

PCI Biotech



Enabling intracellular delivery

HC Wainwright Global Life Sciences Conference 2021

March 9, 2021

Per Walday, CEO

PCI BIOTECH










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PCI BIOTECH – ENABLING INTRACELLULAR DELIVERY

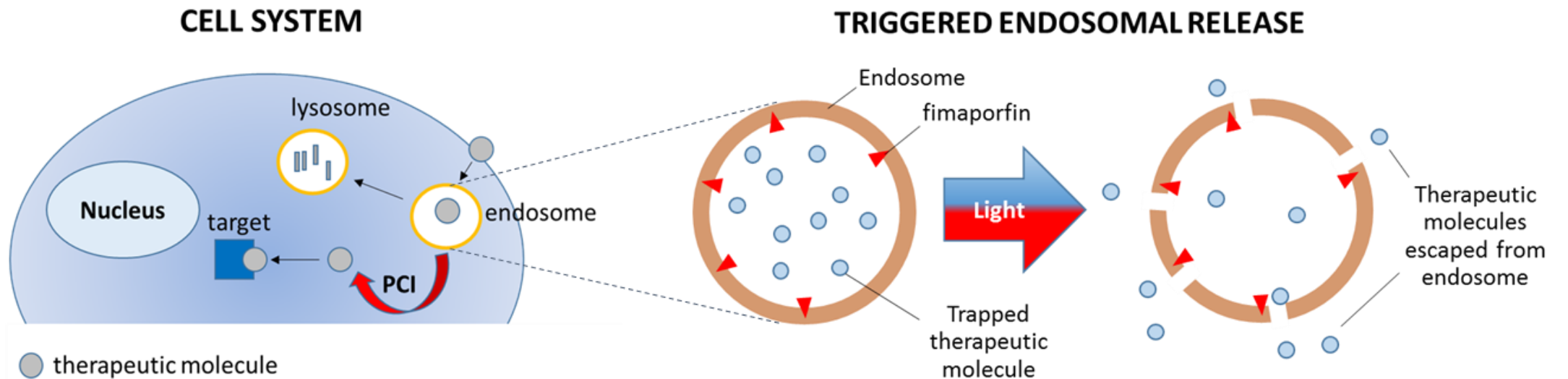
- ▶ A biotech company with an oncology focused pipeline
 - A listed (PCIB:NO) cancer-focused biotech company
 - Solid cash position (approx. 190 mill NOK), partly placed in Euro
 - Photochemical internalisation (“PCI”) technology
 - One platform technology with three well differentiated assets

Programme	Indications/Therapeutics	Preclinical	Phase I	Phase II	Pivotal
 fimaCHEM	 <i>Bile duct cancer / gemcitabine</i>				
 fimaVACC	 <i>Therapeutic cancer vaccines</i>				
 fimaNAC	 <i>Nucleic acid therapeutics</i>				

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 – **fimaCHEM**)
- ▶ Antigens (peptides/proteins – **fimaVACC**)
- ▶ Nucleic acids (mRNA, RNAi – **fimaNAC**)

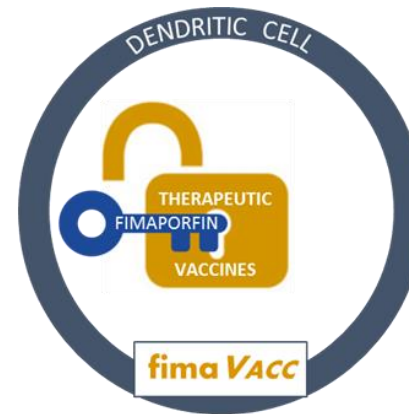
PCI TECHNOLOGY

- ▶ Enabling drugs to reach intracellular therapeutic targets

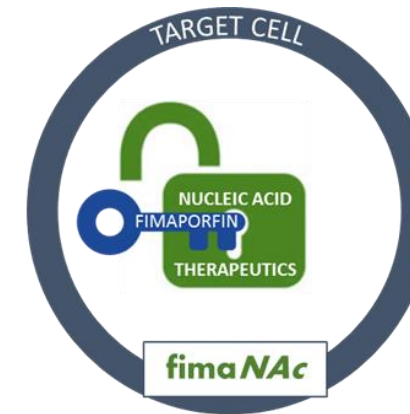
PCI – the solution to a key challenge for several modalities



