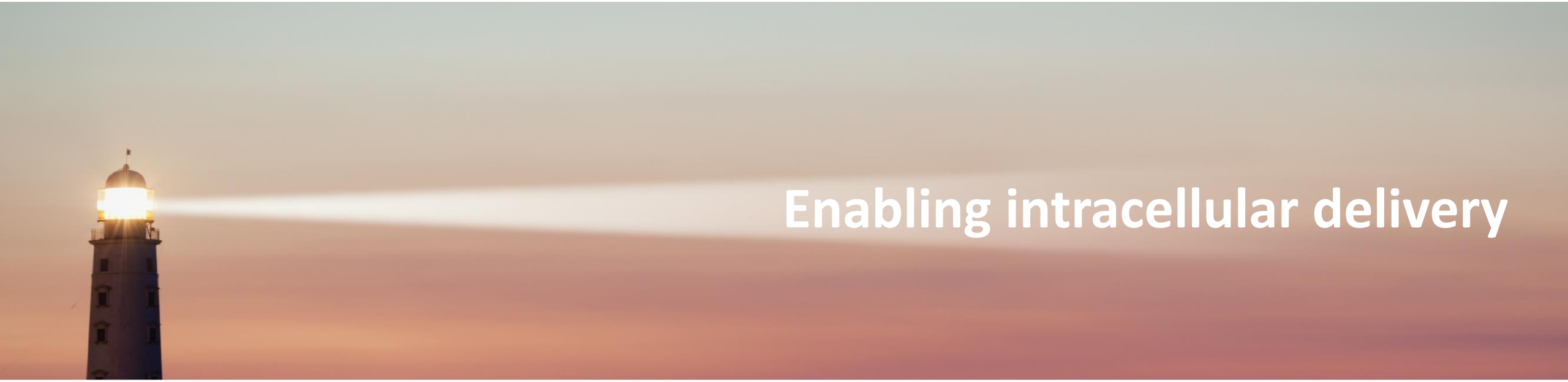
PCI Biotech



DNB Nordic Healthcare Conference 2021

December 16, 2021

Per Walday, CEO

PCI BIOTECH

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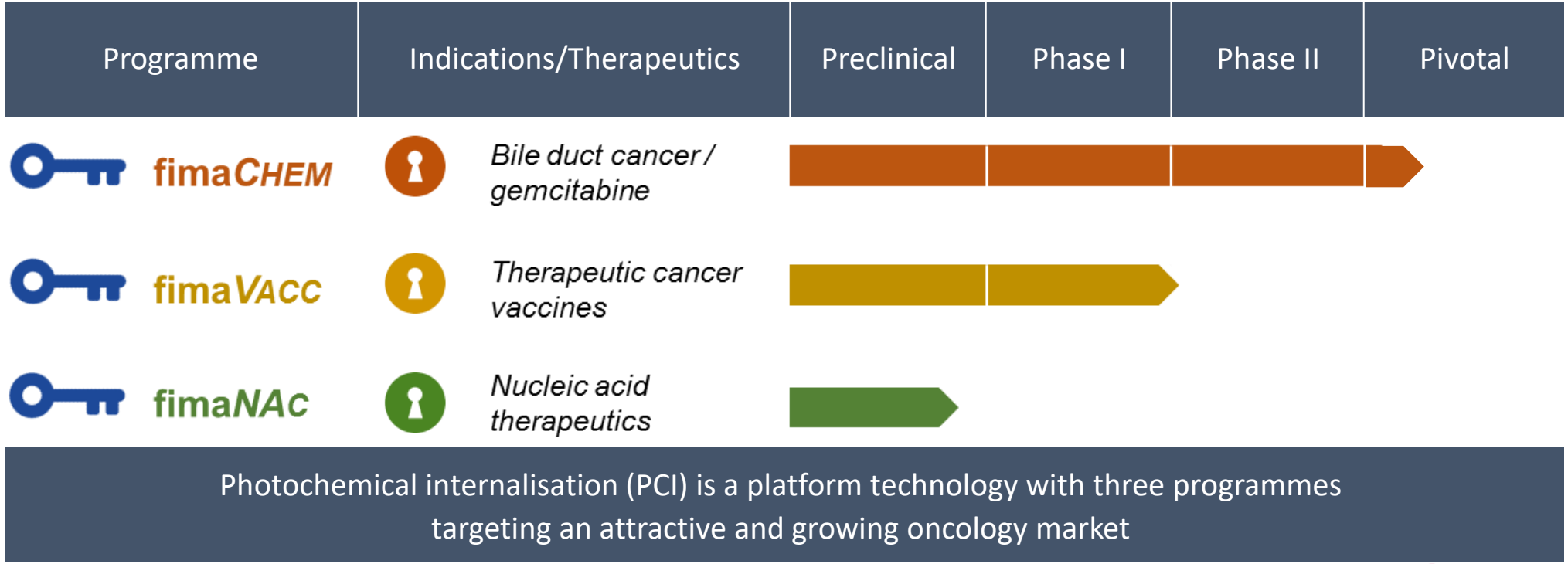
PCI Biotech – enabling intracellular delivery

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



PCI BIOTECH

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

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

fimaCHEM

- Excellent fit with medical need and existing treatments for extrahepatic bile duct cancer

