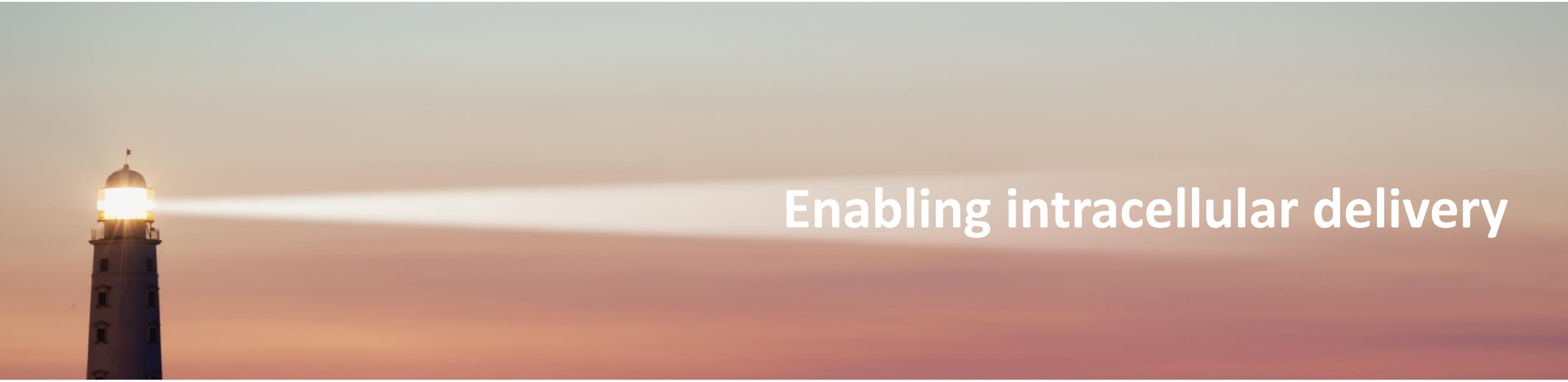
PCI Biotech



LifeSci Advisors Nordic Biotech Summit 2021

June 29, 2021

Per Walday, CEO

PCI BIOTECH

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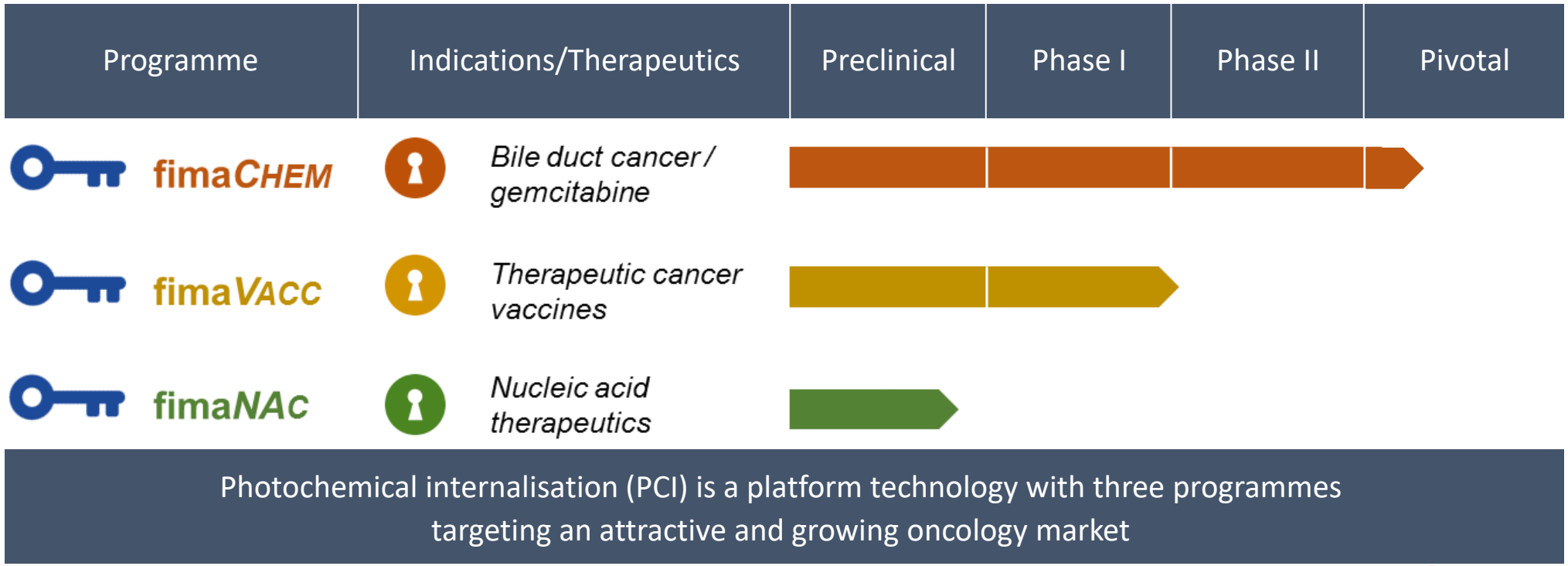
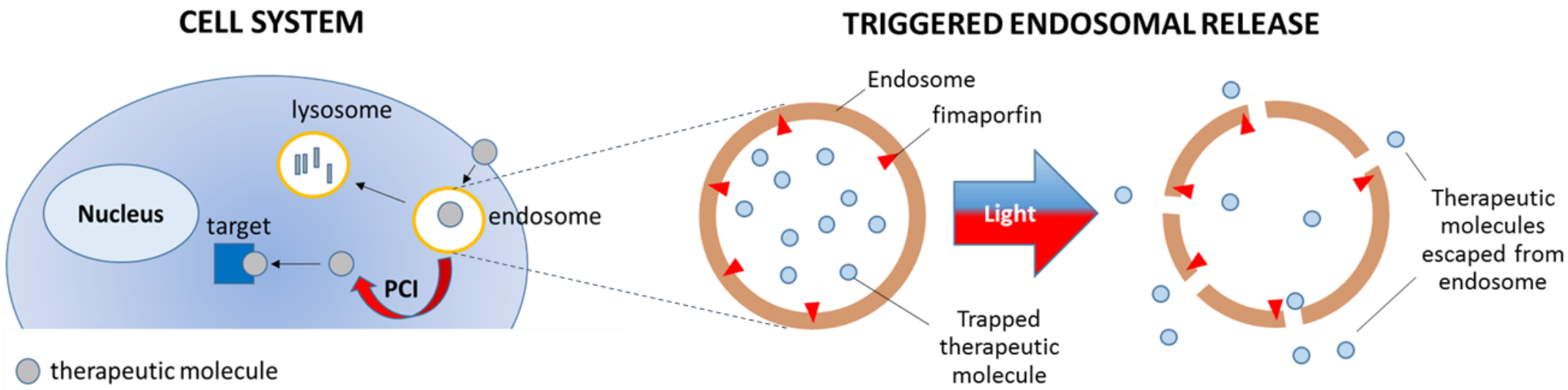
PCI Biotech – enabling intracellular delivery

