases
- After microparticles have lost their capacity for radiation, the calcium-carbonate based carrier material is naturally dissolved, absorbed, and excreted by the body
- Easy-to-use, non-invasive radiotherapy with non-systemic administration.



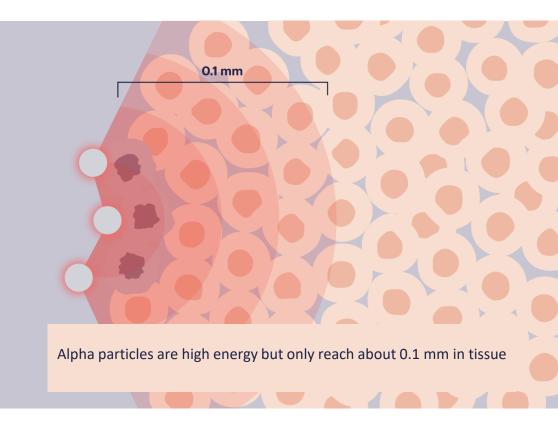
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### **Radspherin® in the treatment of Peritoneal Metastasis**

- Delivering highly effective receptor independent alpha-therapy directly to target area

- Non-systemic, single-dose, intraperitoneal Radspherin<sup>®</sup> aims to eliminate residual micro-metastases after cytoreductive surgery and thus prolong disease-free period and survival
- Effective independently of cancer cell type and cellular resistance mechanisms it is a physical treatment
- The size and slow degradation of the microparticles combined with the half-life of 3.6 days of radium-224, provides sustained treatment effect over days
- Alpha radiation is highly effective, yet short-range in tissue. Ideal for large body cavity surfaces!



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## **Radspherin® - Clinical Development**

- Clinical dose established, enrollment to phase 2a in completion



 Two Phase 1/2a studies - assessing dose, safety and tolerability, dosimetry and signal of efficacy of intraperitoneal Radspherin

RAD-18-001: Ovarian/fallopian tube cancer	<ul> <li>Oslo/Norway(PI: Yun Wang)</li> <li>Leuven, Belgium (PI: Els van Nieuwenhuysen/Ignace Vergote)</li> <li>Madrid/Pamplona, Spain (PI: Luis Chiva)</li> </ul>
RAD-18-002: Colorectal carcinoma	<ul> <li>Oslo, Norway (PI: Stein Larsen)</li> <li>Uppsala, Sweden (PI: Wilhelm Graf)</li> </ul>

For both studies, dose escalation is completed and the highest dose of 7 MBq selected, recruitment to expansion cohorts ongoing – more than 50 patients treated in total. Continued stream of follow-up data



## **Radspherin® - robust safety profile**

- Well tolerated and minimal organ toxicity

Well tolerated and considered safe to use	<ul> <li>No dose limiting toxicities observed at any dose level</li> <li>Well tolerated with only grade 1-2 events reported as possibly related to Radspherin<sup>®</sup></li> </ul>
Clinically relevant dose determined	<ul> <li>7 MBq dose determined to be safe. Single-dosing!</li> </ul>
Biodistribution measured	<ul> <li>80% of radioactivity dose remains in the peritoneal cavity</li> <li>Absorbed doses to other organs way below those associated with any toxicity</li> </ul>
Good safety profile for hospital staff	<ul> <li>Low amount of activity in blood and urine</li> <li>No precautions related to external exposure required</li> </ul>

## Clinical Phase 1/2a

- No peritoneal recurrences in recommended dose group

- Expected median time to progression after CRS-HIPEC is around 12 months
  - Meaning that 50 % of patients are expected to have recurred at 12 months

**15-months** safety and efficacy presented at ASCO 2023, June

 At the 15-month time point of follow-up, only 25% of patients that received the recommended clinical dose of Radspherin<sup>®</sup> had experienced recurrences overall, and no peritoneal recurrences had occurred in the recommended dose group

Frøysnes et al. J Surg Oncol. 2016 Aug;114(2):222-7 Quenet et al. Lancet Oncol. 2021 Feb;22(2):256-266 ASCO 2023 poster presentation, abstract number 3518

CRS: cytoreductive surgery HIPEC: heated intraperitoneal chemotherapy



### Clinical Phase 1/2a

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 At the 15-month time point of follow-up, only 25% of patients that received the recommended clinical dose of Radspherin<sup>®</sup> had experienced recurrences overall, and no peritoneal recurrences had occurred in the recommended dose group **18-months** safety and efficacy presented at PSOGI 2023, October

 At the 18-month time point of follow-up, only 33% of patients that received the recommended clinical dose of Radspherin<sup>®</sup> had experienced recurrences overall, and still no peritoneal recurrences had occurred in the recommended dose group

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## Phase 2b Target Populations in Peritoneal Carcinomatosis

#### Peritoneal Carcinomatosis

Ovarian cancer	Colorectal cancer	
~4 000 pat/year	~20 000 pat/year	Populations in Ph 2b
HRD-negative subgroup with pre-operative chemotherapy Median PFS ~12 months	Adjuvant to CRS/HIPEC Median PFS ~12 months	



