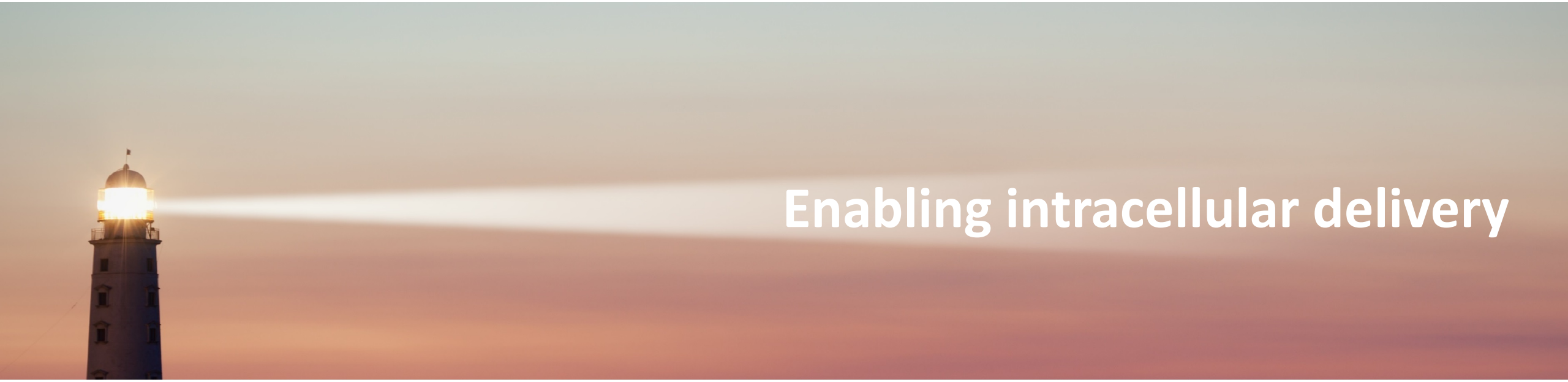
PCI Biotech



Pareto Securities' 12th Annual Healthcare Conference 2021

September 2, 2021

Per Walday, CEO

PCI BIOTECH

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PCI BIOTECH – ENABLING INTRACELLULAR DELIVERY

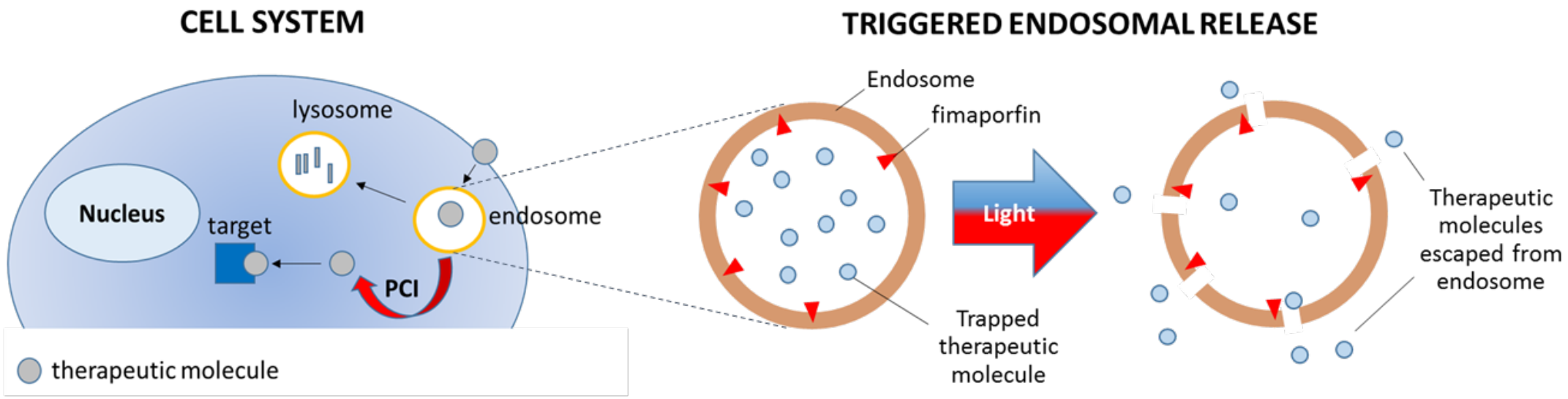
- A biotech company with an oncology focused pipeline
  - A listed (PCIB:NO) cancer-focused biotech company
  - Solid cash position (Q2: NOK 147 mill), partly placed in Euro
  - Photochemical internalisation ("PCI") technology
  - One platform technology with three well differentiated assets