- A biotech company with an oncology focused pipeline
  - A listed (PCIB:NO) cancer-focused biotech company
  - Solid cash position (Q1: approx. 160 mill NOK), partly placed in Euro
  - Photochemical internalisation ("PCI") technology
  - One platform technology with three well differentiated assets



PCI TECHNOLOGY – MODE OF ACTION

- Enabling drugs to reach intracellular therapeutic targets



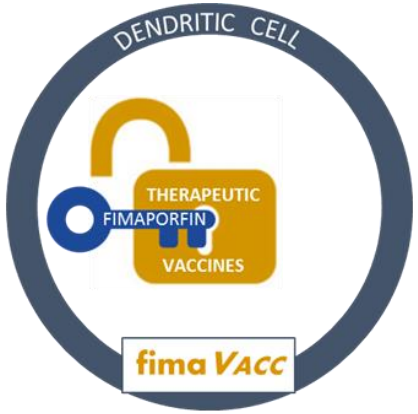
- Small molecules (chemotherapeutics – **fima*CHEM***)
- Antigens (peptides/proteins – **fima*VACC***)
- Nucleic acids (mRNA, RNAi – **fima*NAc***)

PCI TECHNOLOGY

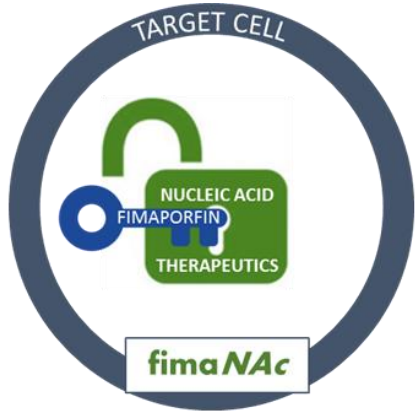
- Enabling drugs to reach intracellular therapeutic targets

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

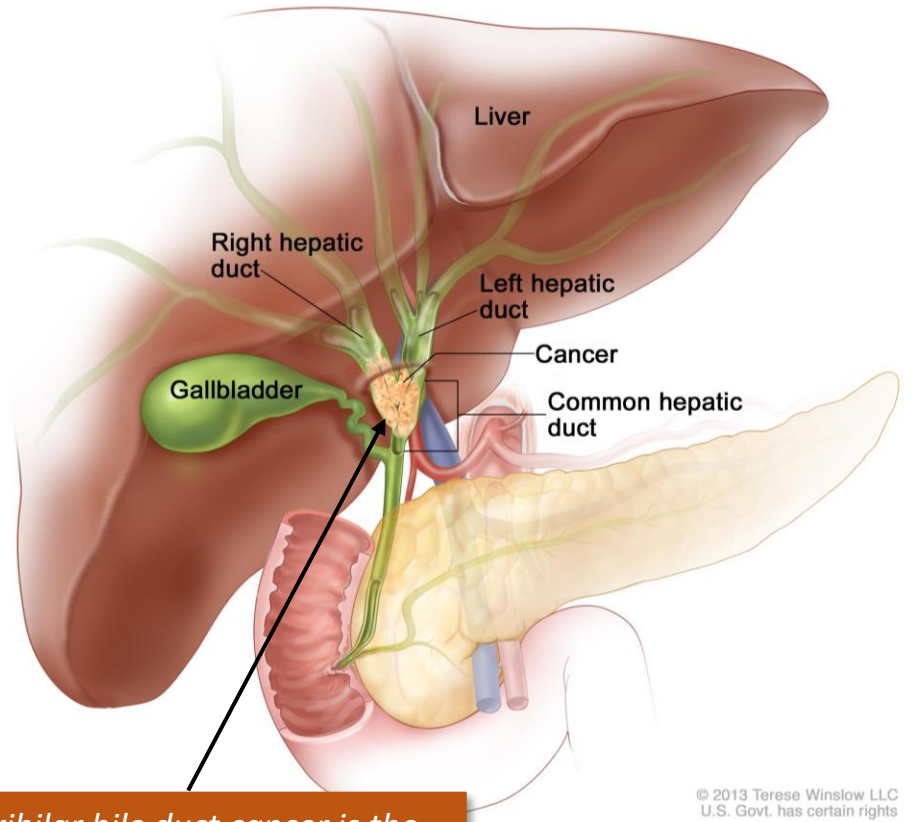
RELEASE – a global pivotal registration intent study

