

# Oncoinvent

Transforming cancer care through direct alpha therapy

December 2025

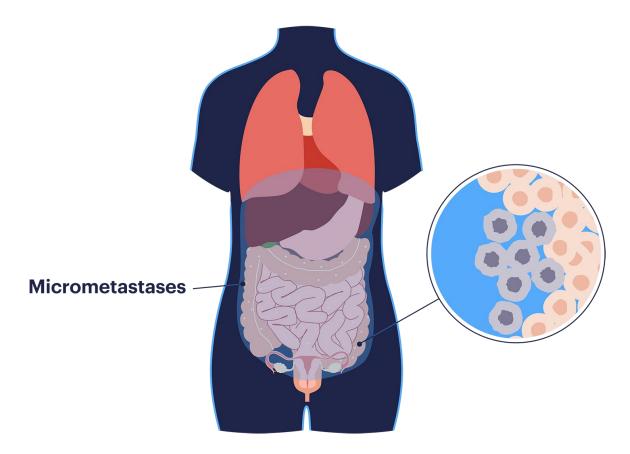
## A unique radiopharmaceutical opportunity



- 1 Targeted, non-biological, **receptor independent** mode of action with alpha emitter
  - 2 Signals of efficacy: potential game changer in ovarian and colorectal cancers
    - 3 In Phase 2 in ovarian cancer
    - 4 High unmet need and limited competition
  - Developed by radiopharma **pioneers** and serial-entrepreneurs

## Peritoneal metastases - urgent need for novel treatments





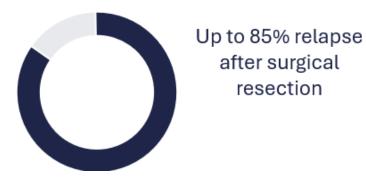
- Peritoneal metastases arise from many different primary cancers
- The only treatment option with curative intent is surgery, effect of systemic therapy limited
- Surgery leaves behind micro-metastases giving rise to new metastases and disease progression
- Peritoneal metastases are confined to the peritoneum creating a 'closed compartment'

#### The main cause of death in ovarian cancer





70% of all ovarian cancer patients have peritoneal metastasis at diagnosis



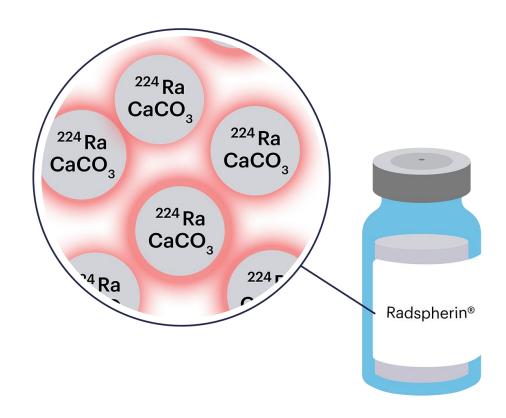
- Despite a comprehensive treatment approach, the majority of patients experience disease recurrence
- Ovarian cancer rarely metastasize hematogenously, recurrences almost exclusively confined to the peritoneum
- Need for improved first-line treatments that keep patients in remission – local control in the peritoneum is key to improving life expectancy
- FDA Fast Track

## Radspherin® - alpha therapy targeted to and retained in the peritoneum



#### Radspherin®

- Combining alpha-emitting <sup>224</sup>Ra with CaCO<sub>3</sub> microparticles
- Half-life 3.6 days
- Therapy with depot effect 75% of radiation dose delivered the first week
- Shelf life 8 days allowing for centralized manufacturing
- Good raw material availability and simple manufacturing