Programme	Indications/Therapeutics	Preclinical	Phase I	Phase II	Pivotal
fimaCHEM	*Bile duct cancer / gemcitabine*				
fimaVACC	*Therapeutic cancer vaccines*				
fimaNAc	*Nucleic acid therapeutics*				

Photochemical internalisation (PCI) is a platform technology with three programmes targeting an attractive and growing oncology market

PCI TECHNOLOGY – MODE OF ACTION

- Enabling drugs to reach intracellular therapeutic targets



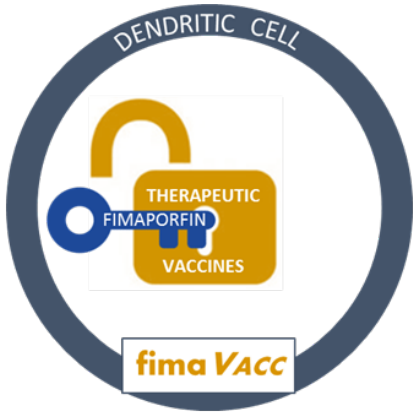
- Small molecules (chemotherapeutics – **fima*CHEM***)
- Antigens (peptides/proteins – **fima*VACC***)
- Nucleic acids (mRNA, RNAi – **fima*NAc***)

PCI TECHNOLOGY

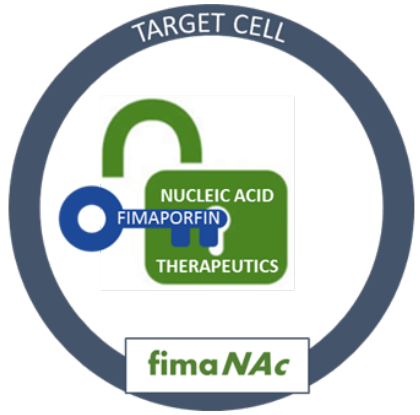
- Enabling drugs to reach intracellular therapeutic targets