- 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 – higher prevalence in Asia
- 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



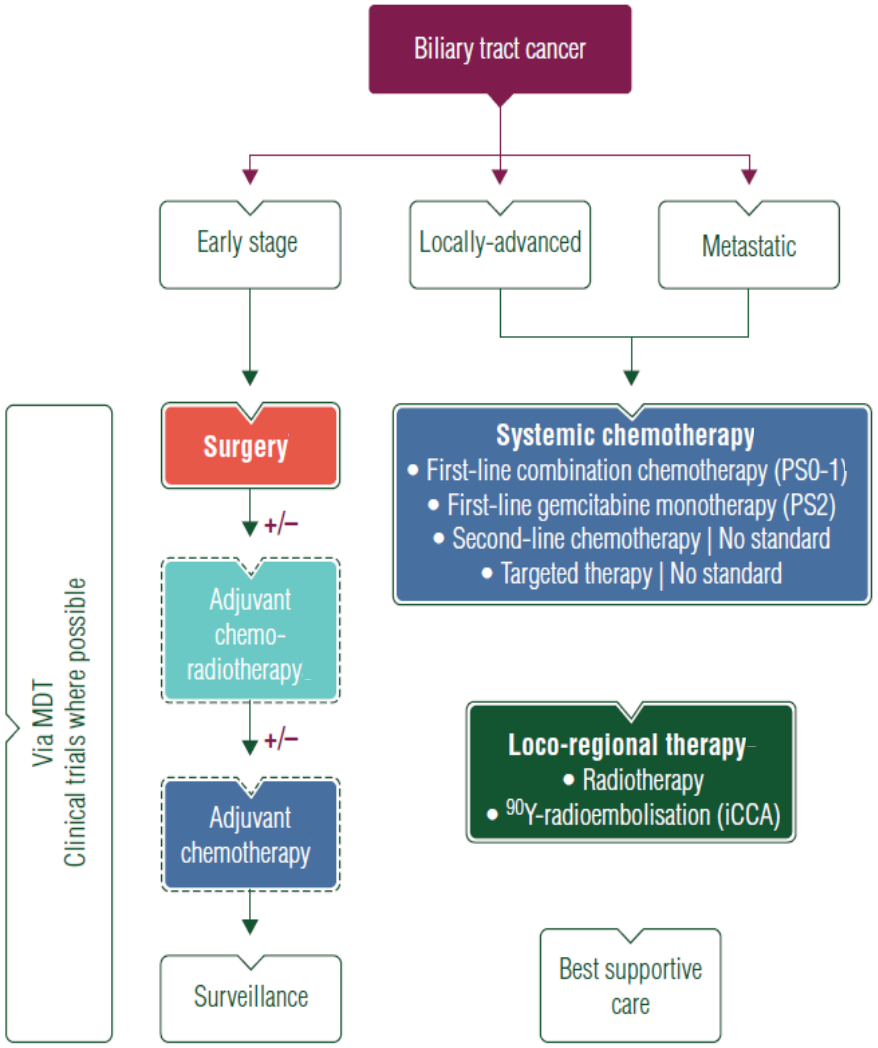
Perihilar bile duct cancer is the main target for PCI treatment

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

fimaCHEM AND BILE DUCT CANCER

- 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 SoC for inoperable CCA treatments)
- **Easy to use:** Illumination through standard endoscopic methods compatible with endoscopic stenting for palliative biliary drainage
- **Positioning:** Enhances recommended first-line chemotherapy for inoperable patients (> $^2/_3$ are inoperable) and boosts effect locally, where most needed
- **Protection:** Granted Orphan Drug designation in US, EU and South Korea
- **Competition:** Precision/gene/small molecules in clinical development are mainly intrahepatic CCA targeted or second line
- **Premium price:** Mean price for OD in the US is $K150 (median $K109)[3]
- **Estimated eligible population[4]:** US & Europe: approx. 3,000 patients/year; Asia: >4,000 patients/year



1) Median overall survival 2) New England Journal of Medicine 2010;362:1273-8 3) EvaluatePharma® Orphan Drug Report 2019 4) PCIB internal analysis

BILE DUCT CANCER – PHASE I DOSE-ESCALATION STUDY

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

Parameters	Cohort IV (N=6)	Phase I – all dose-escalation cohorts (N=16)
Objective Response Rate (ORR)	3/5 patients (2 PR; 1 CR)	4/12 patients (2 PR; 2 CR)
Median Overall Survival (mOS)	22.8 months	16.1 months