  - **Positioning:** Enhances recommended first-line chemotherapy gemcitabine, and boosts the effect locally, where it is most needed

  - **Encouraging early clinical results:** mOS[1] of **22.8 months** at selected dose for development in the Phase I dose-escalation study (vs. **11-12 months**[2] with standard of care for inoperable bile duct cancer treatments)

  - **Easy to use:** Illumination through standard endoscopic methods used for radiography, biopsy and stenting for palliative biliary drainage

  - **Protection:** Rare disease – Orphan Drug designations in EU, US and South Korea offers market exclusivity, and use patent for treatment method approved in Europe (expiry 2037; pending in other major markets)

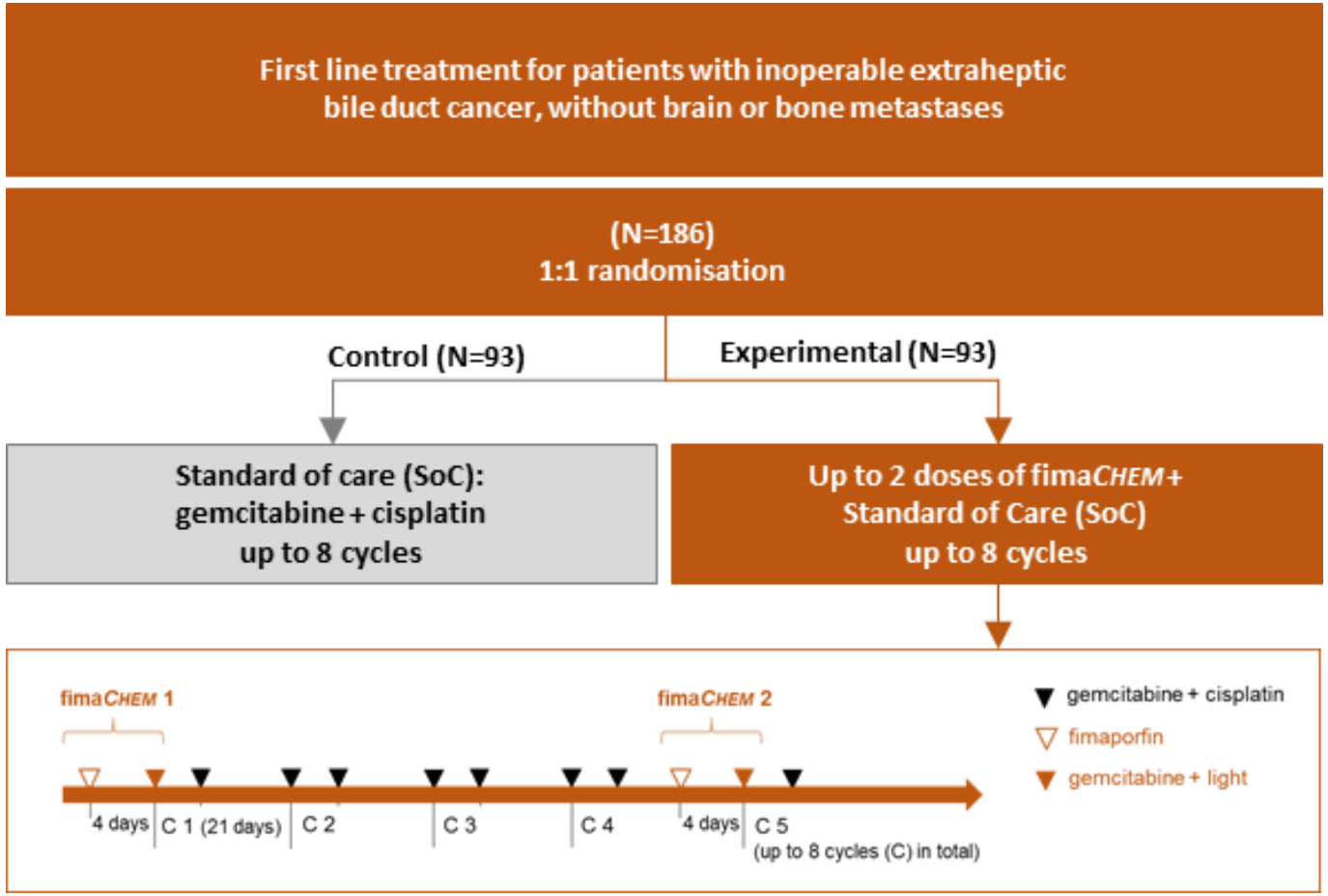
  - **Competition:** Pivotal development of acelarin, durvalumab & pembrolizumab, but these include a wider and more heterogeneous patient population (incl. intrahepatic and gallbladder cancer, as well as recurrent disease)

    - Recent interim read-out for durvalumab – efficacy results in relevant subgroups not yet public

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

BILE DUCT CANCER – RELEASE STUDY

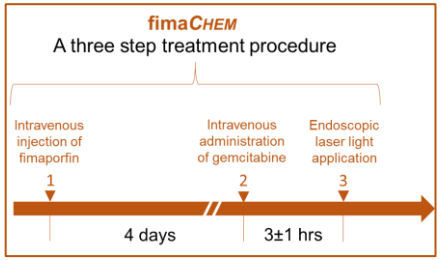
- Pivotal study with potential accelerated/conditional approval on interim analysis