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

- **fima CHEM** – 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

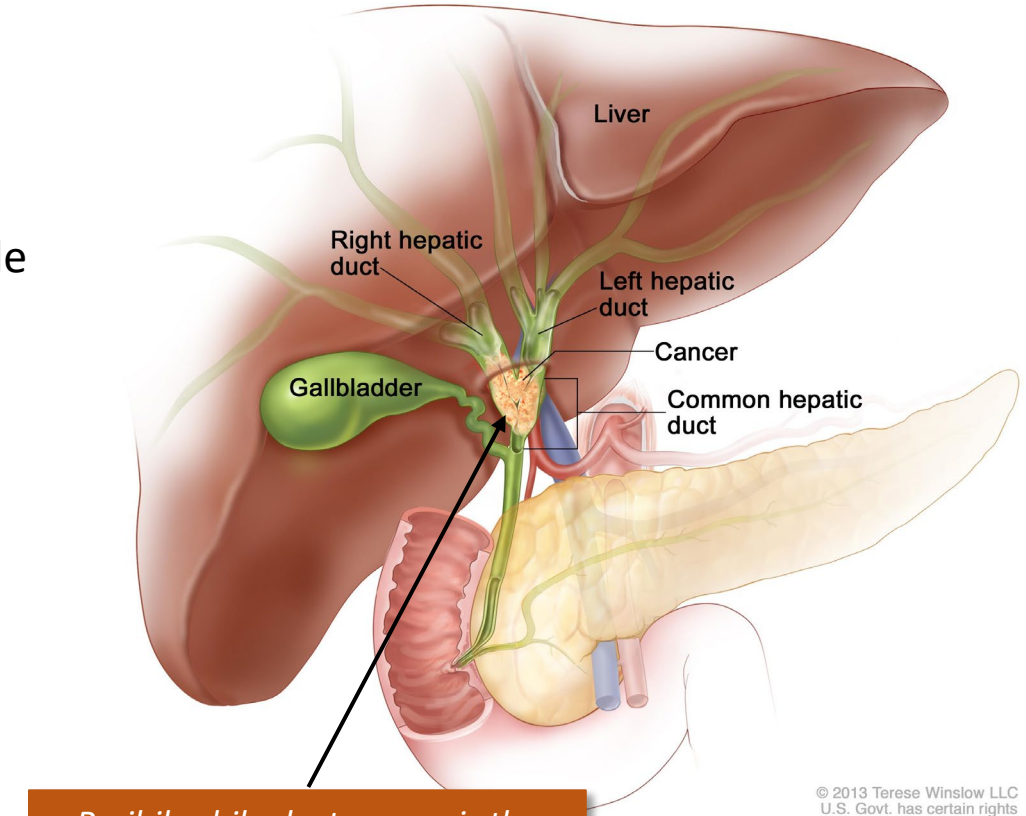
RELEASE – a global pivotal registration intent study

- 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
- **Competition:** Precision/gene/small molecules in clinical development are mainly second line or towards targets mainly present in intrahepatic bile duct cancer
- **Premium price potential:** Mean price for OD in the US is $K150 (median $K109)[3]

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)*

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

*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

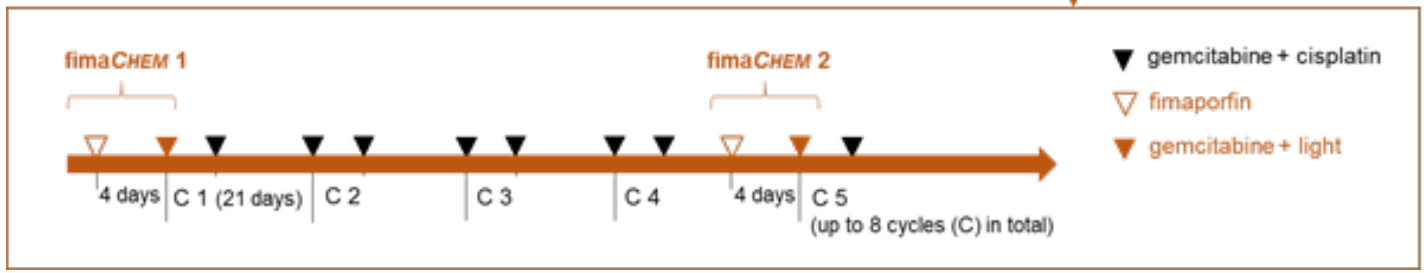
Control (N=93)

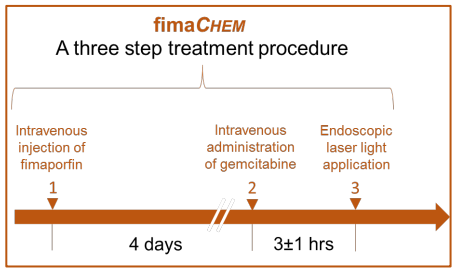
Standard of care (SoC):
gemcitabine + cisplatin
up to 8 cycles