- 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

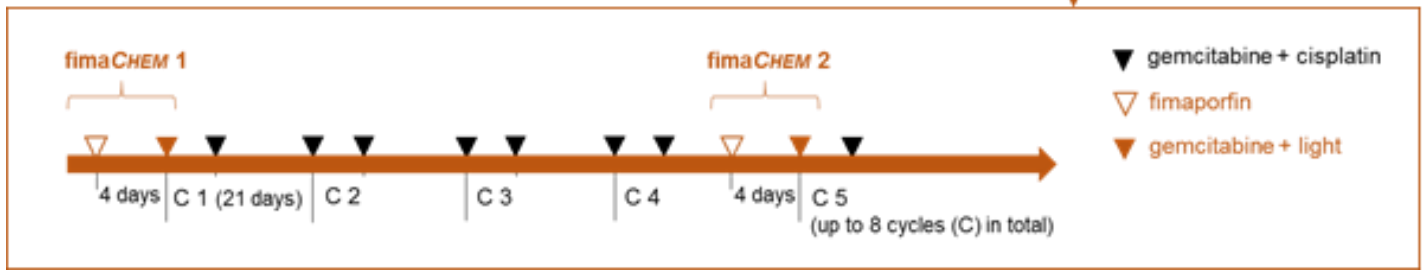
Control (N=93)

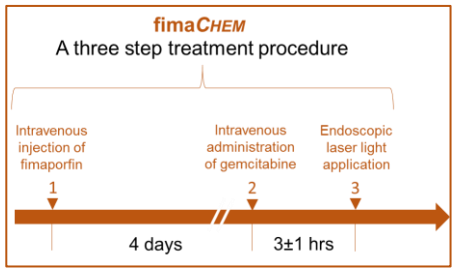
Standard of care (SoC):
gemcitabine + cisplatin
up to 8 cycles