## Radspherin® - alpha therapy targeted to and retained in the peritoneum

CaCO

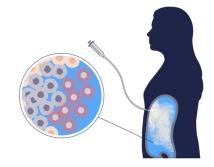


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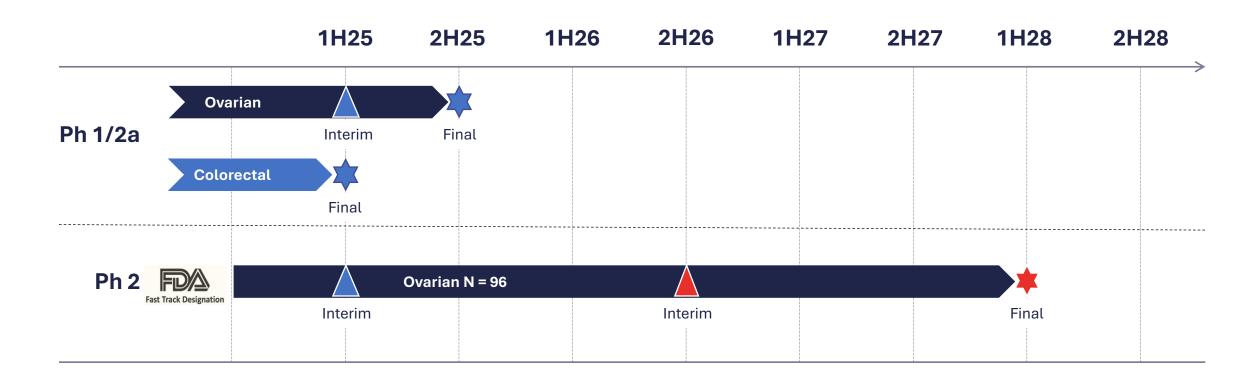
#### How does it work?

- Delivering a high dose of alpha-radiation directly to the peritoneum through an indwelling catheter
- Administration 1-3 days post-surgery
- High energy and short radiation range enables effective killing of the targeted metastases while sparing the surrounding normal tissue



## Ongoing clinical development



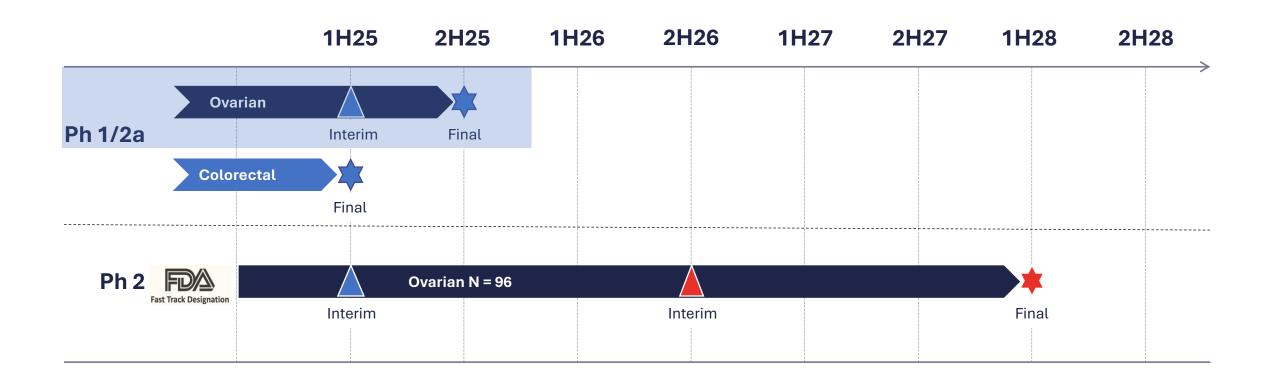


Completed

**Upcoming milestones** 

## Ongoing clinical development





Completed

**Upcoming milestones** 

## Radspherin® - phase 1 study in ovarian cancer

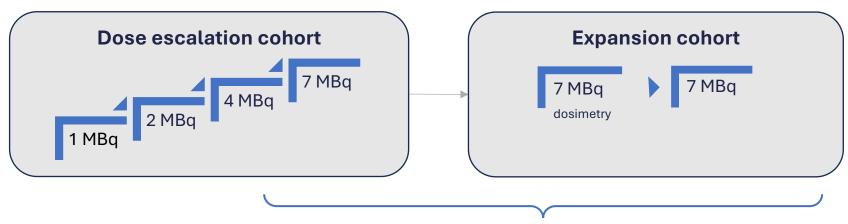


**RAD-18-001:** in patients after secondary debulking surgery of platinum-sensitive recurrent ovarian cancer

- single-arm open label study
- 3 + 3 dose-escalation (1, 2, 4, 7 MBq)
- 24 months follow-up