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

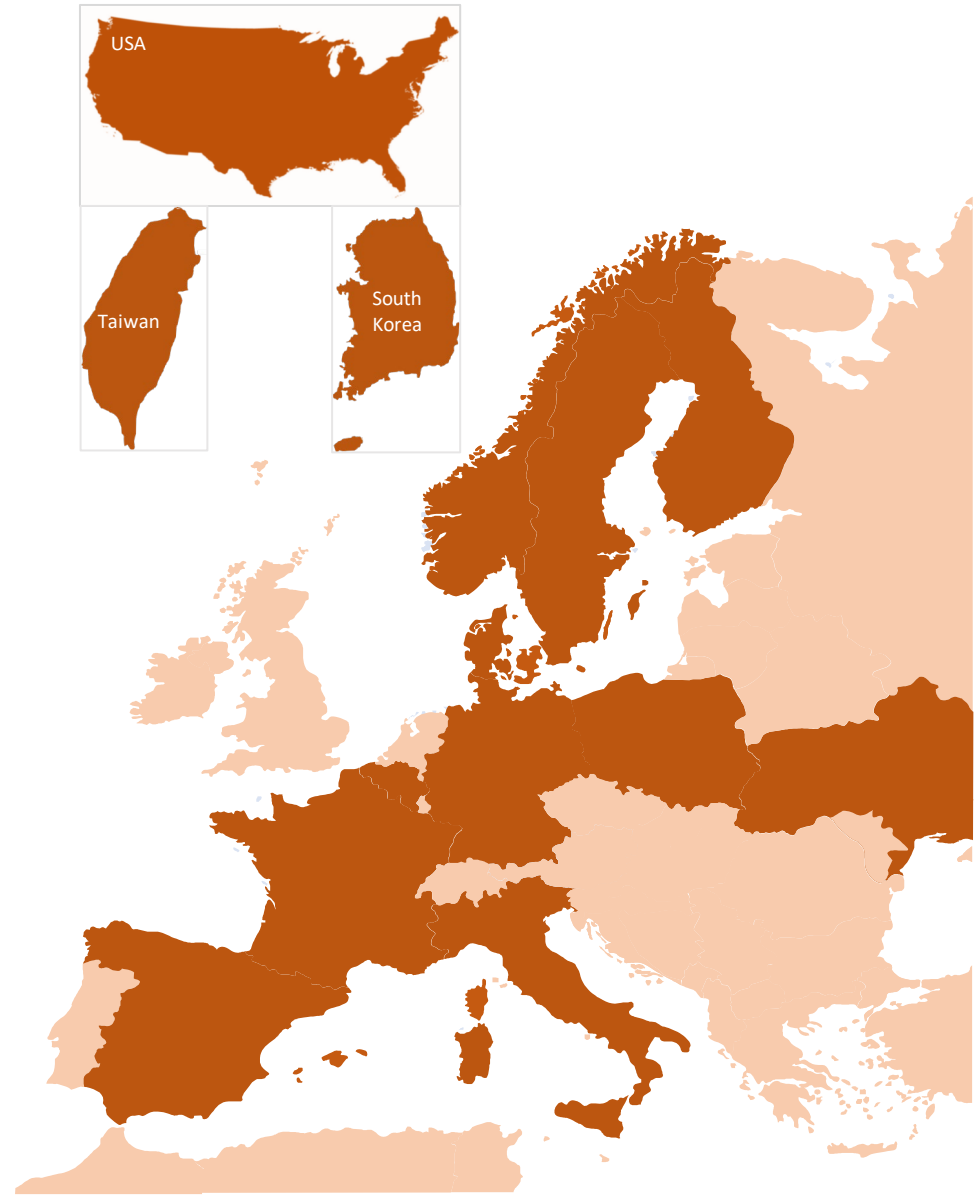




BILE DUCT CANCER – RELEASE STUDY

- Pivotal study status

- Open sites in South Korea, Taiwan, USA and 11 European countries
- Enrolling patients across three continents, with 47 sites open for patient enrolment at Q2'21
- 9 sites open in Asia and 6 sites in the US
- Screening in the RELEASE study has been 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 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, but enrolment still fluctuating and the full effect of these measures is not expected until the COVID-19 situation improves further