Enabling approved drugs to fulfil unmet local treatment need



Enhancing cellular immune responses important for therapeutic effect

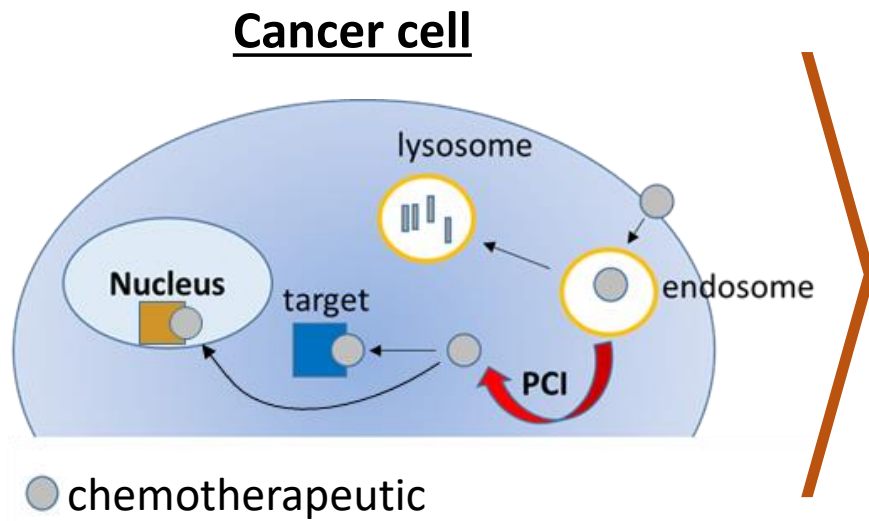


Providing a delivery solution for nucleic acid therapeutics

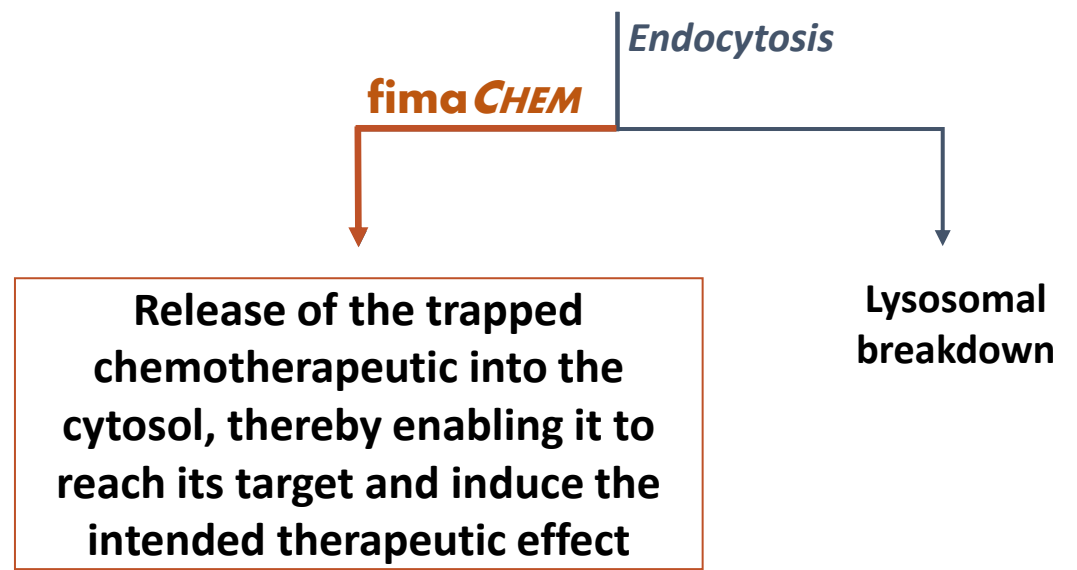