#### 4 clinical sites:

- Oslo, Norway(PI: Yun Wang)
- Leuven, Belgium (PI: Els van Nieuwenhuysen)
- Madrid, Spain (PI: Luis Chiva)
- Pamplona, Spain (PI: Luis Chiva)



Total number of patients recommended dose 7MBq, **n=10** 

## Ovarian cancer: Preventing disease progression

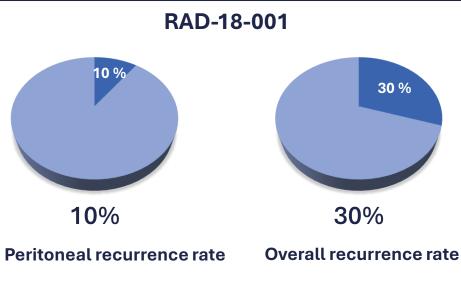


#### 24 months data from 10 patients receiving 7 MBq dose vs historical recurrence rates

## Recurrence rate

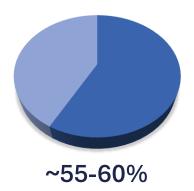
"These final results are truly encouraging, suggesting that Radspherin® could help delay disease progression and offer patients hope for longer, healthier lives."

Dr Luis Chiva, Principal Investigator and Director of Department of Obstetrics and Gynecology Clinica Universidad de Navarra



 One patient with recurrence Additionally, two lymph node recurrences

#### **Historical controls**



Overall recurrence rate\*

\*Peritoneal recurrence rates or distribution of recurrences not available in historical control

## Ongoing clinical development





Completed

**Upcoming milestones** 

## Design: Phase 1/2a in colorectal cancer

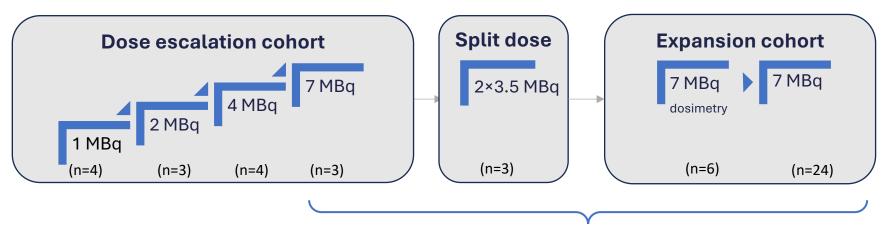


**The trial:** (RAD-18-002) Radspherin after cytoreductive surgery and HIPEC in patients with peritoneal metastasis from colorectal cancer

- Single-arm open label study
- 3 + 3 dose-escalation (1, 2, 4, 7 MBq)
- 18 months follow-up

#### Two clinical sites:

- Oslo, Norway (PI: Stein Larsen)
- Uppsala, Sweden (PI: Wilhelm Graf)



Total number of patients recommended dose 7MBq, **n=36** 

## Colorectal cancer: final phase 1/2a data confirm peritoneal control

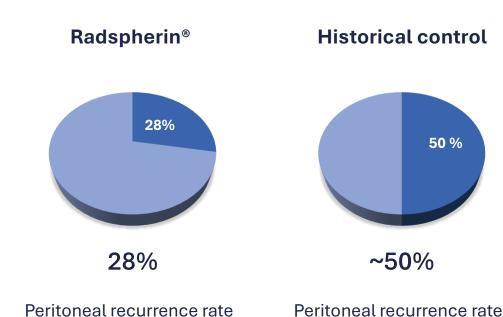


#### Topline 18-months data of 36 patients receiving 7 MBq dose vs historical recurrence rates

#### Peritoneal recurrence rate

"It's highly encouraging to see patients treated with Radspherin achieving outcomes that exceed expectations for this challenging population."