- Majority of cases are inoperable upon presentation
- No approved treatment for extrahepatic disease

- Approx. 50 clinical sites planned in EU, US and Asia
- 11 European countries, 2 Asian countries + USA

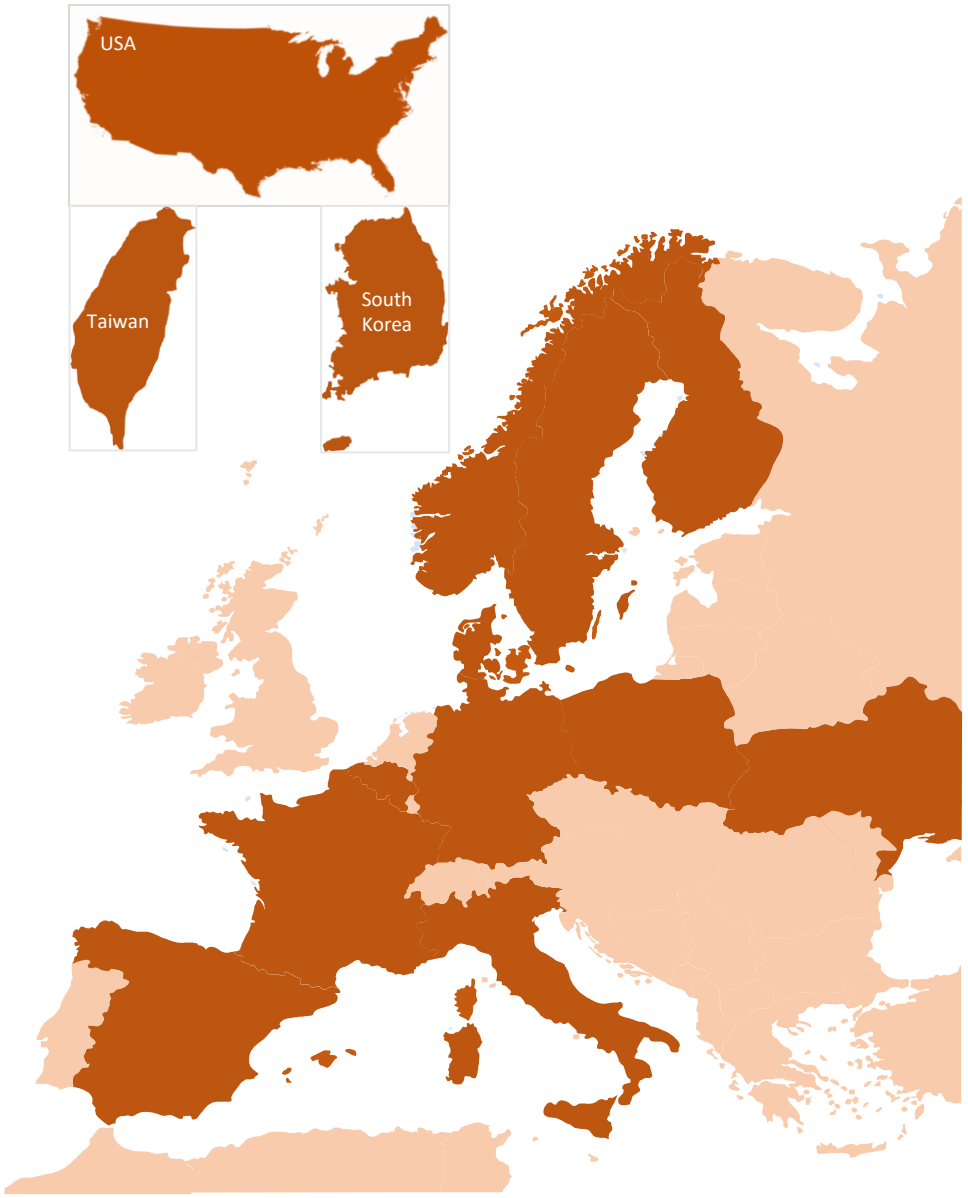
- **fimaCHEM** in addition to current Standard of Care



BILE DUCT CANCER – RELEASE STUDY

- Pivotal study status

- Enrolling patients across three continents, with 47 sites open for patient enrolment at Q3'21
- Screening in the RELEASE study has been affected by the COVID-19 pandemic – 30 patients enrolled at Q3 reporting
- Several initiatives implemented with the aim to recoup the COVID-19 caused delay, the most important being:
  - Eligibility criteria modifications
  - Study expansion, including Asia
- Active site management (>10% replaced in 2021)
- A somewhat higher discontinuation observed in the control arm – continue to assess all opportunities to address retention and recruitment



BILE DUCT CANCER – RELEASE STUDY DESIGN

- Randomised study with interim analysis for potential accelerated/conditional approval

- Orphan designation granted in the US, EU and South Korea
- Fastest way to market determined through regulatory interactions with authorities