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

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

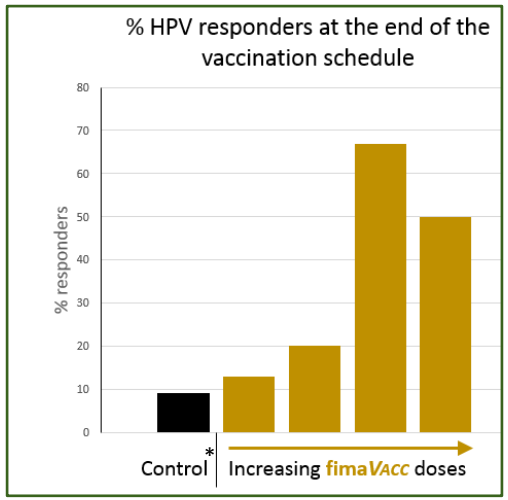
- Phase I study in healthy volunteers with peptide- and protein-based vaccines

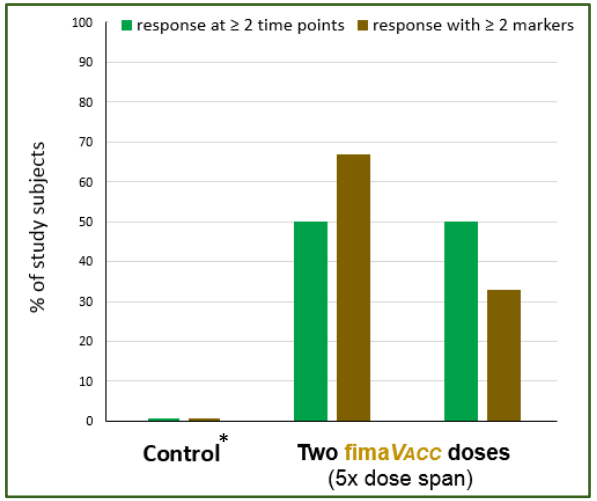
Versatile vaccination platform

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

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

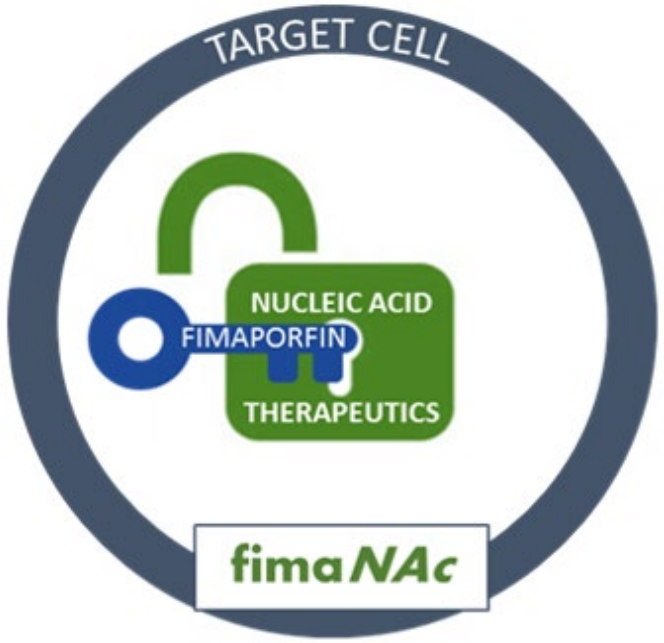
  - The full study results were published early January 2021 in Frontiers in Immunology*, a high impact immunology journal
  - Patent portfolio covering several use areas – latest US patent granted in June covering the use with immune checkpoint inhibitors
  - Strengthening the organisation with highly skilled resources in clinical science and business development
  - 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