Dr. Stein Gunnar Larsen Principal Investigator at the Oslo University Hospital, Norway



14 Quenet et al. Lancet Oncol. 2021 Feb;22(2):256-266

## Controlling peritoneal disease may significantly improve survival in colorectal cancer



First disease recurrence after treatment 1

Impact of site of first site of recurrence <sup>1</sup>

1/3 peritoneal only

1/3 combined peritoneal and distant

1/3 distant only

## Median overall survival - from the time of recurrence:

After distant metastasis only: 44 months
After peritoneal metastasis: 22 months

## 5-year overall survival – from the time of treatment

Distant metastasis only: 53 %Peritoneal metastasis: 19 %

## Strong safety profile demonstrated in the completed phase 1/2a studies in ovarian and colorectal cancer



- Well tolerated and safe
- No dose limiting toxicity
- Only two SAEs possibly related to Radspherin\*

- No evidence of systemic radiation toxicity
- Radiation dose retained in the peritoneal cavity
- Absorbed doses to other organs well below toxicity levels

Low exposure for hospital staff

- Low radioactivity dose in blood and urine
- No precautions related to external exposure required

## Microparticle retention limits off-target organ exposure



- Absorbed doses below 1 Gy\* for all organs measured
  - Highest absorbed doses to organs at risk for endosteal bone surface cells, followed by kidney, liver, and red bone marrow
- No signs of hematological, kidney or liver toxicity observed in clinical studies

Tissue	Tolerance levels for external beam radiotherapy	Corresponding administered activity of Radspherin (MBq)*
Colon	< 11 Gy	>800
Small intestine	≤ 15 Gy	>1 000
Stomach	≤ 45 Gy	>3 500
Liver	≤ 30 Gy	>150
Kidney	< 20 Gy	~100
	Threshold for possible major hematotoxicity	
Red bone marrow	≤ 2 Gy	~20

## Near-term significant milestone



Phase 2 ovarian cancer

2H26: First randomized interim data

• 2028: Final data



Phase 1 ovarian cancer

- Final 24 months data
- 10 patients 7 MBq
- October 2025



Phase 1/2a colorectal cancer

- Final 18 months data
- 36 patients 7 MBq
- June 2025

## Ongoing clinical development





Completed

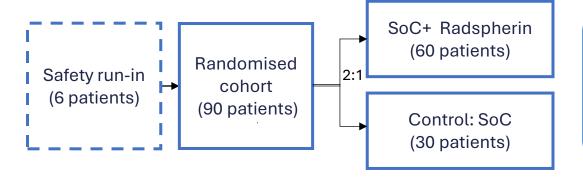
**Upcoming milestones** 

### Phase 2 study in ovarian cancer – enrollment on track 6 centers active - more sites to be included



#### **Patients**

- with peritoneal metastases
- after neoadjuvant chemotherapy
- eligible for complete resection (R0)
- with HRD negative ovarian cancer



6 study sites actively enrolling: NO, BE, ES (2), UK, US











More sites to be included

Assessment every 3 months up to 24 months. including CT/MRI

Long-term follow- up for up to 5 years according to standard of care

pPFS OS **TFST TSST** Safety **AESI** 

QoL **Biomarkers** 

**PFS** 

## Peritoneal metastases represent a significant market opportunity



#### High addressable patient number

- Large number of patients ovarian and colorectal cancer patients in US and Europe
- Treatment is receptor- and targetindependent –effective for peritoneal cancers regardless of origin – i.e., gastric cancer; orphan indication in the US, highly frequent in Asia, and prophylactic in highrisk patients
  - Significant potential for label expansion
- Future opportunities for tailoring to treatment of cancers in other body cavities

#### **Limited competition**

- Distinguished by its unique mechanism of action
- Untapped market no modern therapies and limited industry development in the specific area of peritoneal metastases
- Strategic advantage: complementing cytoreductive surgery, reduced threats from new therapies

#### Adds perfectly to existing patient flow

- Surgery is and will remain the cornerstone of treatment
- Treatment given 1-3 days post-operative while the patient is still hospitalized
- Simple and quick bedside administration
- Single and localized administration sustained therapeutic efficacy and decreased risk for off-target effects

Potential for Radspherin® to emerge as a leading treatment option for patients with resectable peritoneal metastases

## Effective targeting in radionuclide therapy

Delivering high doses to tumors while protecting healthy tissue

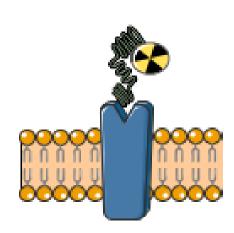


#### **Natural homing**

# New abnormal bone formation (woven bone) Range of alpha particle Osteoblasts Radium-223 binds with hydroxyapatite and is incorporated into the bone matrix Prostate cancer cells Radium-223

