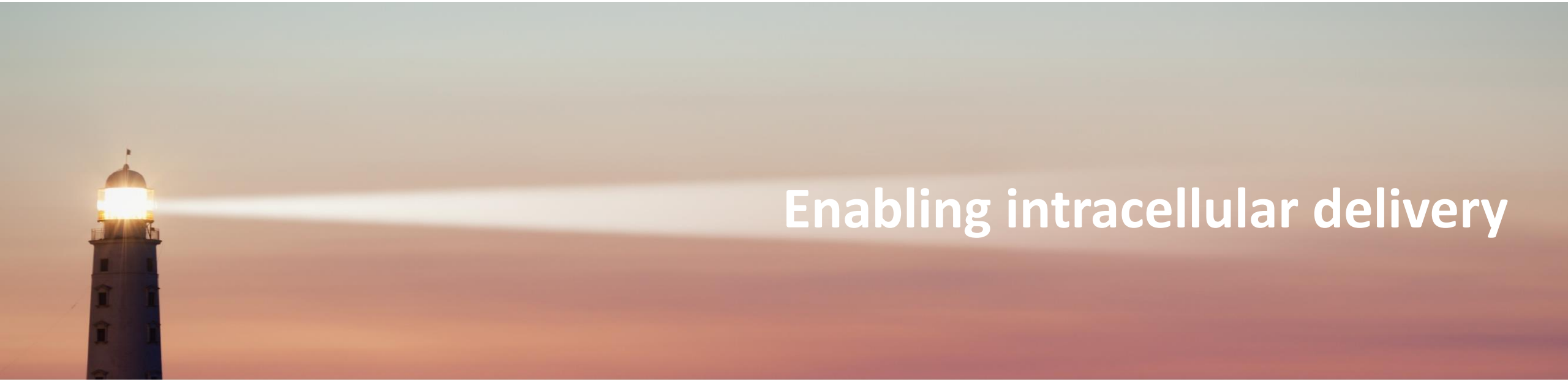
PCI Biotech



NORDIC RARE DISEASE SEMINAR

ABG Sundal Collier – November 29, 2021

Per Walday, CEO

PCI BIOTECH

- Important notice and disclaimer

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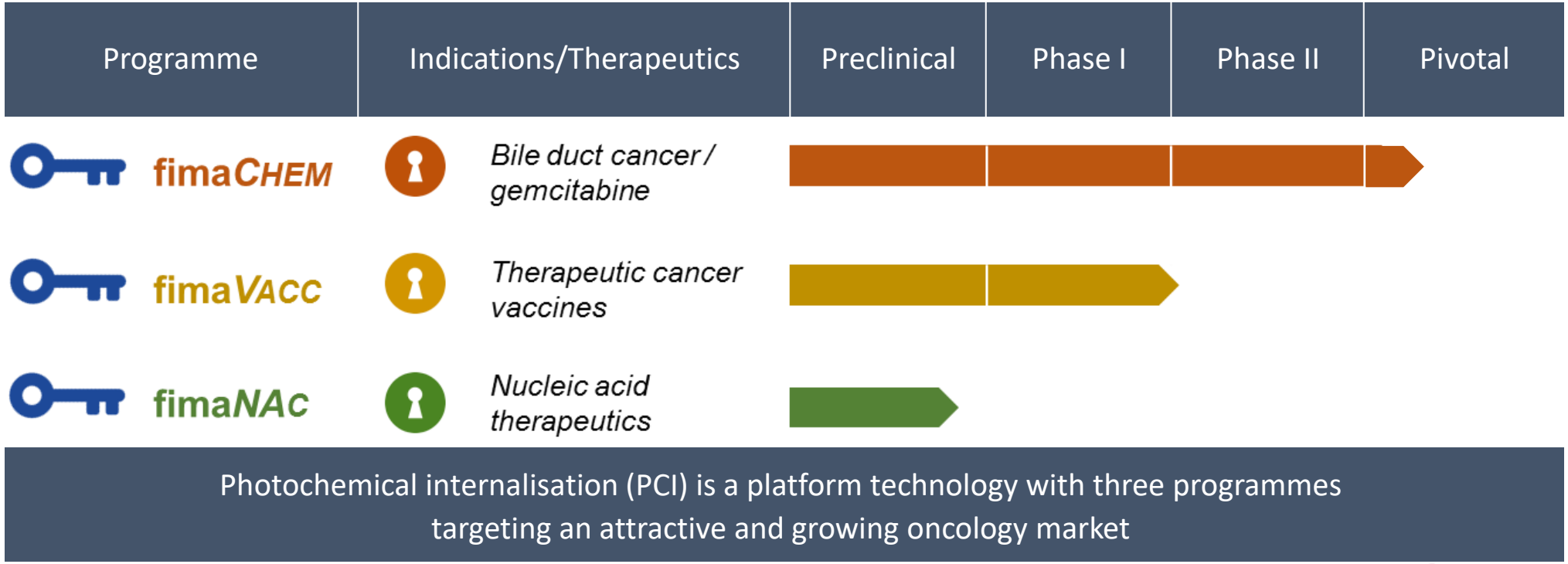
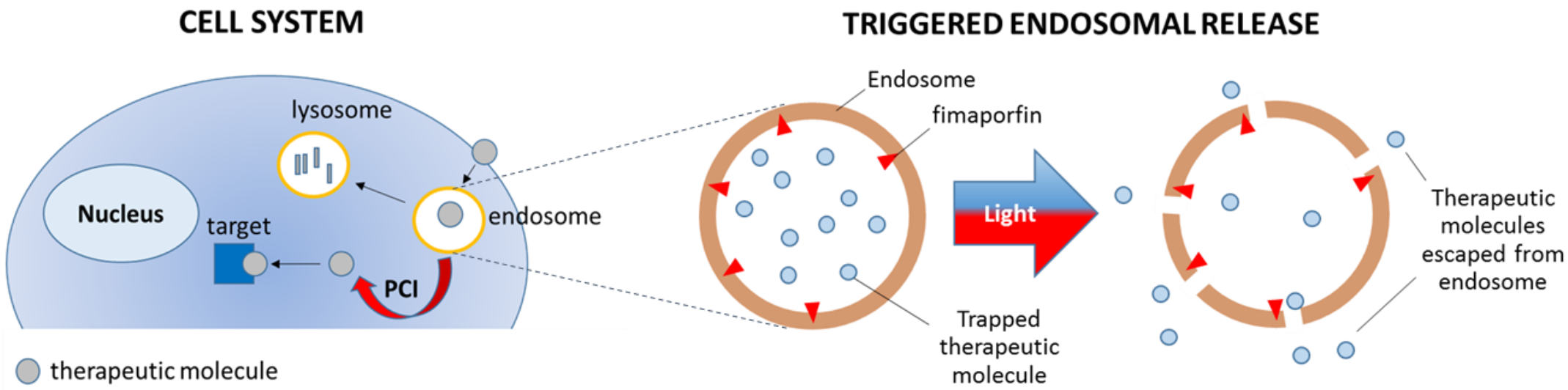
PCI Biotech – enabling intracellular delivery