PCI TECHNOLOGY

- ▶ **fima CHEM** – mode of action

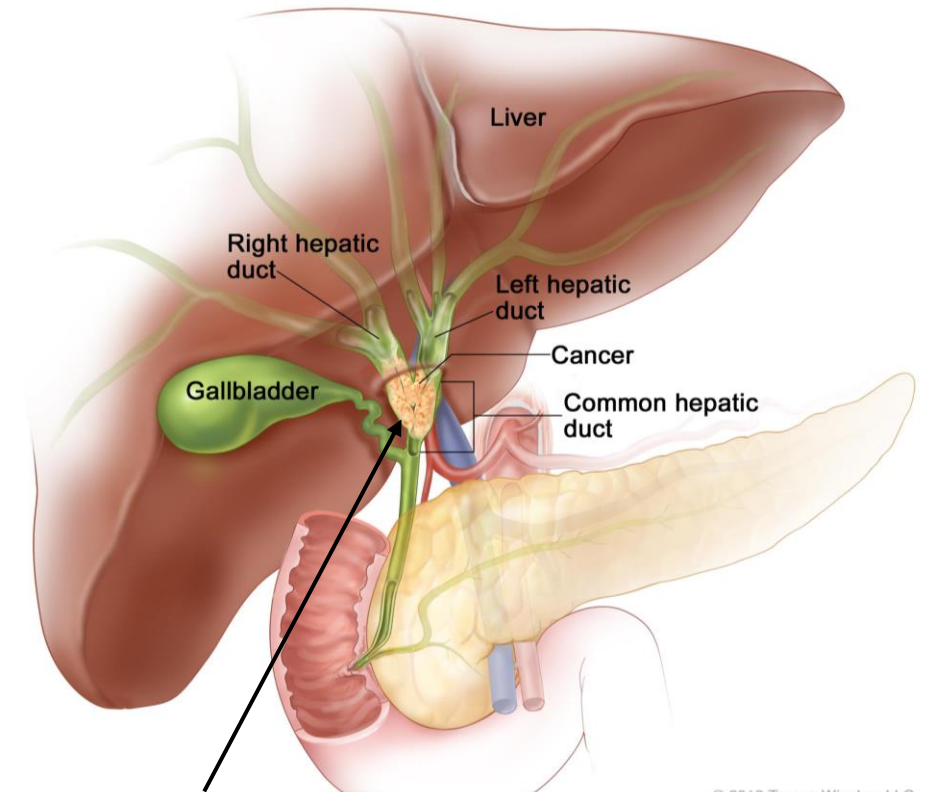


Chemotherapeutics



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



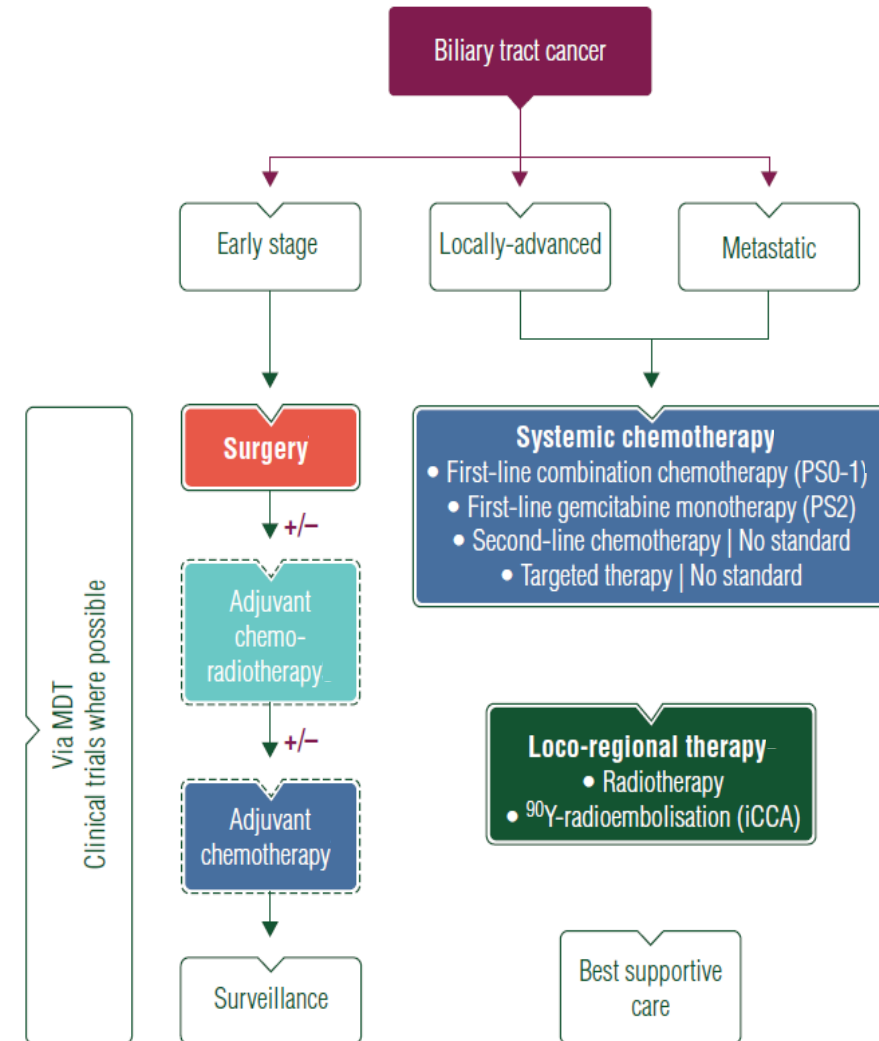
Perihilar bile duct cancer is the main target for PCI treatment