## **Total Target Populations**

#### Peritoneal Carcinomatosis

Ovarian cancer	Colorectal cancer	Gastric cancer	Other peritoneal and other body cavity lesions (Bladder, Pleura)	
~4 000 pat/year	~20 000 pat/year			Populations in Ph 2b
~ 4 000 - 8 000 pat/year	~20 000 pat/year			Populations in Ph 3 / MA
Same as Ph2b or possibly extended	Same as Ph2b as it is extended to Ph2b/3			
~28 000 pat/year	~90 000 pat/year	~25 000 pat/year	Significant potential	Potential Future Expansion
HRD independent Primary & Secondary	Prophylactic after surgery for high-risk primary tumors			

## **Radspherin® Radiopharmaceutical Pricing benchmarks**

Product	PFS Benefit	OS Benefit	Price
Xofigo	N/A	3.6 m	USD 69.000
Lutathera	8.5 m	N/A	USD 190.000
Pluvicto	N/A	4.0 m	USD 255.000

PFS = Progression Free Survival, OS = Overall Survival

 Radspherin<sup>®</sup> has a targeted PFS improvement of 12 months and a minimum acceptable profile of 6 months.

## **Key tenets of the Oncoinvent Business Case**

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- Targeted Patient Population: 24.000 eligible patients per year (US & Europe)
  - CRC: 20.000 eligible patients (based on Phase 3 target only)
  - Ovarian Cancer: 4.000 eligible Patients (based on conservative, no extension, Phase 3 target only)
- Peak Penetration Estimate (assuming Standard of Care): 70% and rapid uptake
- Average Pricing Estimate given PFS Target: 50.000 USD per treatment

20% of US & Europe sales estimate added for RoW

Peak Sales Estimate (*Phase 3 target only*): 24.000 patients x 70% x 50.000 USD/pat x 120% ~ <u>1 Bill. USD</u>

**Implied future Enterprise Value:** 3-5 x Peak Sales Estimate ~ <u>3-5 Billion USD</u>

## **Peritoneal Carcinomatosis – room for further expansion**

- Addressable market, beyond ph3 target, with significant unmet medical need

#### Long-term survival rates of patients with PC Five-year survival rates in ovarian cancer<sup>2</sup> by disease stage of colorectal origin<sup>1</sup> 90% 70% 78% 39% 36% 24% 17% 2 3 1 year 3 year 5 year 1 4

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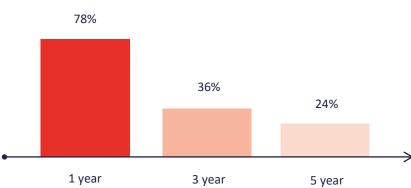
"Historically, the survival rate for gastric carcinoma patients with peritoneal carcinomatosis has been poor, ranging from 2.2 to 8.8 months and no survival at 5 years."<sup>3</sup>

1 source: <u>https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4655111/</u>

2 source: <u>http://www.cancer.org/cancer/ovariancancer/detailedguide/ovarian-cancer-survival-rates</u>

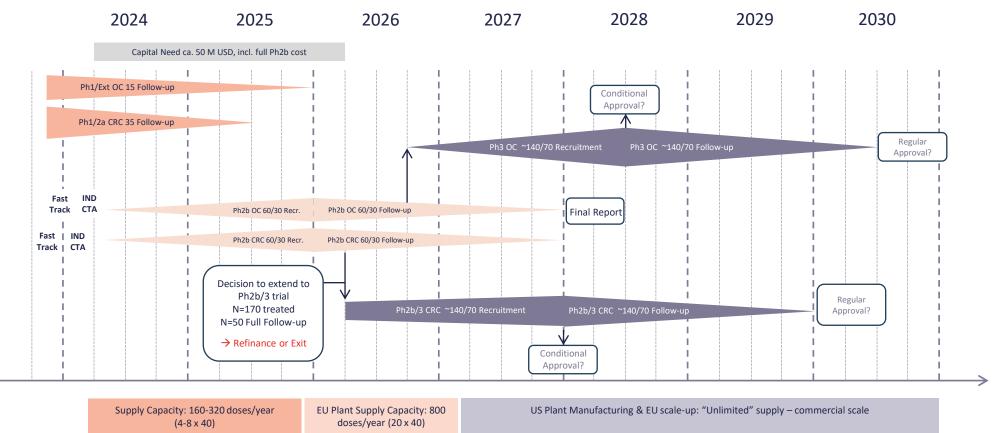
3 source: Cytoreductive Surgery and Hyperthermic Intraperitoneal Chemotherapy for Gastric Cancer - PMC (nih.gov)





## **Radspherin® Clinical Development Plan**





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## **Identified Partner Candidates**



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## **O**CO Invent

## Thank You!

Questions are more than Welcome!

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