- A biotech company with an oncology focused pipeline
  - A listed (PCIB:NO) cancer-focused biotech company
  - Cash position at Q3: NOK 135 mill
  - Photochemical internalisation ("PCI") technology
  - One platform technology with three well differentiated assets



PCI TECHNOLOGY – MODE OF ACTION

- Enabling drugs to reach intracellular therapeutic targets



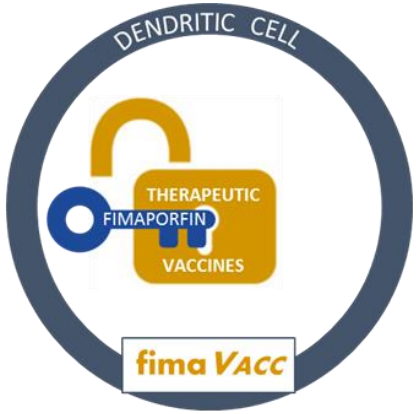
- Small molecules (chemotherapeutics – **fima*CHEM***)
- Antigens (peptides/proteins – **fima*VACC***)
- Nucleic acids (mRNA, RNAi – **fima*NAc***)

PCI TECHNOLOGY

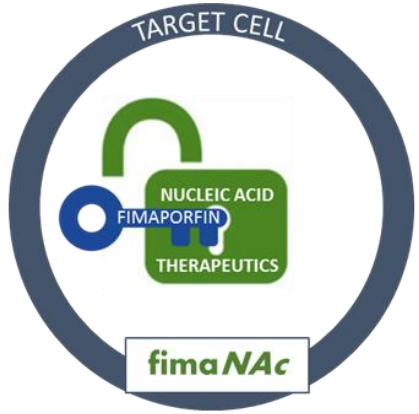
- Enabling drugs to reach intracellular therapeutic targets

PCI – the solution to a key challenge for several modalities

Enabling approved drugs to fulfil unmet local treatment need



Enhancing cellular immune responses important for therapeutic effect



Providing a delivery solution for nucleic acid therapeutics

PCI BIOTECH

- **fimaCHEM** – first line treatment for the orphan indication bile duct cancer

Positive early clinical results

- Encouraging tumour response and survival data

Pathway to market settled by regulatory interactions

- Single pivotal study with potential accelerated approval based on interim analysis