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

fimaCHEM AND BILE DUCT CANCER

- ▶ Excellent fit with medical need and existing treatments
- ▶ **Efficacy:** mOS¹ 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 EU and US, offering 7 to 10 years exclusivity
- ▶ **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



BILE DUCT CANCER – PHASE I DOSE-ESCALATION STUDY

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

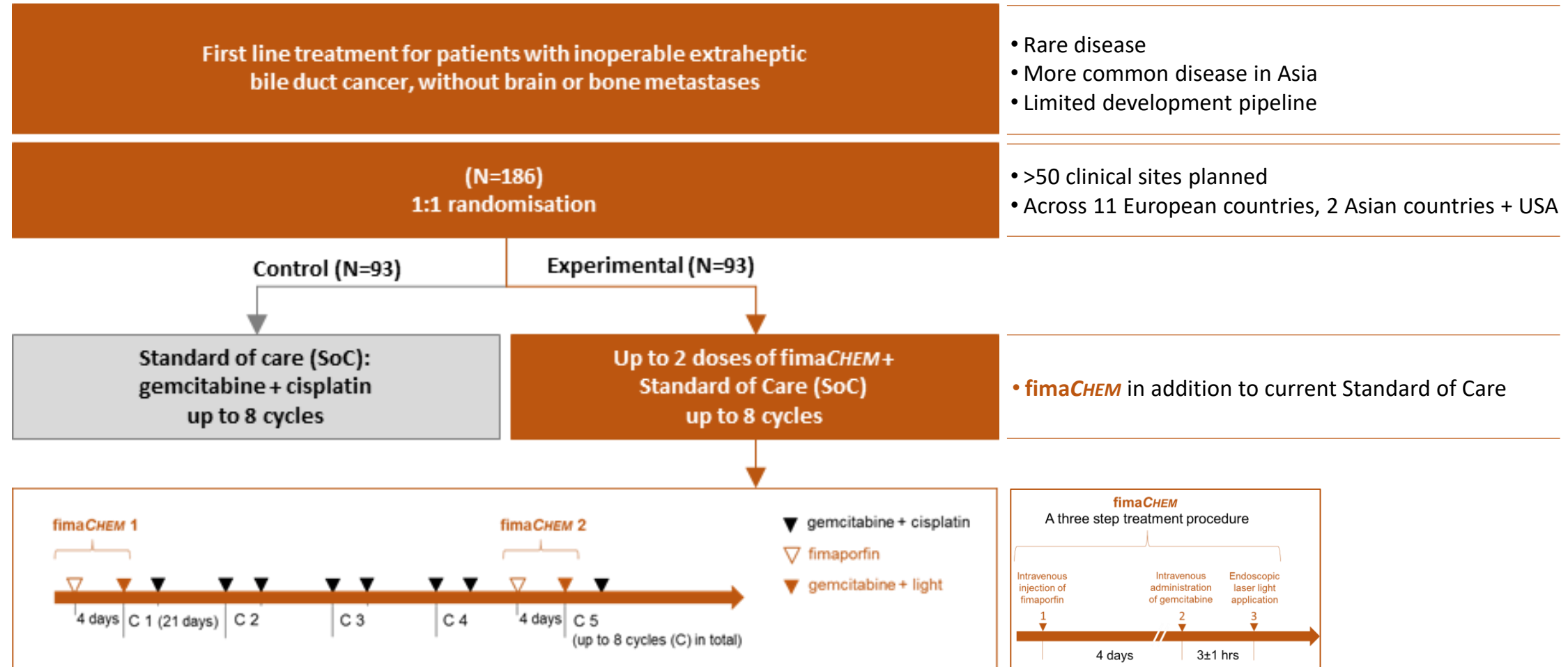
Parameters	Cohort IV (N=6)	Phase I – all dose-escalation cohorts (N=16)
Objective Response Rate (ORR)	3/5 patients (2 PR; 1 CR)	4/12 patients (2 PR; 2 CR)
Median Overall Survival (mOS)	22.8 months	16.1 months

- 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)