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

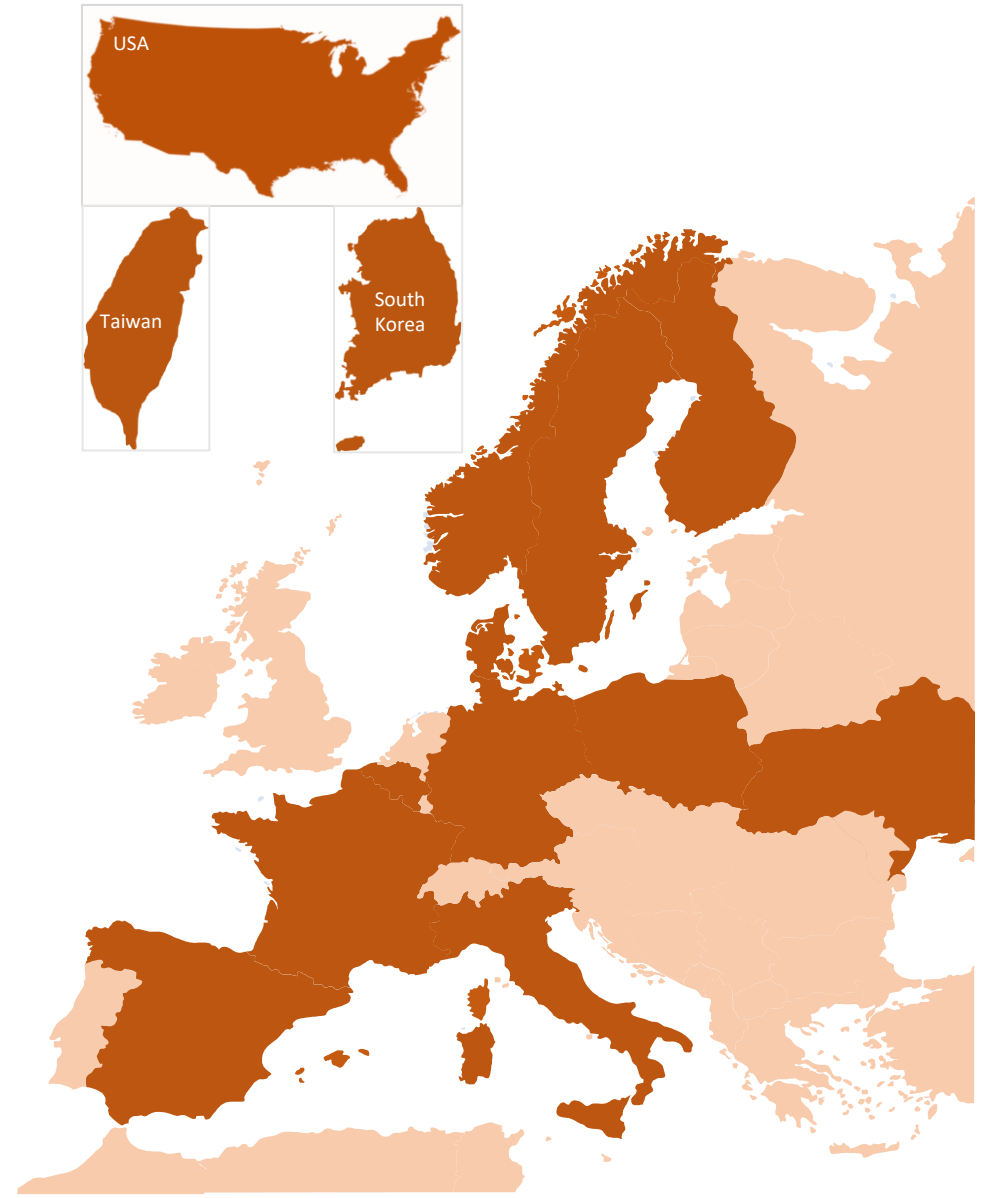




Bile Duct Cancer – Release Study

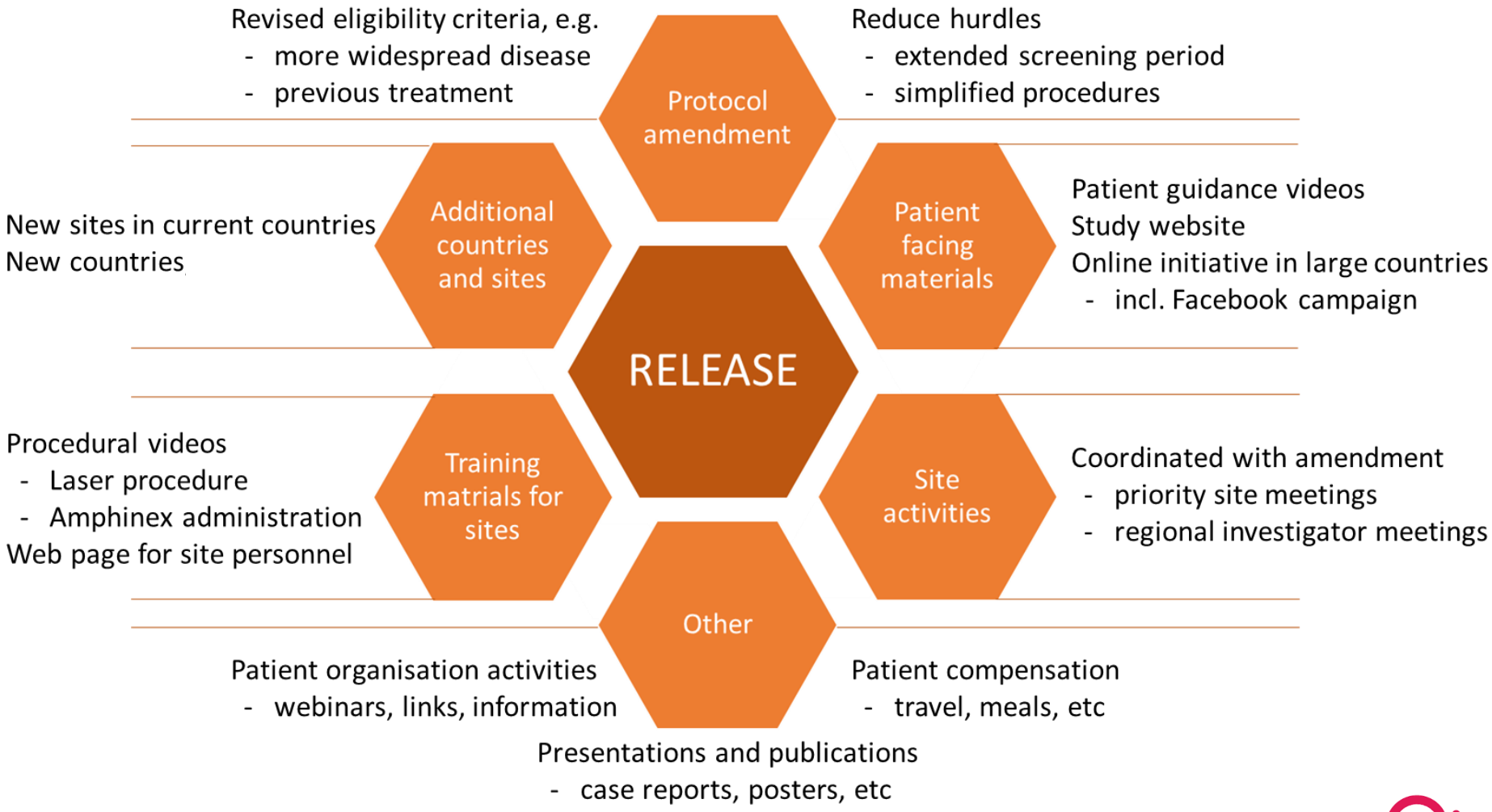
- Pivotal study status

- Open sites in South Korea, Taiwan, USA and 11 European countries
- 46 sites open for patient enrolment at Q1’21 – plan to have approx. 50
- 9 sites open in Asia – first Asian patient enrolled Oct’20
- 6 sites open in the US – first US patient enrolled Apr’21
- Screening in the RELEASE study affected by the COVID-19 pandemic
- Several initiatives implemented with the aim to recoup the COVID-19 caused delay