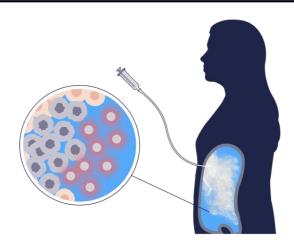
- Simple, proven in routine clinical practice, selective for tissues
- Limited to diseases with natural avidity, less adaptable
- Xofigo for bone metastases, radioactive iodine-131 for thyroid cancer

#### Molecular targeting



- Selective, personalized, treats systemic disseminated disease
- Expensive, requires specific targeting molecules and chelators, risk of off-target effects
- Lutathera, Pluvicto

#### **Direct delivery**

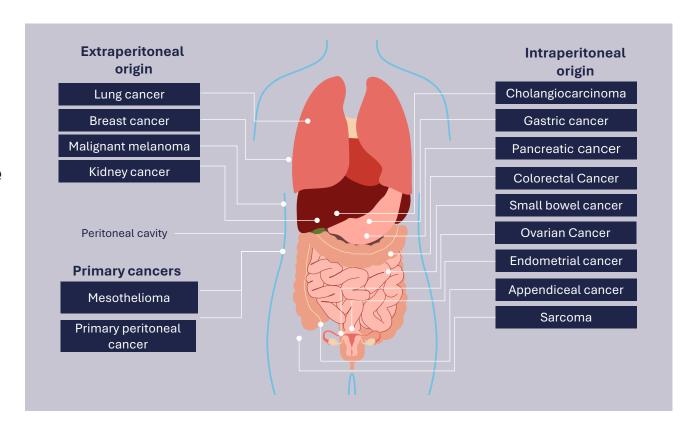


- High local concentration, minimal systemic toxicity
- Requires direct access to site, not suitable for systemic disseminated disease
- Radspherin®, TheraSphere,
   REYOBIC

## Pipeline in one product - broad clinical application



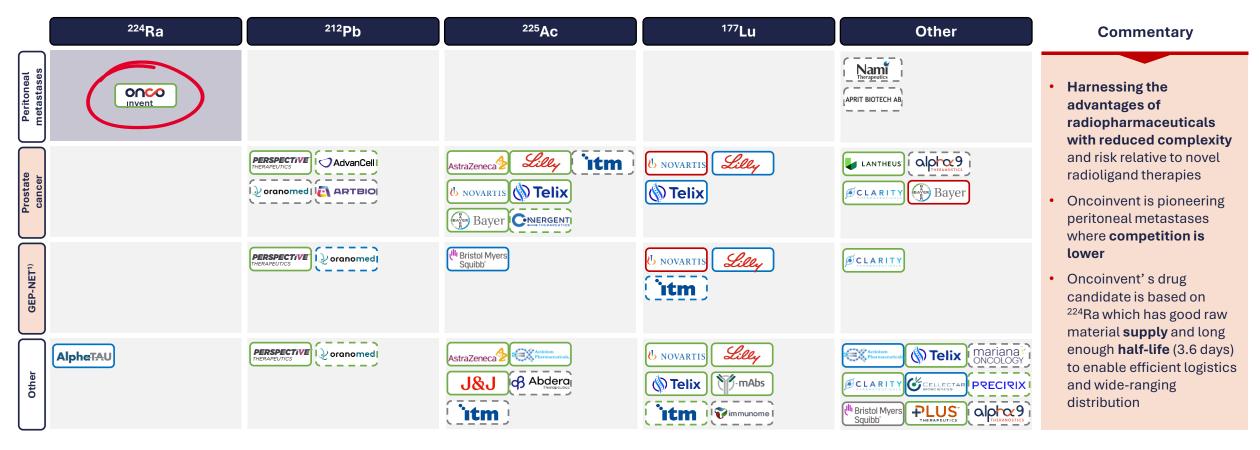
- Peritoneal metastases arise from many different cancers
- Radspherin® is a receptor-independent treatment:
  - effective regardless of the origin of the primary malignancy