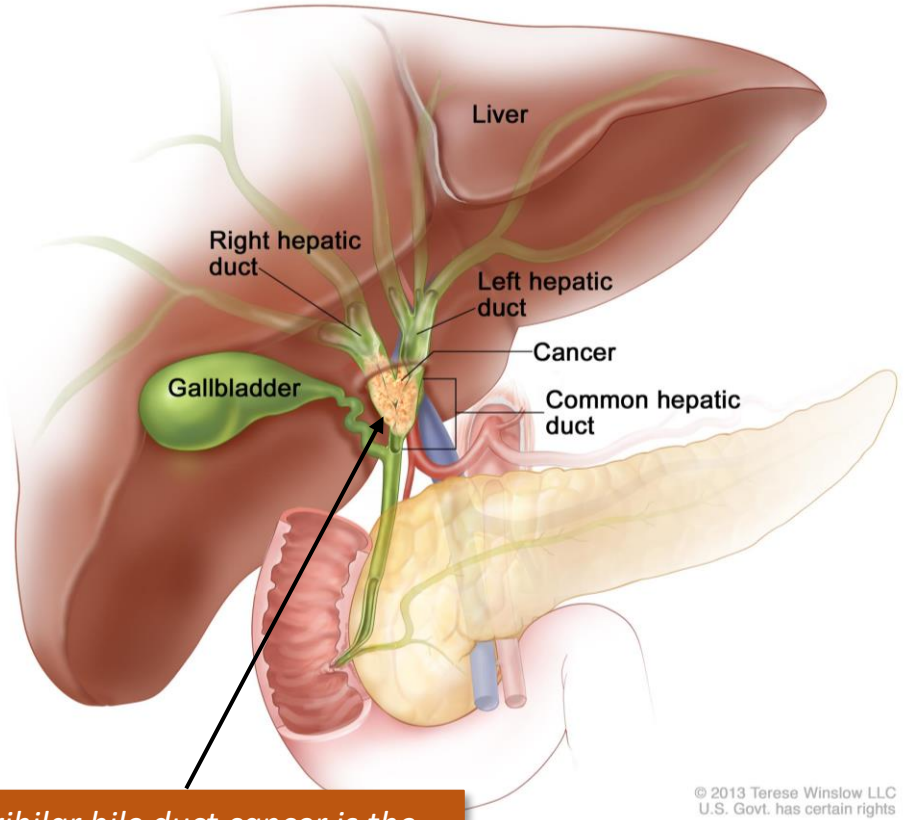
RELEASE – a global pivotal registration intent study

- Recruitment ongoing at approx. 50 hospitals across three continents

BILE DUCT CANCER

- Incidence, location and classification

- Rare disease: 1-2/100,000 in Western world
- Often referred to as cholangiocarcinoma
- The cancer cells originates from the cells inside the bile duct (called cholangiocytes)
- Cholangiocarcinoma includes:
  - Intrahepatic tumours (10%[1])
  - Perihilar tumours (60-70%[1])
  - Distal tumours (20-30%[1])
  - Different incidence, pathobiology and management



Perihilar bile duct cancer is the main target for PCI treatment

1) Bile duct cancer, American Cancer Society, 30 October 2013

fimaCHEM

- Excellent fit with medical need and existing treatments

  - **Efficacy:** mOS[1] of **22.8 months** at selected dose (cohort IV) in Phase I dose-escalation (vs. **11-12 months**[2] with standard of care for inoperable bile duct cancer treatments)

  - **Easy to use:** Illumination through standard endoscopic methods compatible with endoscopic stenting for palliative biliary drainage

  - **Positioning:** Enhances recommended first-line chemotherapy and boosts effect locally, where it is most needed (no direct competition)

  - **Protection:** Orphan Drug designations in EU, US and South Korea offers market exclusivity, and use patent for treatment method approved in Europe (pending in other major markets)

  - **Competition:** Limited pipeline – three other products in commercial pivotal development (acelarin, durvalumab & pembrolizumab), but otherwise mainly precision/gene/small molecules in second line or towards targets mainly present in intrahepatic bile duct cancer

1) Median overall survival 2) New England Journal of Medicine 2010;362:1273-8 3) EvaluatePharma® Orphan Drug Report 2019

BILE DUCT CANCER – PHASE I DOSE-ESCALATION STUDY

- Positive early signs of efficacy – median Overall Survival of 22.8 months at selected dose

- Encouraging tumour response and survival in Cohort IV, with a single **fimaCHEM** treatment
- Half of the patients in Cohort IV survived >30 months
- Cohort IV dose has been selected for the pivotal RELEASE study
- Safety of two **fimaCHEM** treatments provided in a Phase I Extension
- Results paved the way for a study with interim analysis for potential accelerated approval
- Phase I case reports published in peer-reviewed medical journal (open access)*

*Endoscopy International Open, December 2020; 08: E1878–E1883 (DOI 10.1055/a-1276-6366)

BILE DUCT CANCER – RELEASE STUDY

- Pivotal study with potential accelerated/conditional approval on interim analysis