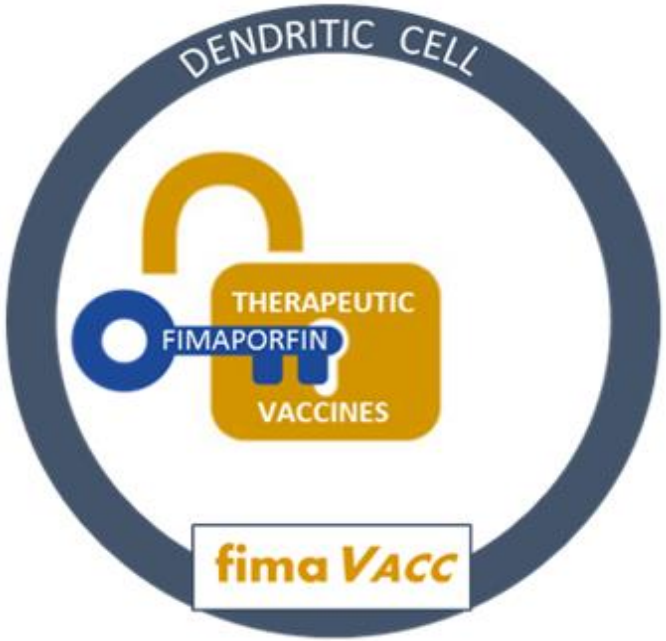
- Formal interim analysis when 120 patients are enrolled
- Interim read for potential accelerated approval expected 2H 2023
- Interim analysis primary endpoint: ORR[a]
- Final analysis primary endpoint: PFS[b], with OS[c] as key secondary

- At a recent safety review of two fima*CHEM* treatments, the IDMC[d] recommended that the trial continues as planned – a clear majority of eligible patients opted for the second treatment
- Several initiatives to enhance recruitment implemented in 2020 and study expanded to Asia
  - Increased screening and enrolment in 2021, but COVID-19 still affects the study and recruitment has been fluctuating

[a]ORR: Objective Response Rate; [b]PFS: Progression Free Survival; [c]OS: Overall Survival; [d]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

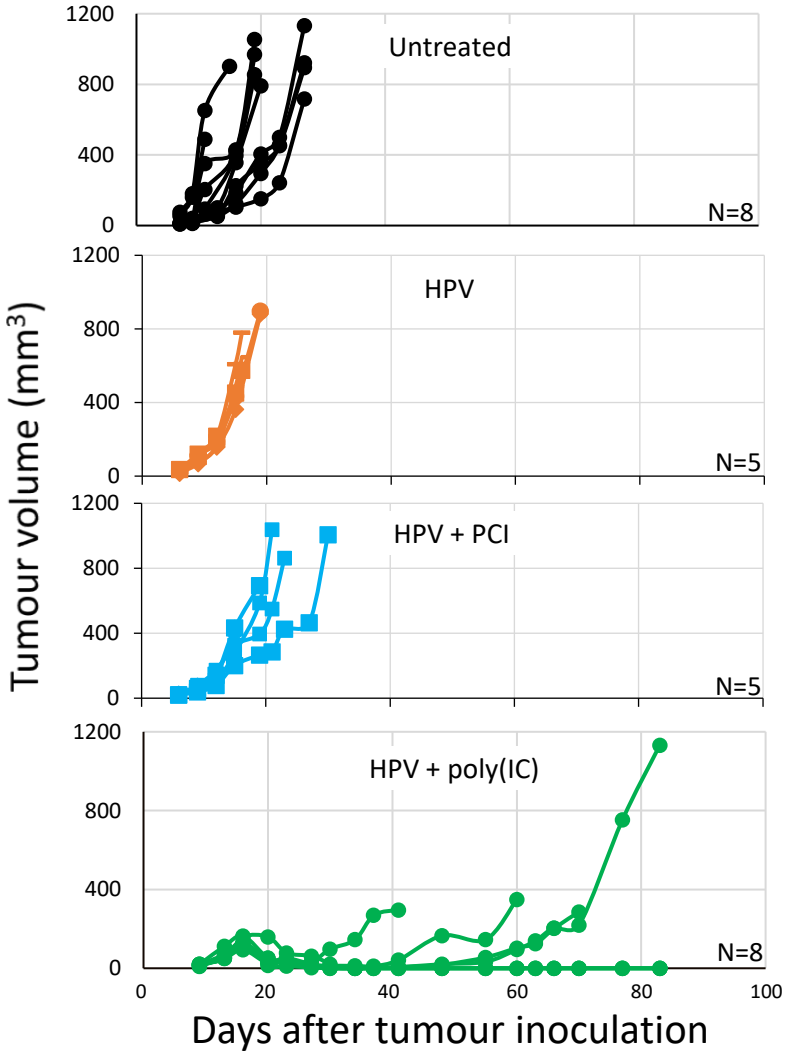
- Phase I study in healthy volunteers with peptide- and protein-based vaccines