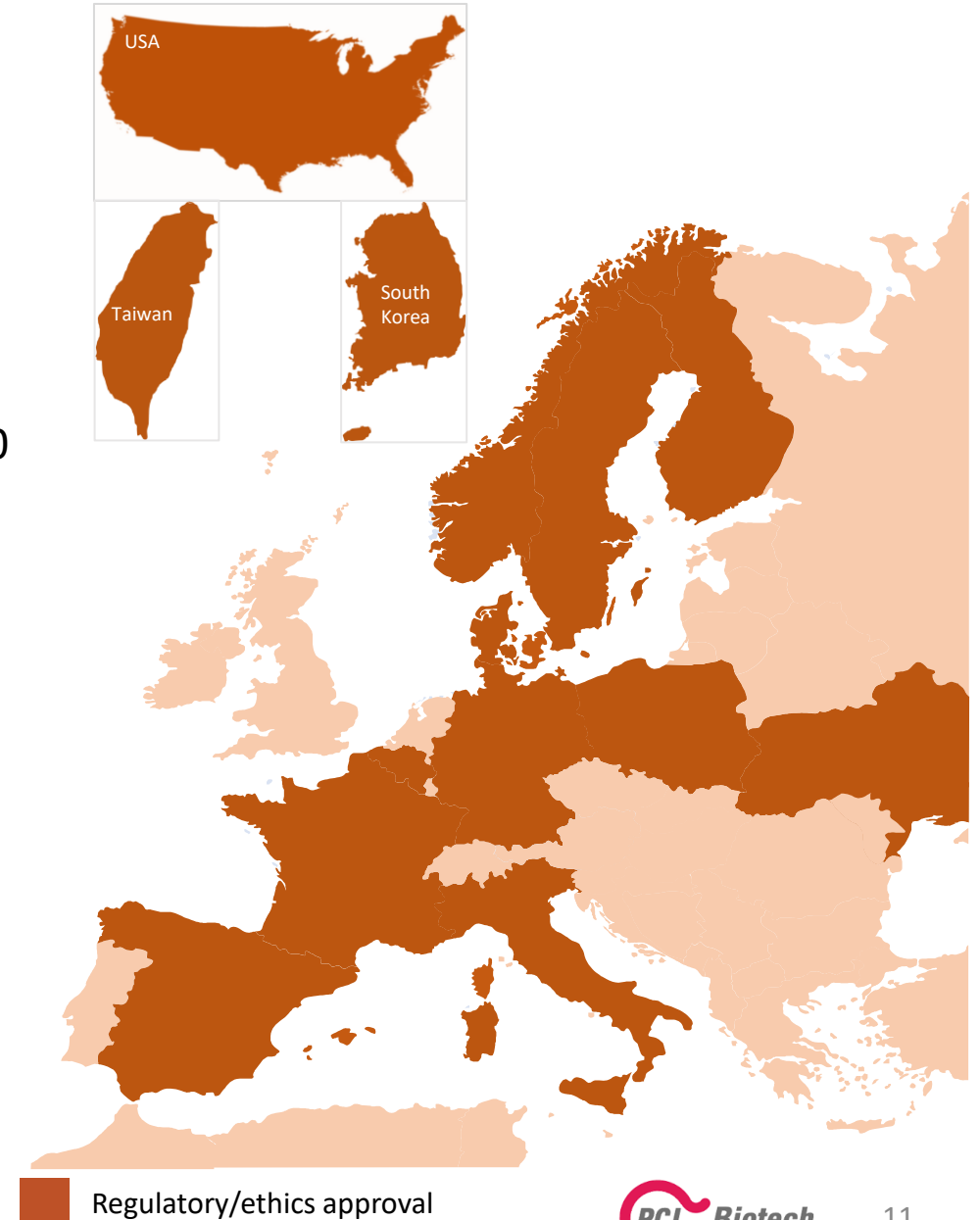
BILE DUCT CANCER – RELEASE STUDY

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



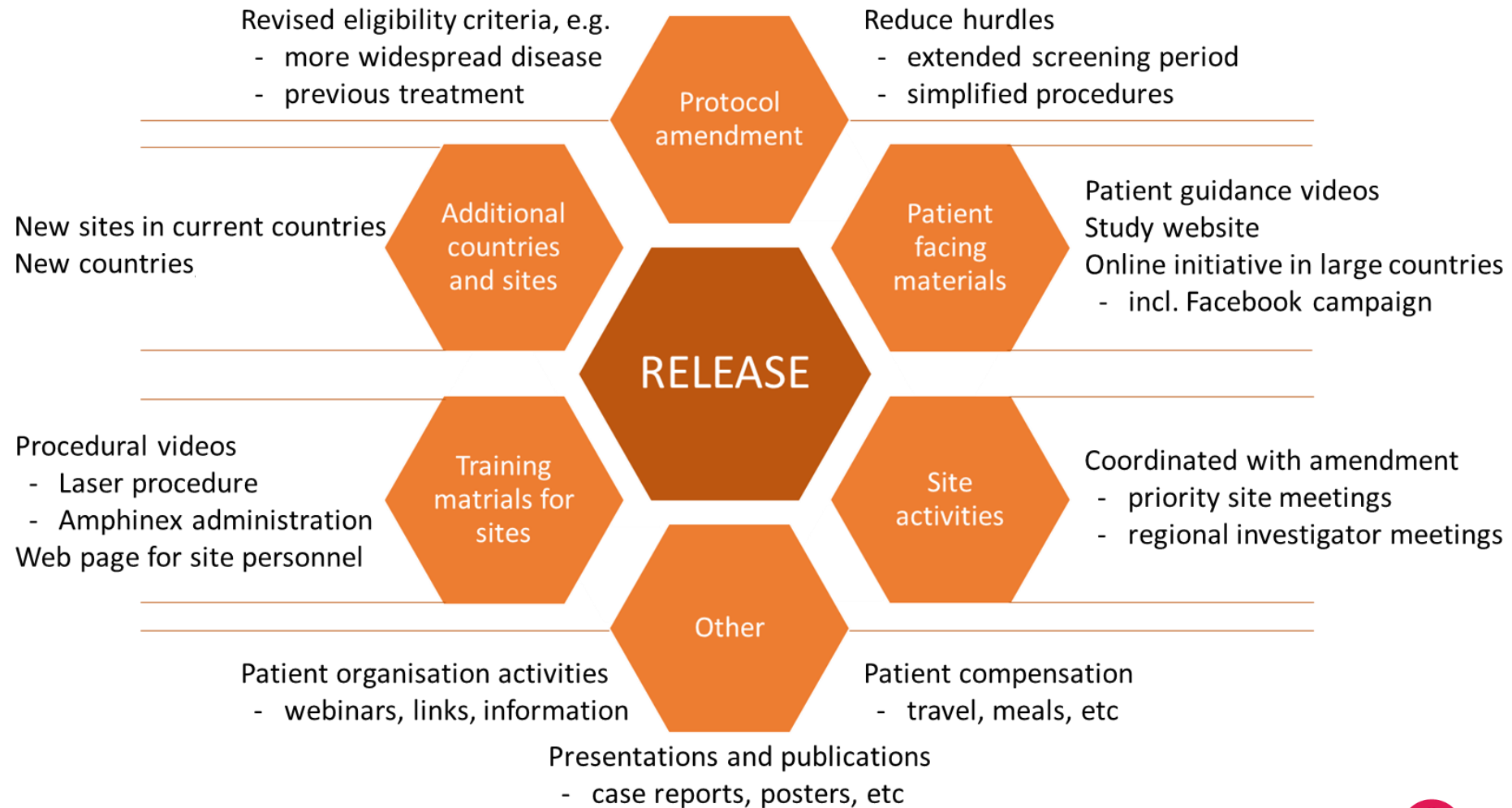
BILE DUCT CANCER – RELEASE STUDY

- ▶ Pivotal study status
 - ▶ Open sites in South Korea, Taiwan, USA and 11 European countries
 - ▶ 47 sites open globally by Q4 2020 report – plan to open >50
 - ▶ 9 sites open in Asia – first Asian patient enrolled Oct'20
 - ▶ 6 sites open in the US – awaiting first US patient
 - ▶ 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