First line treatment for patients with inoperable extraheptic bile duct cancer, without brain or bone metastases

- Rare disease
- More common disease in Asia
- Limited development pipeline

(N=186)
1:1 randomisation

- Approx. 50 clinical sites planned
- Across 11 European countries, 2 Asian countries + USA

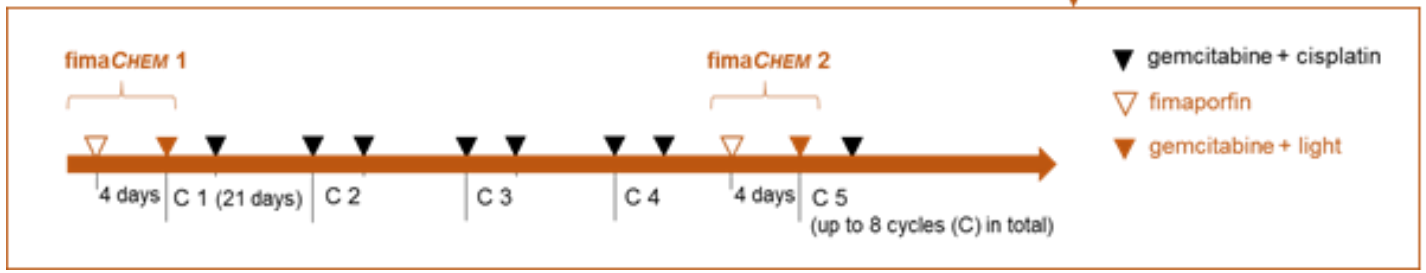
Control (N=93)

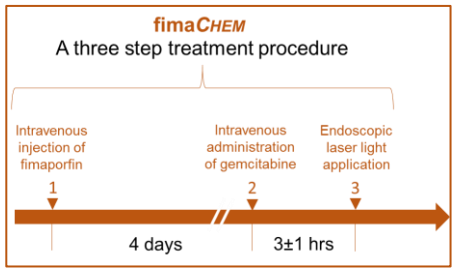
Standard of care (SoC):
gemcitabine + cisplatin
up to 8 cycles

Experimental (N=93)