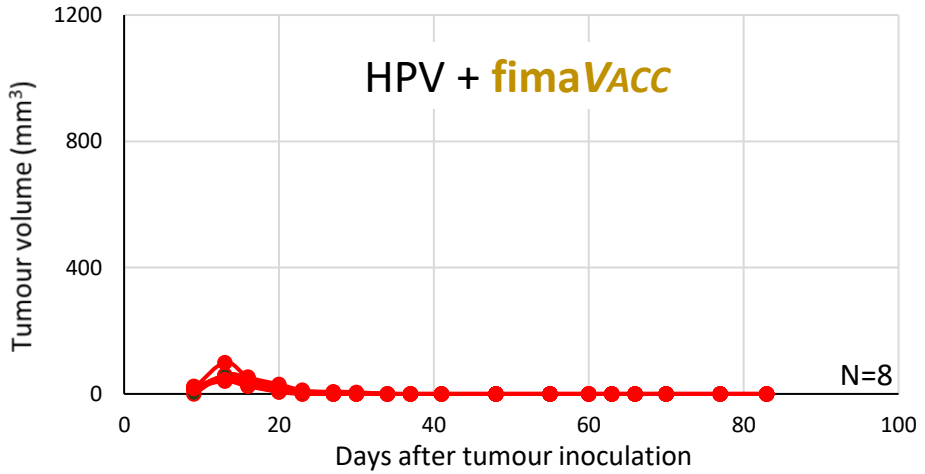
Versatile vaccination platform

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

TC-1 MOUSE MODEL FOR HPV-INDUCED CANCER

- Intradermal therapeutic vaccination with **fima VACC** induces strong anti-tumour response

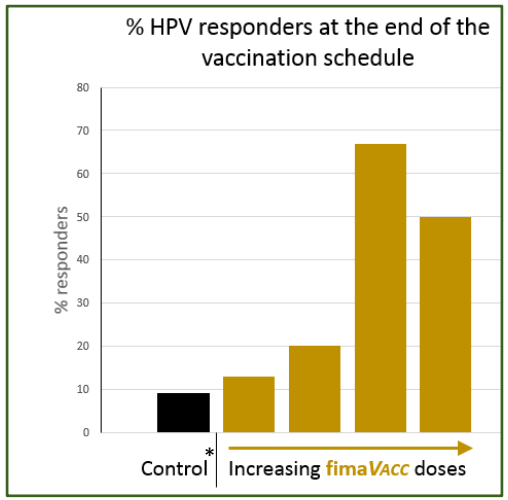


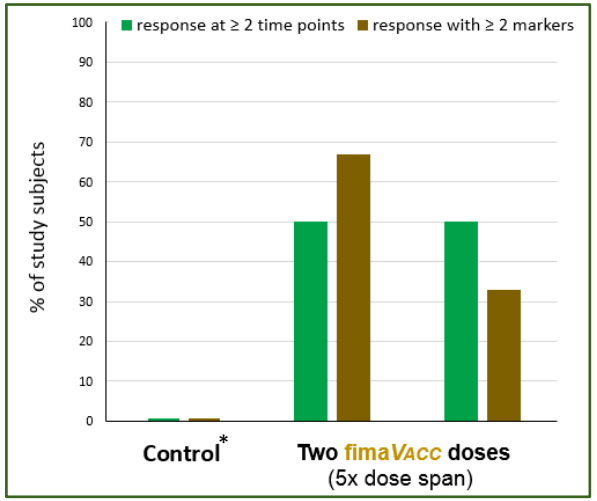


- **fima VACC** (PCI + poly(I:C) adjuvant) with HPV long peptide antigen (HPV)
- All mice became tumour free and were immune to a new challenge with tumour cells

SUCCESSFUL CLINICAL PROOF-OF-CONCEPT IN HEALTHY VOLUNTEERS

- Phase I study shows enhanced immune responses compared to a state-of-the-art adjuvant





fimaVACC provides:

- ✓ ***Increased number of responders***
- ✓ ***Enhanced T-cell responses***
- ✓ ***Improved T-cell functionality***

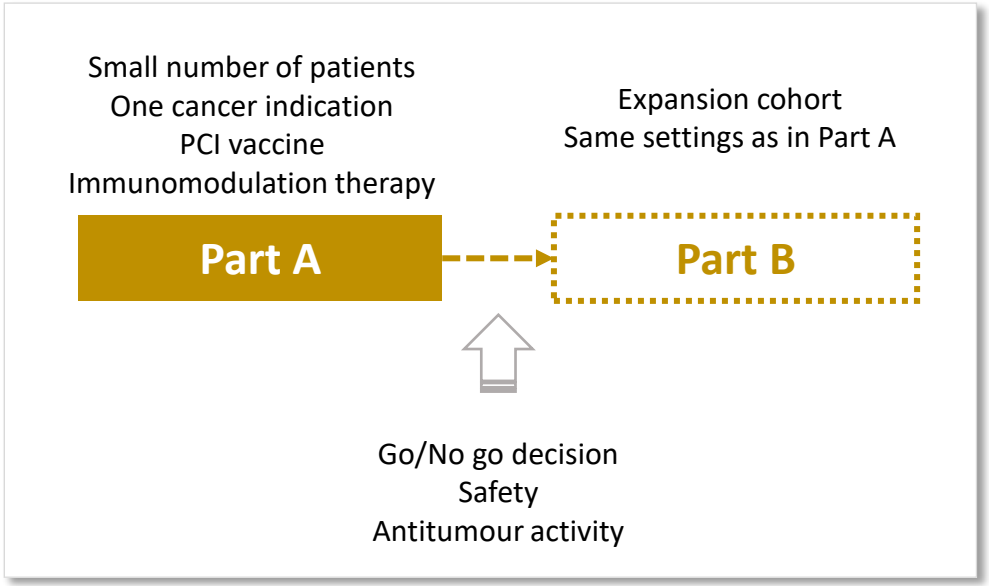
- Results show that the addition of **fimaVACC** induces:
  - Substantial increase in number of T-cell responders to HPV E7 peptides
  - Clearly enhanced overall T-cell responses
  - More robust CD8 T-cell responses, which are notoriously difficult to induce with E7
  - Increased functionality of the induced CD8 T-cells
- Highly sought-after features – especially for therapeutic vaccination
- Next step: moving to Phase II – proof-of-concept in a disease setting