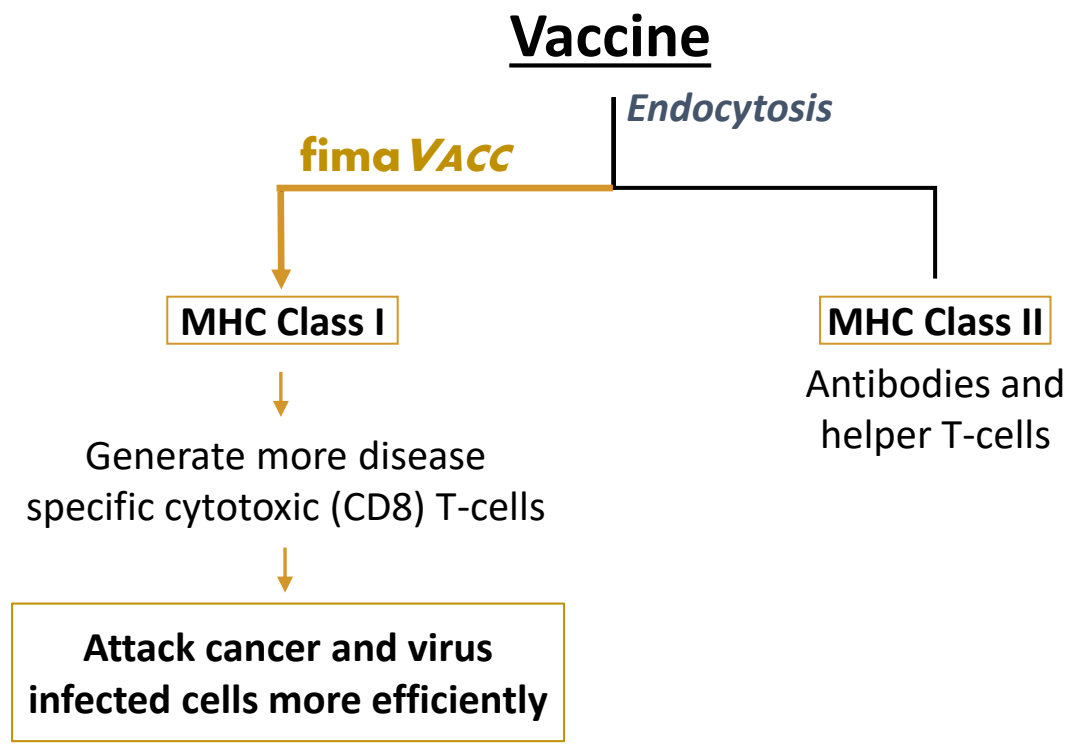
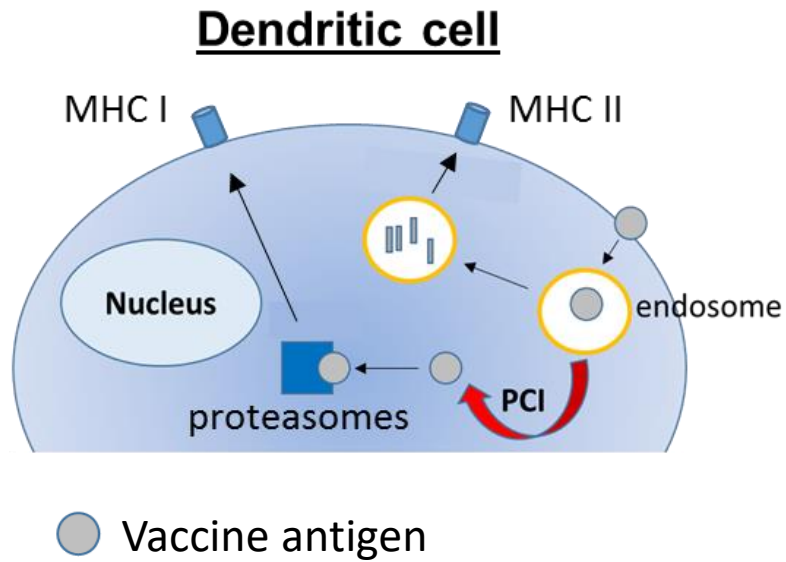
BILE DUCT CANCER – RELEASE STUDY DESIGN

- ▶ Randomised study with interim analysis for potential accelerated/conditional approval
 - ▶ **Orphan designation granted in both the US and EU**
 - ▶ **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 and in Asia October 2020**
 - ▶ **Several initiatives to enhance recruitment implemented and study expanded to Asia autumn 2020**
 - ▶ **Indications of increased screening and enrolment after implementation, but the full effect of these measures is not expected until the COVID-19 situation improves**



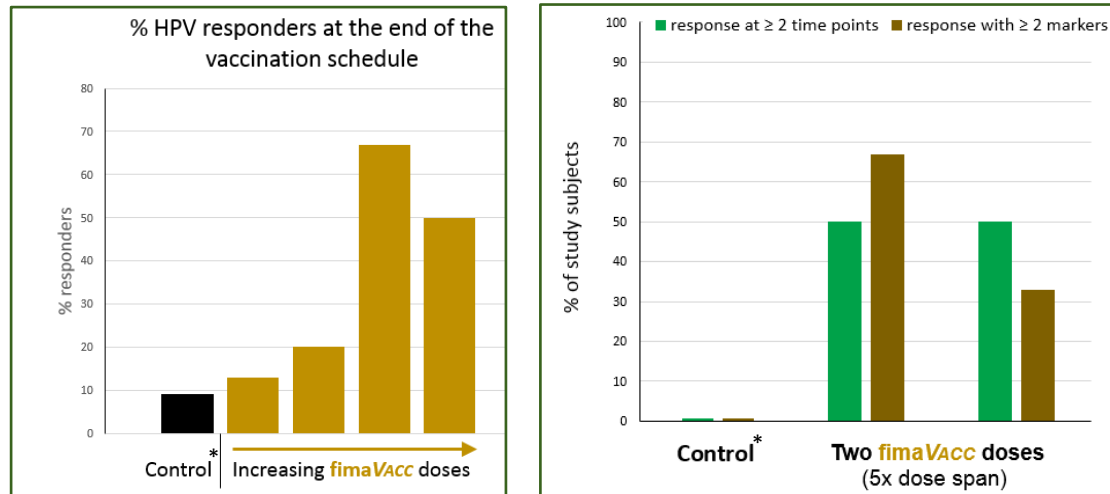
PCI TECHNOLOGY

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



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)