Up to 2 doses of fimaCHEM +
Standard of Care (SoC)
up to 8 cycles

- **fimaCHEM** in addition to current Standard of Care

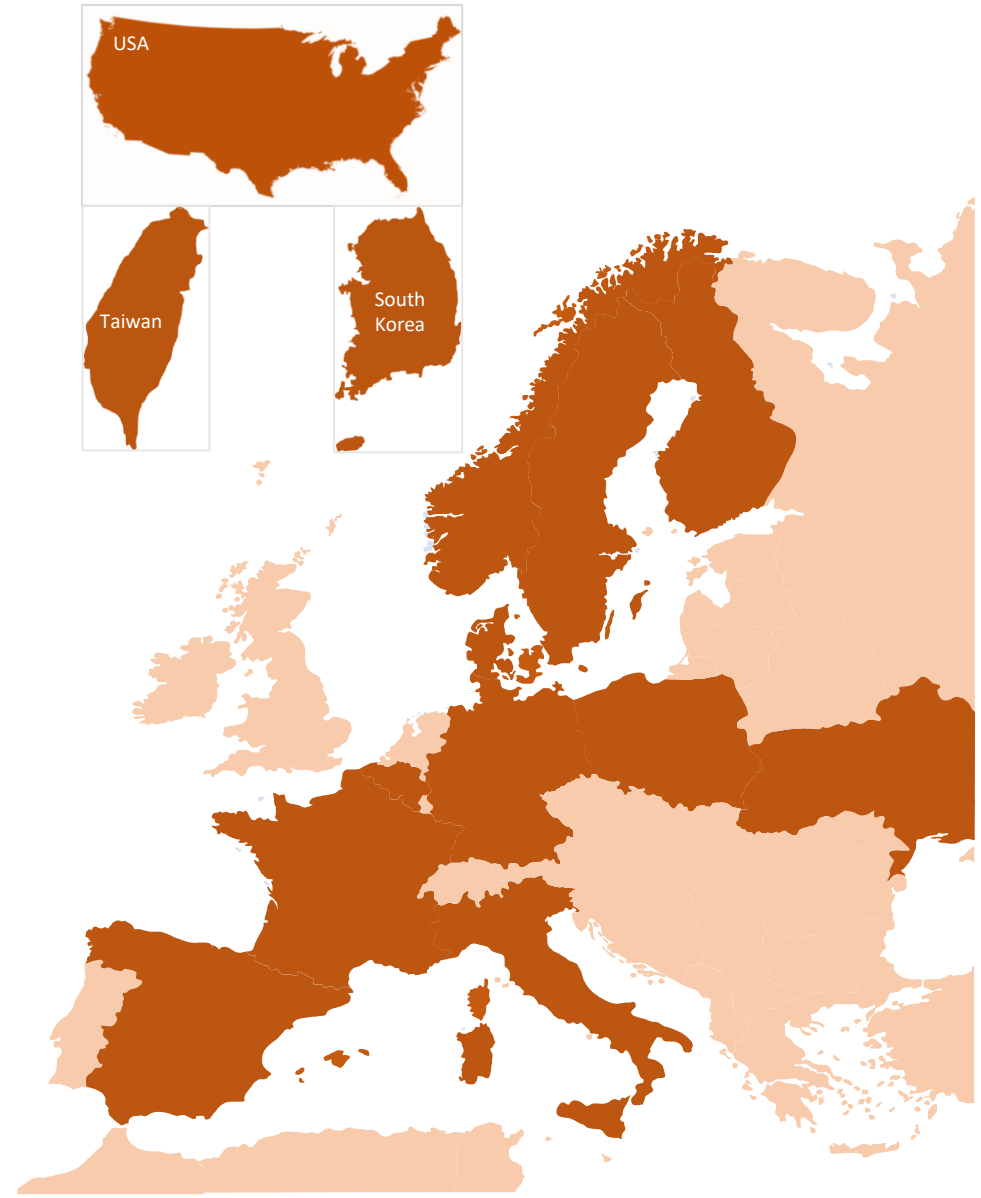




Bile Duct Cancer – Release Study

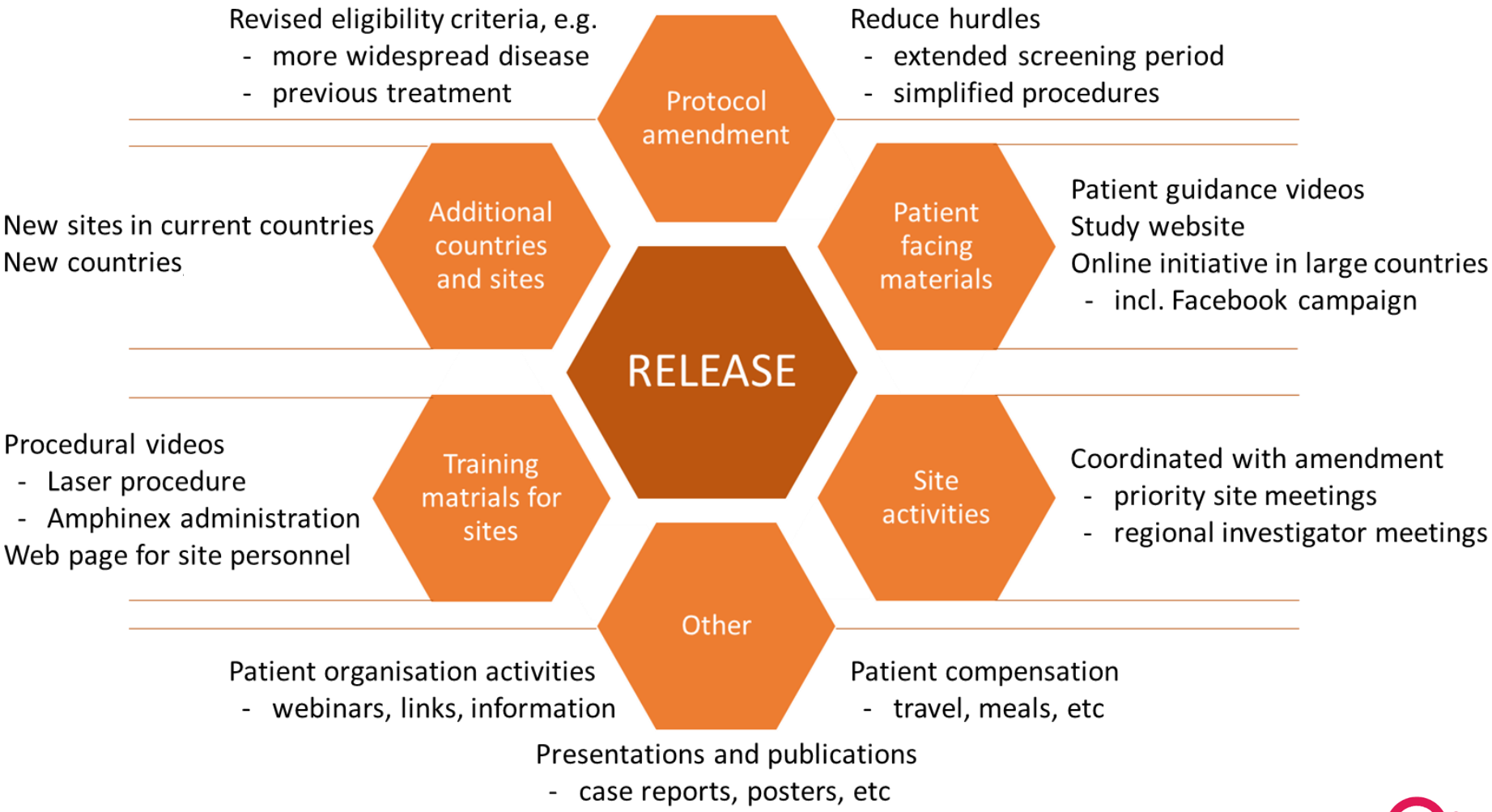
- Pivotal study status

- 47 sites open for patient enrolment
  - 32 sites in Europe, 9 in Asia and 6 in the US