# While the radiopharma sector is largely concentrated in two indications, Oncoinvent pursues peritoneal metastases



#### **Snapshot of the Radiopharma Landscape**



## Targeting by proximity – brilliant in its simplicity



#### **Bypasses**

the need of biological targeting and systemic distribution of the radioactive payload



#### Retains

the radioactive payload in the target area



#### Increases

the radionuclide exposure at the tumor target sites



#### Reduces

the radionuclide exposure to radiation sensitive organs

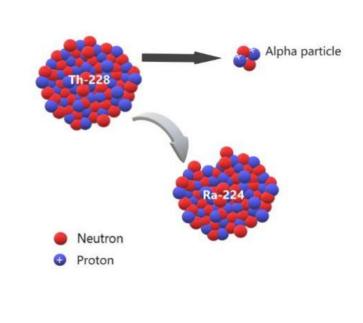


## In-house GMP pilot plant with attractive capabilities





Oncoinvent has in-house GMP production capability



<sup>224</sup>Ra produced from <sup>228</sup>Th, which has multiple sources



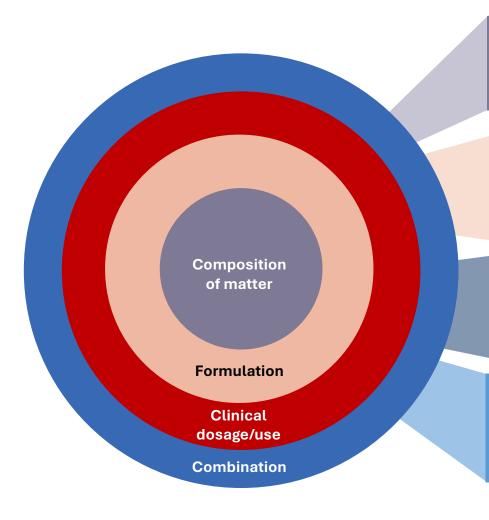
Microparticles and finished goods produced in-house

- Capacity of ~200 doses Radspherin annually, outsourcing and scale-up required for phase 3
  - On selective basis offer GMP laboratory services to similar non-competing companies

GMP: Good manufacturing practice 28

## Radspherin® - solid multilayer intellectual property protection





#### Radspherin® composition of matter & use

- Granted in US, EU, China, Japan and additional countries
- Patent expiry 2035 (2036 in some countries) with an option for 5 years extension

#### Radspherin® formulation

- Filed in 2021 in: USA, Europe, Japan, China, Canada, India, Mexico, Hong Kong
- Patent expiry 2041 with an option for 5 years extension

#### Radspherin® clinical doses, application: use patent

- Filed in January 2024
- Patent expiry: 2044 with an option for 5 years extension

#### Radium-224 combination with PARP inhibitors

- Filed in 2020 in: USA, Europe
- Patent expiry 2041 with an option for 5 years extension

## Radiopharmaceutical expertise at all levels



#### Scientific founders





Roy Larsen

Øyvind Bruland





#### Management





















**Chief Operations Officer** ALGETA



Kari Myren Chief Medical Officer **U** NOVARTIS

Roche

Tore Kvam Chief Financial Officer

• SYKEHUSAPOTEKENE KPMG Institut: for energitekniki Gjensidige 👔



Chief Production Officer

Head of Regulatory Affairs PHARMAQ

SMERUD Hedical Research

**Board** 



Gillies O'Bryan-Tear

Fusion



Kari Grønås





Ingrid Teigland Akay







Anne Cecilie Alvik







🎎 ALGETA

Hilde Steineger

**D** · BASF



∠ Zenas
BioPharma MIRATI

Orlando Oliveira

Johan Häggblad



Olav Hellebo **BerGenBio** ReNeuron

## A unique radiopharmaceutical opportunity



- 1 Experienced **team** with track record from radiopharmaceutical developments and exits
  - Targeted, non-biological, receptor independent lower risk mode of action

3 Compatible with established treatment regimes - adds well to existing patient flow

4 Signals of efficacy: potential game changer in ovarian and colorectal cancers

**High unmet need** and limited competition