*Control group with the Poly-IC adjuvant Hiltonol

PLANNED fimaVACC STUDY IN CANCER PATIENTS

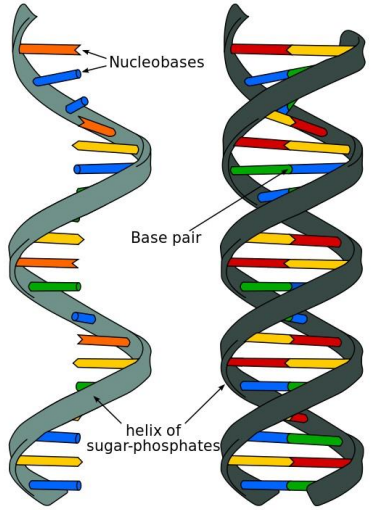
- Strategy

- Study in cancer patients with a goal to demonstrate anti-tumour activity – start small and build upon the results
- Working closely with international experts in the fields of the disease and immunotherapy
- One specific cancer type with perceived high likelihood of response and high unmet medical need
- Combine different therapeutic approaches to achieve maximal immunotherapy effect
- Patients with recurrent/metastatic solid tumours who progressed on 1st line immune checkpoint inhibition therapy



- Aim to convert cold tumours into hot tumours and thereby achieve long-term response in more patients
- The study is planned to start in Europe and expand to US upon good results – timelines TBA

Nucleic Acid Delivery with PCI



- Nucleic acids – a rapidly growing area with potential for the treatment and prophylaxis for many diseases, and with approvals in e.g.:
  - Covid-19 – mRNA prophylactic vaccines
  - Treatment of spinal muscular atrophy (SMA)
    - Zolgensma - gene therapy (virus based) – approved for use in Norway
- Delivery to the target tissues still represents a major barrier
  - Lipid nanoparticles work well for prophylactic intramuscular vaccination approaches
  - Technologies for liver delivery are available
  - Effective delivery systems remain to be established for most other tissues
  - Optimal delivery solution will probably vary between different tissues
- PCI can enhance and direct nucleic acid delivery to target sites that can be illuminated, on the body surface or inside the body (e.g. tumours via an optical fibre)

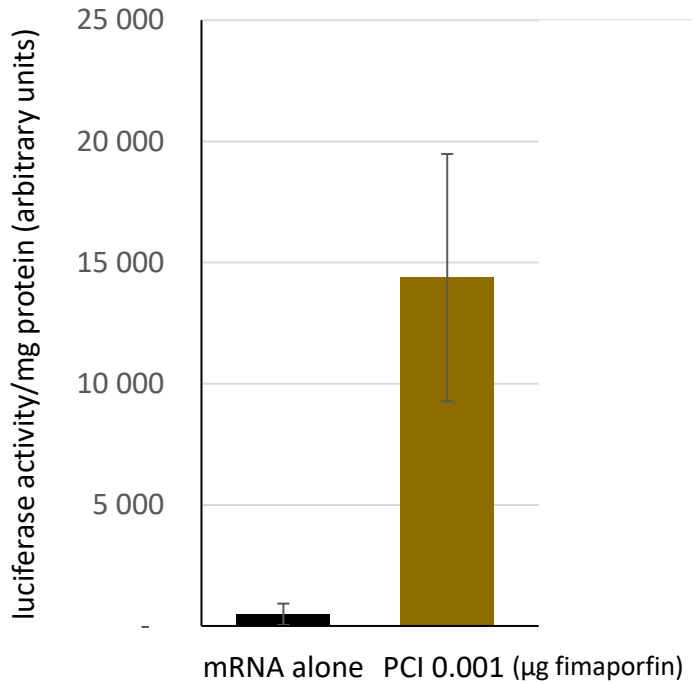
PCI Strongly Improves Delivery of Naked mRNA to Skin

- PCI can enhance functional naked mRNA delivery to skin (intradermal inj.) about 30 times

IVIS imaging after i.d. inj. of luciferase mRNA and subsequent i.v. inj. of the substrate luciferin