- COVID-19 pandemic has delayed the study and several counteracting initiatives have been implemented
- Most important initiatives are increased number of sites and protocol amendment to expand eligible patient population



BILE DUCT CANCER – RELEASE STUDY

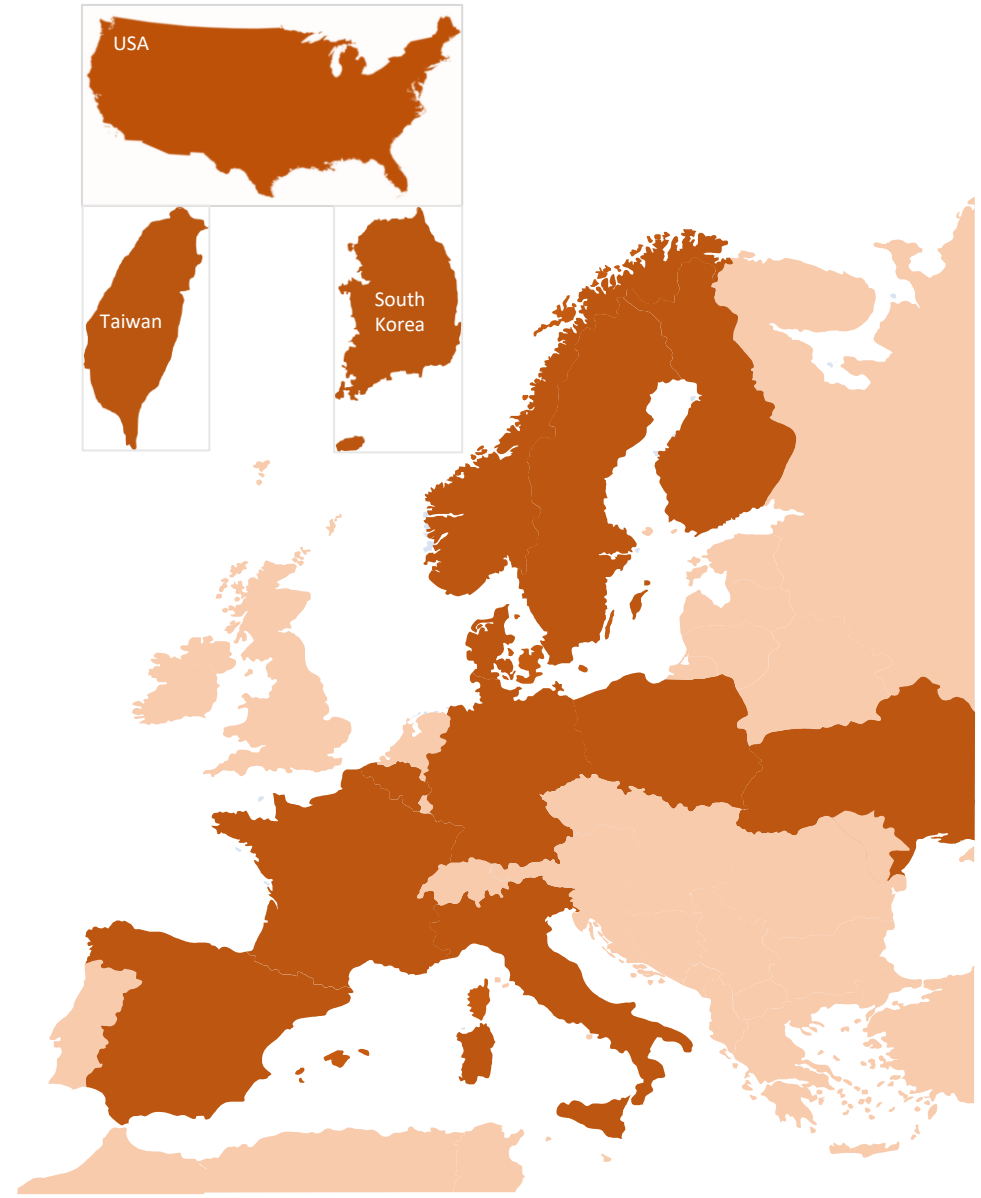
- Initiatives to enhance recruitment – based on KOL and site feedback