BILE DUCT CANCER – RELEASE STUDY

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



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**

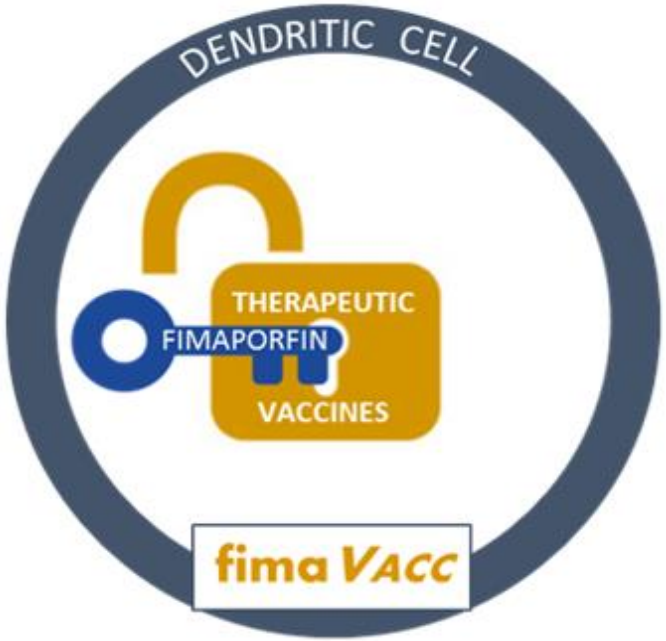
- Formal interim analysis of ORR when 120 patients are enrolled
- Interim read for potential accelerated approval expected 2H 2022 / 1H 2023
- Primary endpoint: PFS[a], with OS[b] as key secondary
- Interim analysis primary endpoint: ORR[c]

- **First patient included in EU May 2019, in Asia October 2020, and in US April 2021**
- **Several initiatives to enhance recruitment implemented and study expanded to Asia autumn 2020**
- **Increased screening and enrolment after implementation and study expansion**

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

PCI BIOTECH

- **fima VACC** – aiming to enhance immunogenicity of vaccines for immunotherapy field



Compelling preclinical results

- Particularly strong CD8 T-cell immune responses

Successfully translated into humans

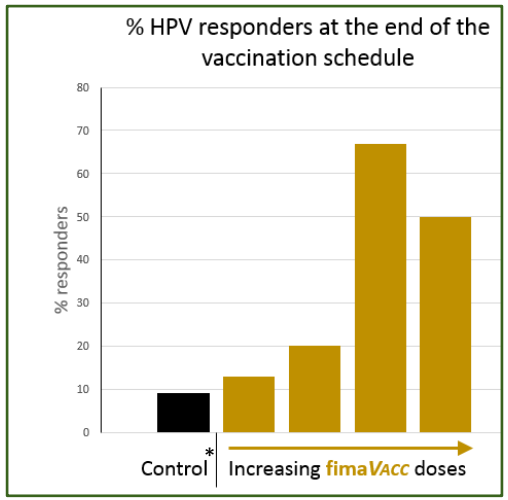
- Phase I study in healthy volunteers with peptide- and protein-based vaccines

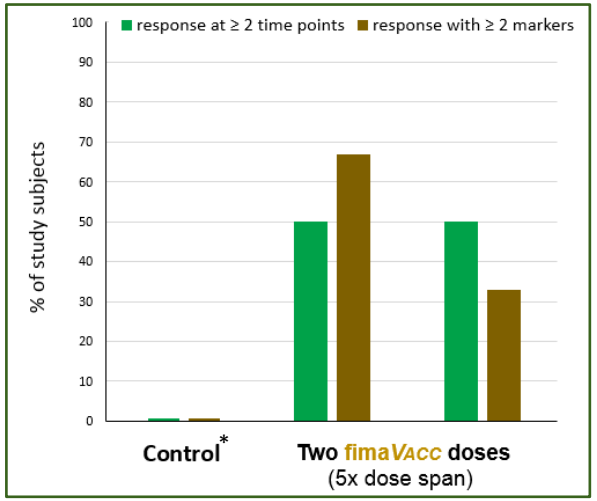
Versatile vaccination platform

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

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**

*Control group with the Poly-IC adjuvant Hiltonol

PROGRESS OF THE fimaVACC PROGRAMME

- Growing robust evidence, with Phase I study published

  - Positive clinical study results presented at ESMO Immuno-Oncology Congress in December 2019

  - The full study results were published early January 2021 in Frontiers in Immunology*, a high impact immunology journal

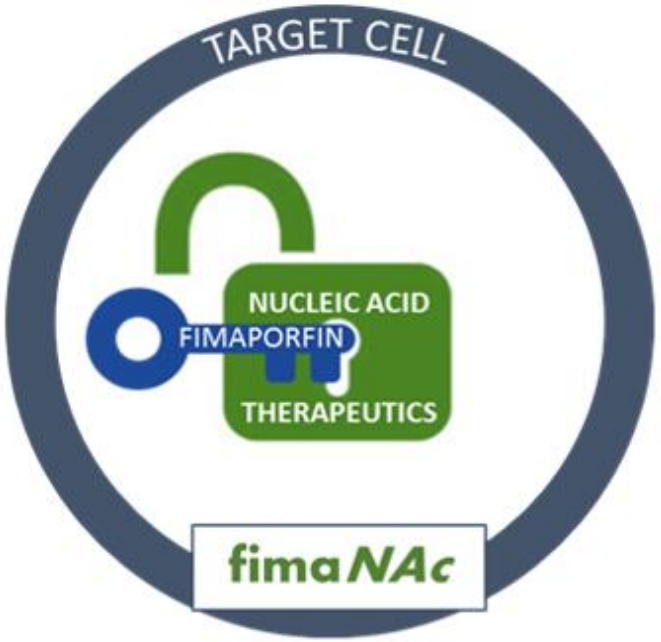
  - Next step: moving to Phase II with a partner or by ourselves (proof-of-concept in a disease setting)