Control PCI

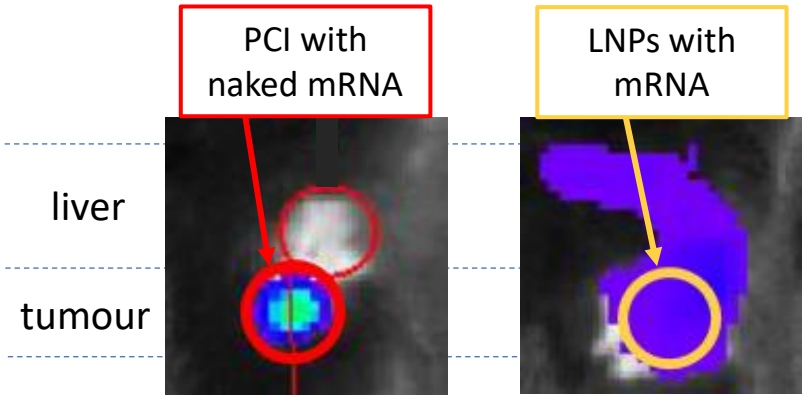
Enzymatic luciferase activity in skin samples after i.d. inj. of luciferase mRNA



PCI vs. LNPs for mRNA Delivery to Tumours

- PCI enhances delivery and prevents undesirable off-target effects

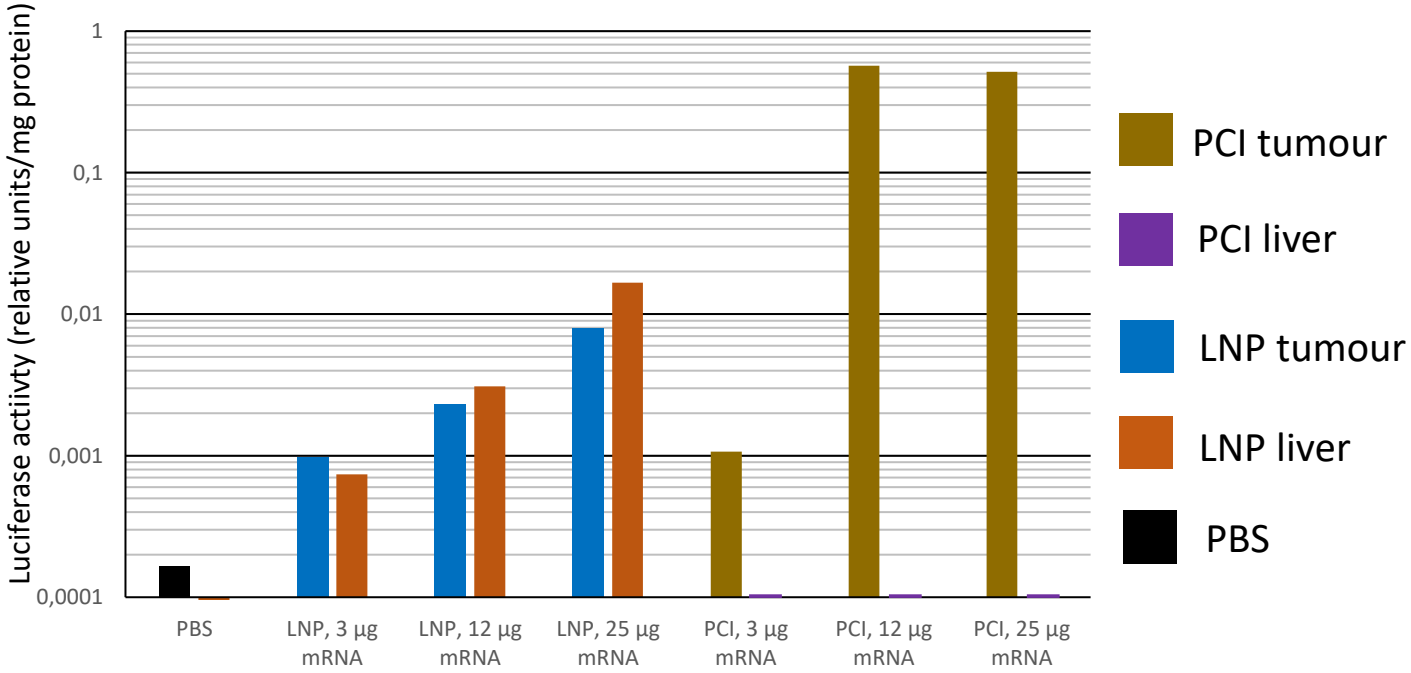
IVIS imaging after intratumoural inj. of luciferase mRNA and subsequent i.v. inj. of the substrate luciferin