Bile Duct Cancer – Release Study

- Pivotal study status

- Initiatives have provided increased screening and enrolment, but COVID-19 is still affecting the study and enrolment level has been fluctuating in 2021
- A total of 30 patients had been enrolled at Q3 reporting (by end October)
- Strong focus on patient recruitment and retention, with emphasis on regular trial management, including overall performance evaluation and site replacement – more than 10% of sites have been replaced so far in 2021



BILE DUCT CANCER – RELEASE STUDY

- Endpoints, milestones and timelines

Endpoints:

Interim analysis: Primary Endpoint: Objective Response Rate (ORR) Secondary endpoint: Overall Survival (OS)	• Orphan drug designation in EU, USA and South Korea – potential accelerated approval
Final analysis: Primary endpoint: Progression Free Survival (PFS) Secondary endpoint: Overall Survival (OS)	• Single randomised trial considered sufficient based on interaction with US and EU regulatory authorities

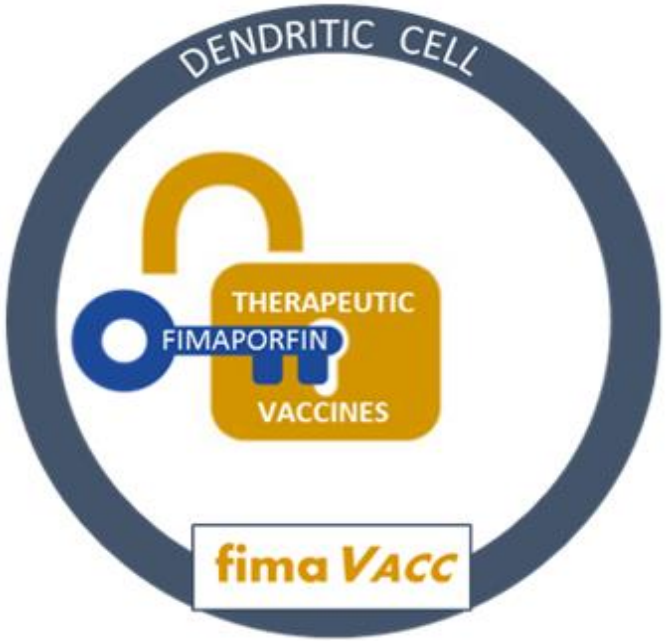
Milestones and timelines:

First patients enrolled in Europe in May 2019, in Asia in October 2020 and in the US in April 2021	• Enrolling patients on three continents
Seamless safety review by IDMC* when 8 patients have undergone two fimaCHEM treatments	• IDMC safety review expected 2H 2021
Objective Response Rate (ORR) when 120 patients have been enrolled	• Interim analysis expected 2H 2023
Timing and format for study conclusion may be impacted by outcome of Interim analysis	• Final analysis expected approximately 2H 2024

*IDMC = Independent Data Monitoring Committee

PCI BIOTECH

- **fima VACC** – aiming to enhance the effect of immunotherapeutics



Compelling preclinical results

- Particularly strong CD8 T-cell immune responses

Successfully translated into humans

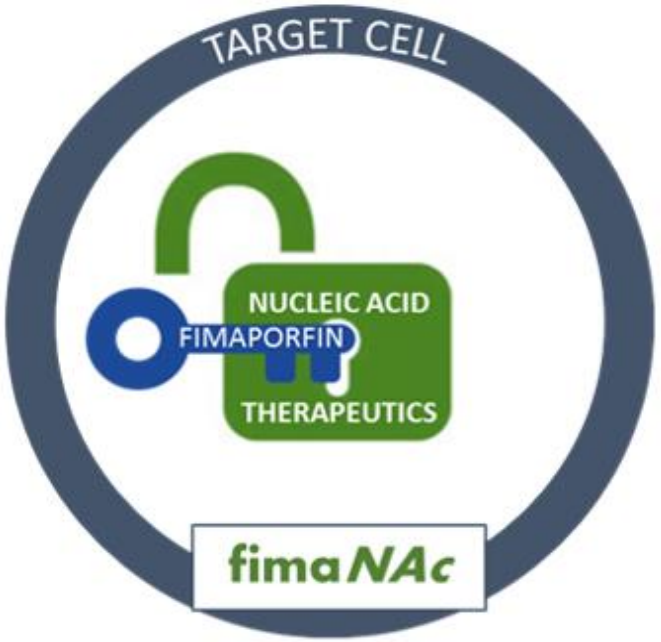
- Phase I study in healthy volunteers with peptide- and protein-based vaccines

Versatile vaccination platform

- Can potentially be used with several modalities, including nucleic acid based technologies

PCI Biotech

- **fimaNAc** – efficient and targeted intracellular delivery of nucleic acid therapeutics



Compelling preclinical results

- Strong data for a range of nucleic acid therapeutics and works in synergy with several vehicles