Patented disposable "band-aid-like" device for user-friendly illumination of the vaccination site

*Front. Immunol., 08 January 2021 | https://doi.org/10.3389/fimmu.2020.576756

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

Research Collaborations

- Collaborations within nucleic acid therapeutics

fimaNAc

- Currently five active collaborations to explore synergies with partner products
- 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

OliX Pharmaceuticals

eTheRNA

IMMUNICUM

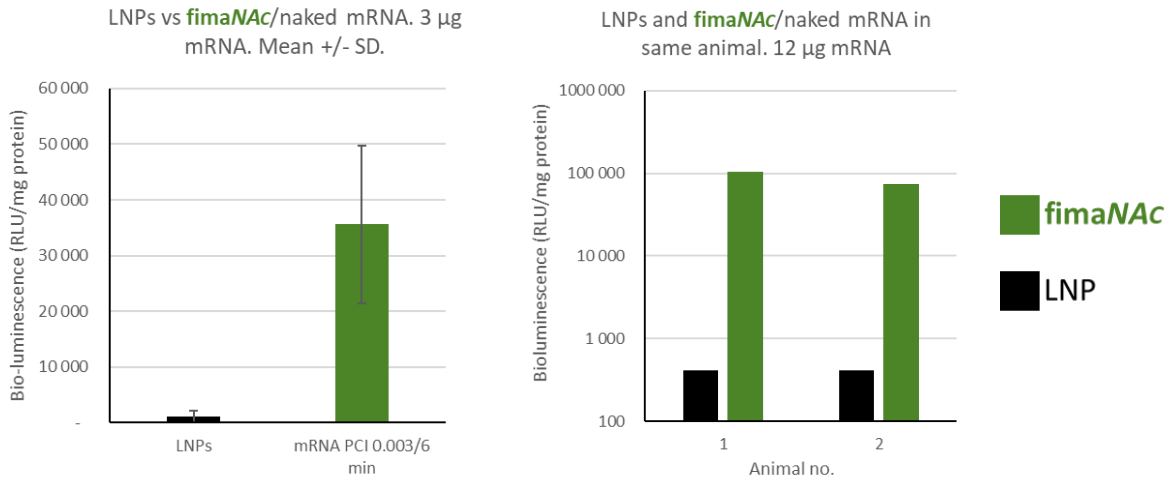
APOSENSE®

imv™ IMMUNOVACCINE

INTRATUMOURAL DELIVERY WITH fimaNAc IS CONVINCINGLY SUPERIOR TO LNPS

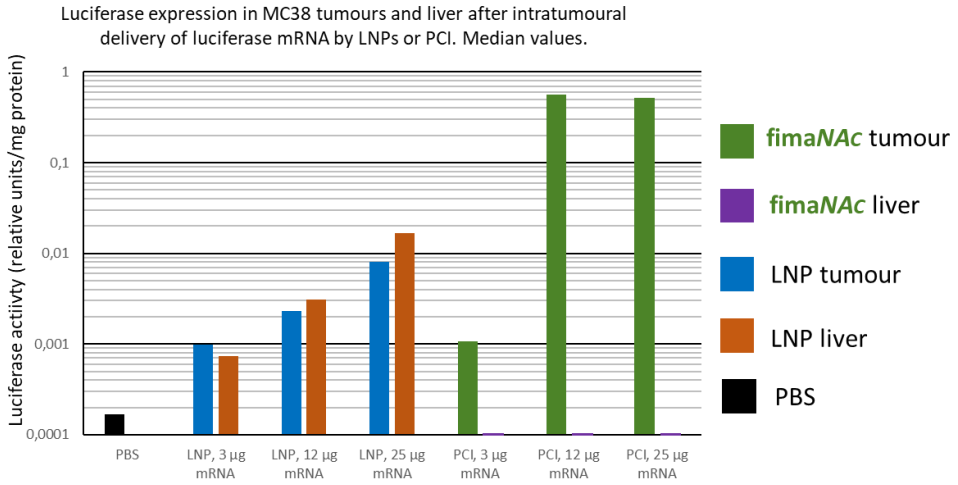
- Substantially higher and more targeted mRNA delivery to tumours compared to LNPs

Consistently improves delivery compared to LNPs



- 35x higher activity with fimaNAc compared to LNPs (3µg mRNA)
- 200x in intra-animal (2 tumours) comparison (12µg mRNA)