High expression in tumour – no expression in liver

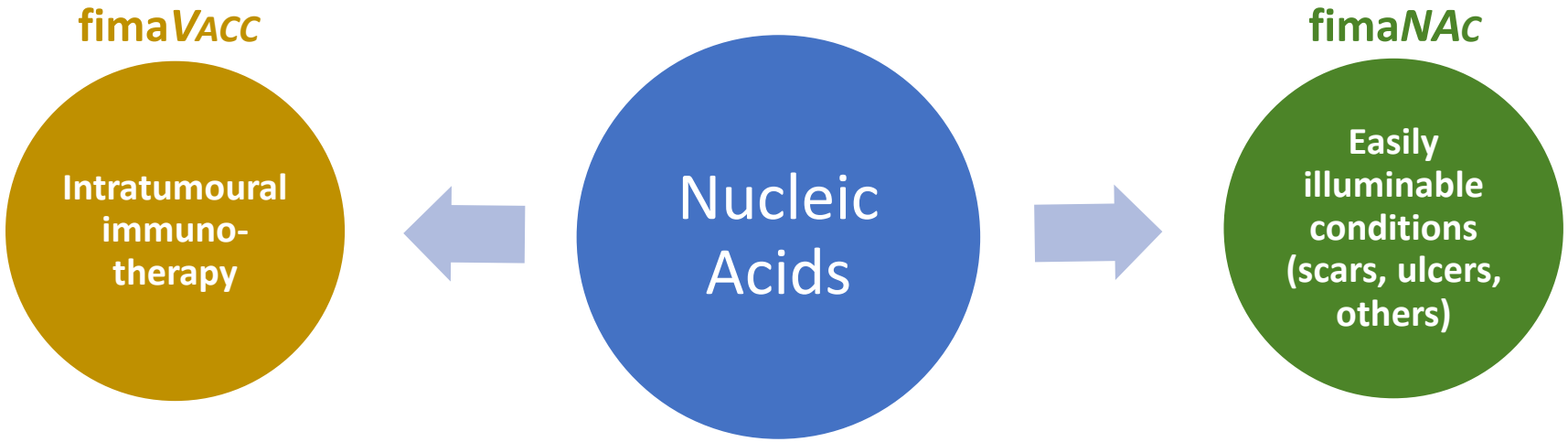
Low expression in tumour, significant expression in liver

Luciferase expression in MC38 tumours and liver after intratumoural delivery of luciferase mRNA by LNPs or PCI. Median values.



- Off-target delivery can give serious safety problems in patients
- With PCI-mediated delivery of naked mRNA, expression in the tumour is higher than with LNPs, and confined to tumour
- LNPs seem to leak out of the tumour, leading to unwanted expression in the liver, at equal expression levels as in tumour

PCI for Nucleic Acid Delivery – Top Priorities



- Good technological fit – a lot of interesting options
- PCI delivery works well in animals
- Treatment of tumours can be performed at several sites in the body
- Treatment of one tumour can give systemic effects
- On-going collaboration: eTheRNA

- Good technological fit – a lot of interesting options
- PCI delivery works well in animals
- Easy illumination access
- Many relevant diseases
- On-going collaboration: OliX Pharmaceuticals

Research Collaborations

- Collaborations within **fima*NAc*** and **fima*VAcc***

  - Currently five collaborations, spanning across different classes of drugs and therapeutic applications
  - Providing valuable scientific knowhow, encouraging results and intellectual property
  - The most recently established collaboration is with OliX Pharmaceuticals, a South Korean biotech company with a novel RNAi technology
  - PCI Biotech continues to pursue new and value-adding collaborative opportunities

GOOD PROGRESS AND EXCITING OUTLOOKS

fimaCHEM

Progressing development in bile duct cancer towards marketing authorisation application

- Encouraging tumour response and survival data from Phase I
- Orphan drug status granted in EU, USA and South Korea
- Global pivotal RELEASE study with interim read for accelerated approval

fimaVACC

Successful clinical PoC with enhanced immune responses

- Phase I results recently published in high-impact immunology journal
- Vaccination technology available for licensing
- Strengthened the organisation to move into clinical proof of concept in a disease setting

fimaNAc

Providing an intracellular delivery solution for nucleic acid therapeutics

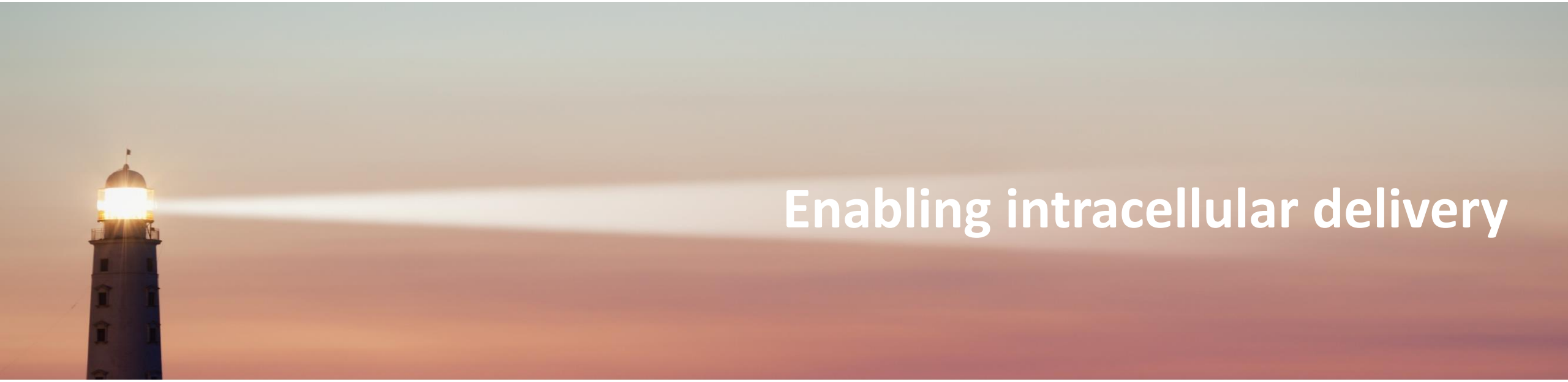
- A versatile technology with strong preclinical data
- Research collaborations with several players in the field

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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