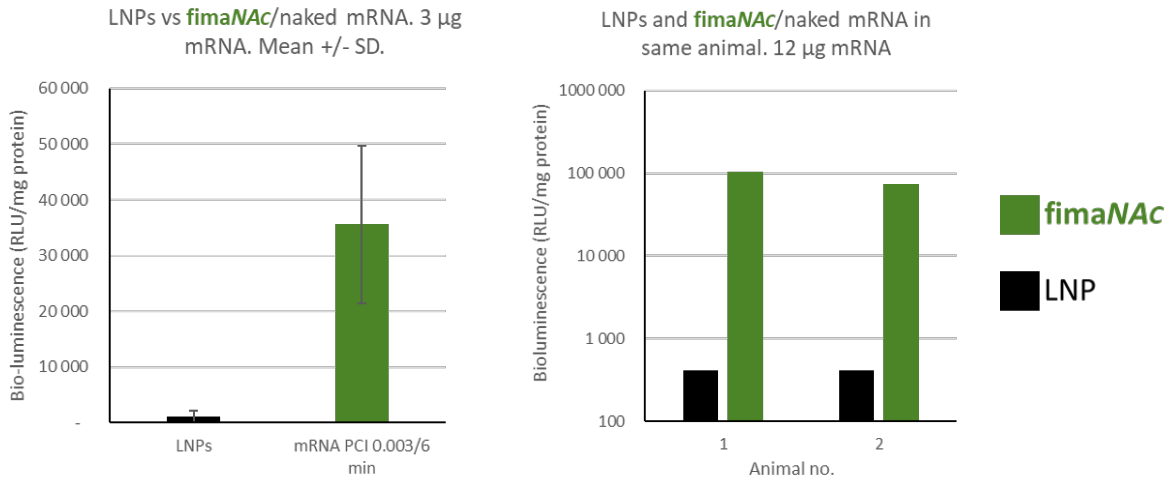
Collaborations with several players in the field

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

Intratumoural Delivery with fimaNAc is Convincingly Superior to LNPs

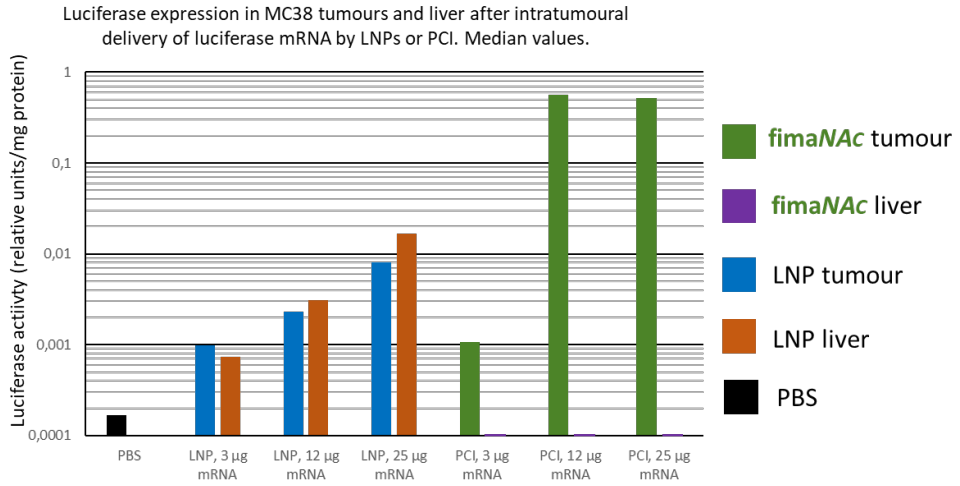
- Substantially higher and more targeted mRNA delivery to tumours compared to LNPs

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)