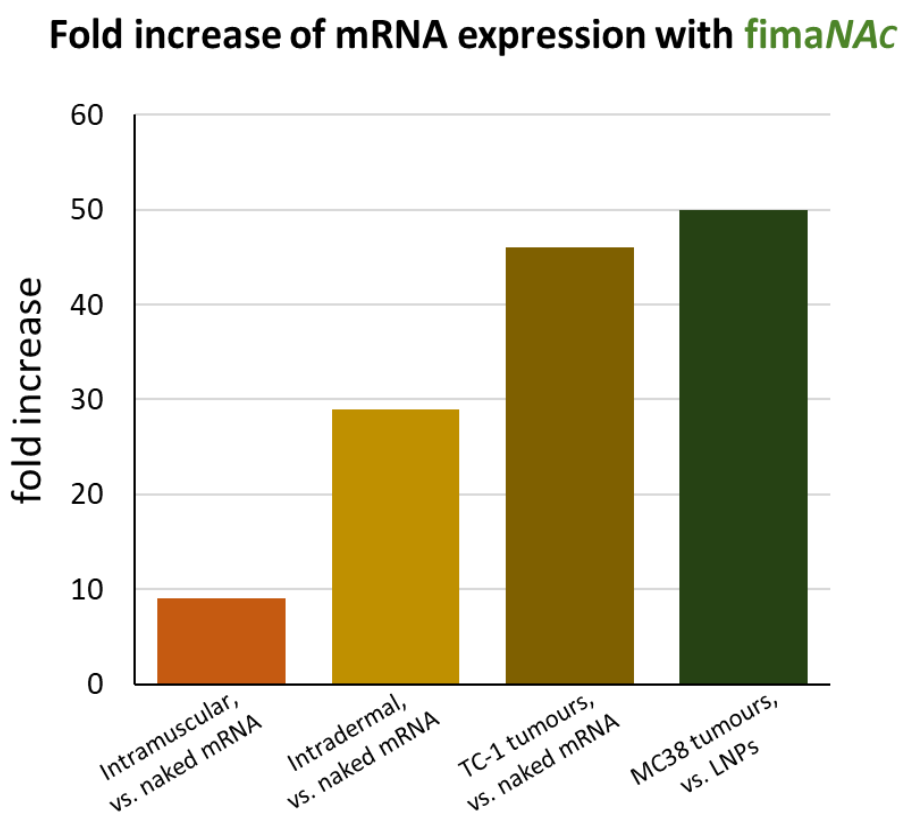
Preventing undesirable off-target delivery



- fimaNAc -mediated delivery confined to tumour
- LNPs seem to leak out of the tumour leading to unwanted expression in the liver

NAKED MRNA DELIVERY WITH fimaNAc – DIFFERENT APPLICATIONS

- Substantially enhanced delivery to tumour, muscle and skin



- Local delivery technology
  - Delivery demonstrated to tumour, muscle, and skin
  - Convincing superiority to LNPs demonstrated in tumour
  - Administered as one injection without side effects
  - Injection and illumination as one procedure
  - mRNA expression spatially restricted to illuminated area
- Clinically proven platform technology
  - fimaVACC and fimaCHEM using the same platform technology
  - Ample safety data in humans – systemic and local administration
- Applications where a local effect may be desired
  - Skin, muscles, tumours, eye, joints, lymph nodes

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 USA, EU and South Korea
- Fastest way to market determined through regulatory interactions with authorities
- 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
- Plan for clinical proof of concept in a disease setting

fimaNAc

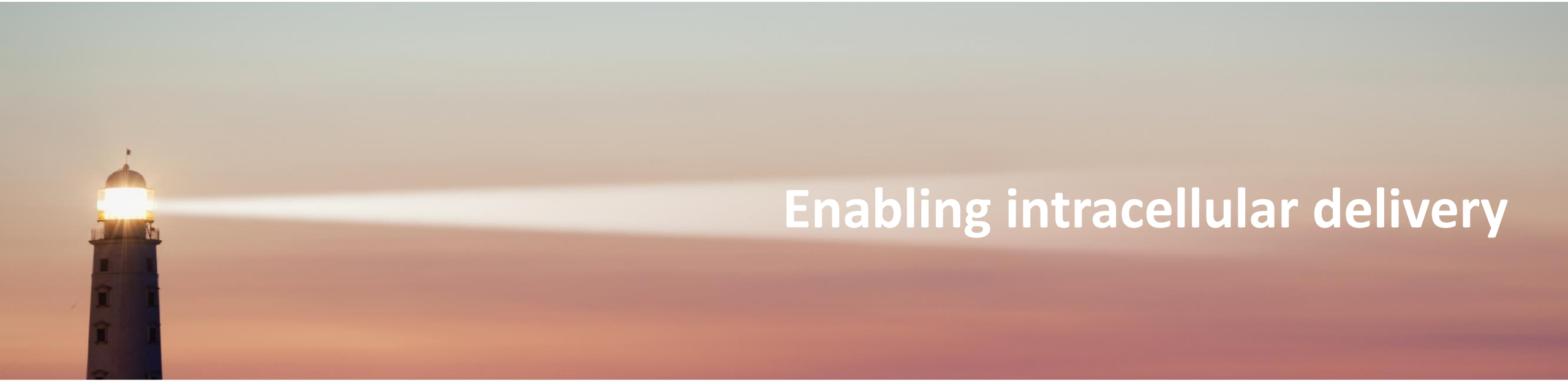
Providing an intracellular delivery solution for nucleic acid therapeutics

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

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 (US, EU & 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



For enquiries:

Per Walday, CEO
Mobile phone: +47 917 93 429
E-mail: pw@pcibiotech.com

Ronny Skuggedal, CFO
Mobile phone: +47 940 05 757
E-mail: rs@pcibiotech.com