Addressing a major hurdle for this class of drugs

- Intracellular delivery of sufficiently high payloads remain a major obstacle for many applications

Collaborations with several players in the field

- Strategy to build a range of partnerships for different applications with a clear technology fit

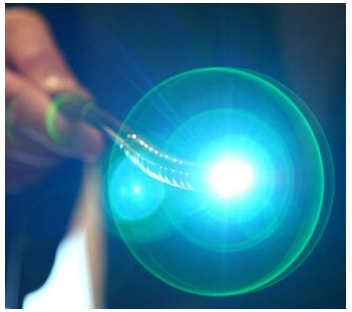
OliX Pharmaceuticals · eTheRNA · APOSENSE · IMV IMMUNOVACCINE · IMMUNICUM · PCI Biotech

PROGRESSING THE PCI-TECHNOLOGY PIPELINE

fimaCHEM

Progressing development in bile duct cancer towards marketing authorisation application

- RELEASE with interim read for potential accelerated approval ongoing across three continents
- Improved trial design and several initiatives to optimise execution during the pandemic
- Proactively pursuing strategies to address recruitment and retention of patients
- IDMC safety review of two treatments expected 2H 2021
- Interim analysis for potential accelerated approval expected 2H 2023



fimaVACC

Programme progressing towards initiation of a Phase II clinical proof of concept study

- Phase I results published in high-impact immunology journal: Frontiers in Immunology
- Clinical proof of concept study aiming to improve the response to immune checkpoint inhibitors
- Versatile vaccination technology available for partnering and licensing

fimaNAC

Providing an intracellular delivery solution for nucleic acid therapeutics

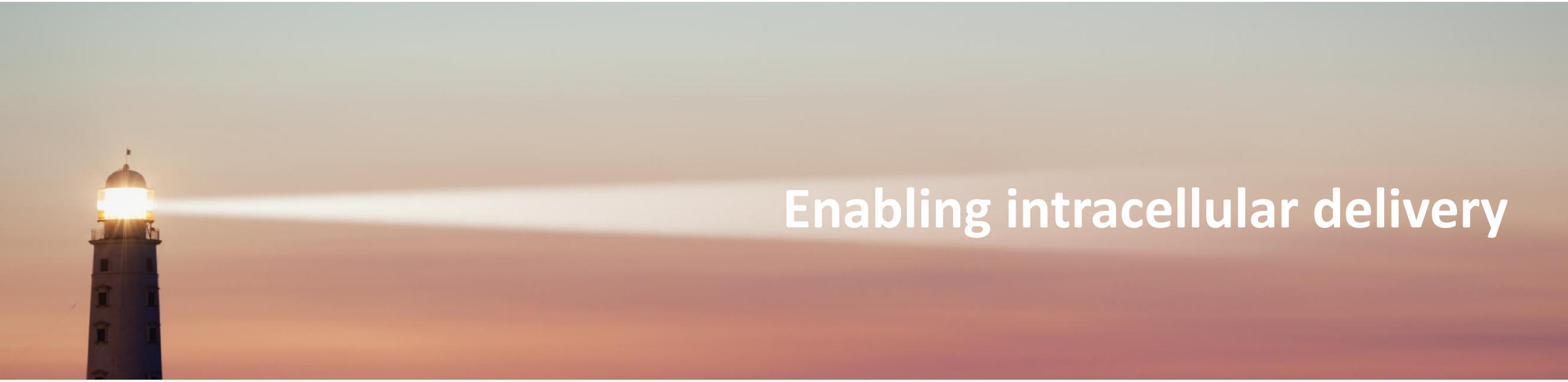
- Collaborations with several players in nucleic acid therapeutics
- Actively centre internal research efforts towards the most attractive applications

Q&A

Investment Highlights

Broad platform technology	PCI is a platform technology with three programmes targeting an attractive and growing oncology market, with a clear path to a high unmet need orphan oncology market for the lead candidate
Advanced lead product candidate	**fima CHEM** – Amphinex® is an orphan designated (EU, US, South Korea) first-in-class product candidate in pivotal development for treatment of bile duct cancer – a disease without approved drugs
Encouraging clinical results	Positive early signs of tumour response in a first-in-man study published in Lancet Oncology, and in a Phase I study specifically targeting bile duct cancer – encouraging survival data
Defined development strategy	Development strategy for lead candidate established based on thorough regulatory discussions with FDA and EMA – a single randomised pivotal study with accelerated/conditional approval potential
Pipeline opportunities	**fima VACC** – a clinical stage vaccination technology with encouraging cellular immune responses **fima NAc** – a preclinical gene therapy delivery solution with established key player collaborations
Experienced leadership	Management team, Board of Directors and advisors with extensive pharmaceutical industry experience across a range of medical development and commercial areas

PCI Biotech



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