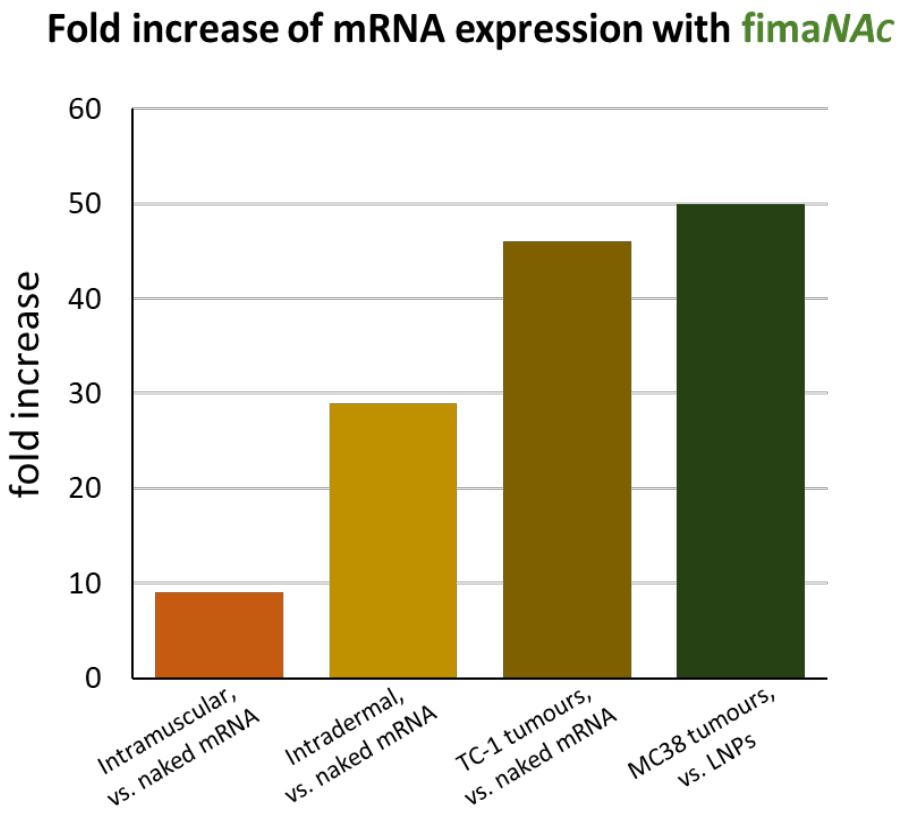
Preventing undesirable off-target delivery



- fimaNAc -mediated delivery confined to tumour
- LNPs seem to leak out and 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

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 and USA
- 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
- Strengthening the organisation for clinical proof of concept in a disease setting

fimaNAc

Providing an intracellular delivery solution for nucleic acid therapeutics

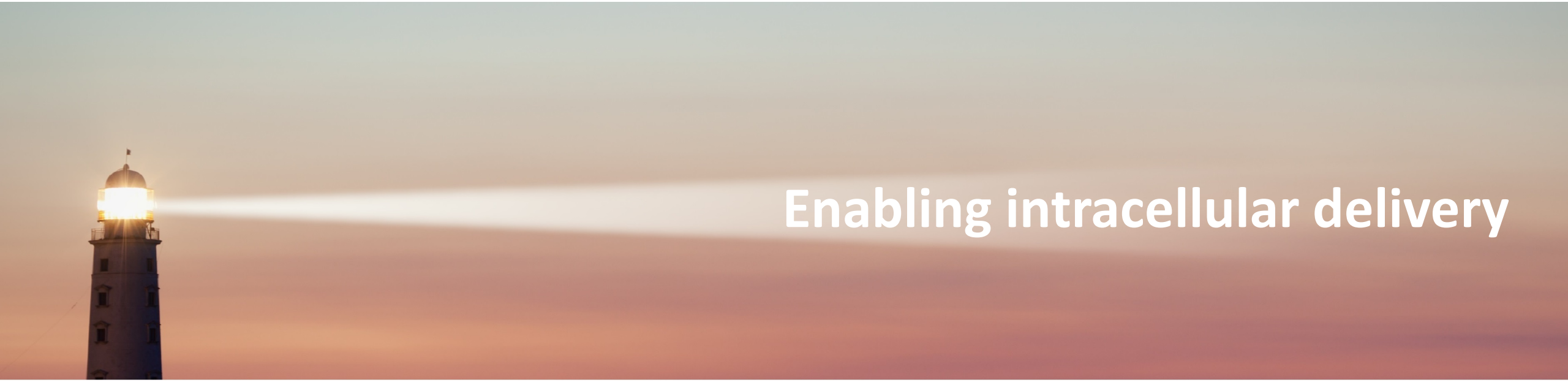
- A versatile technology with strong preclinical data
- Research collaborations with several players in the field

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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