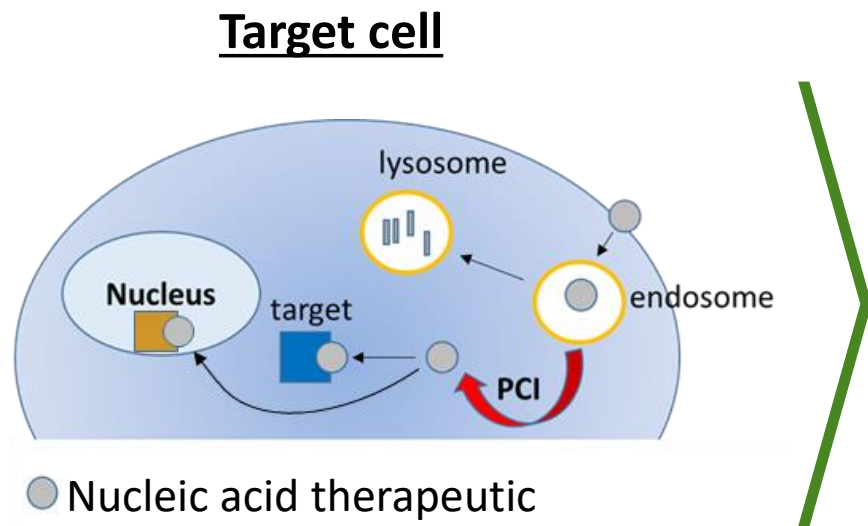


Patented disposable "band-aid-like" device for user-friendly illumination of the vaccination site

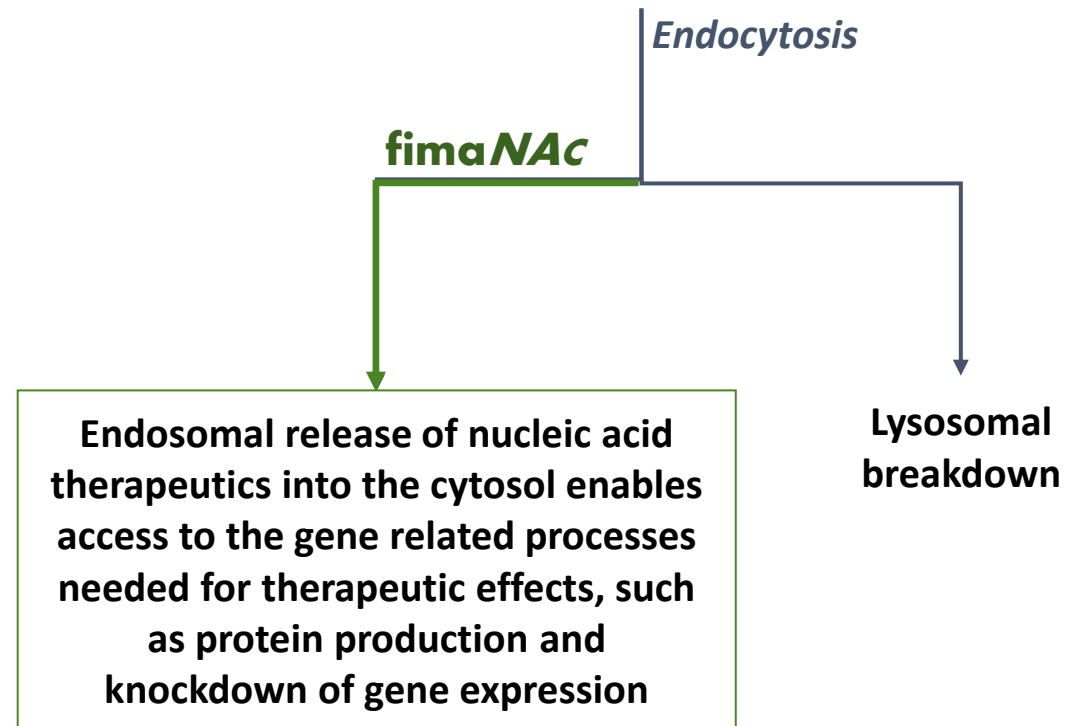
^{*}Front. Immunol., 08 January 2021 | <https://doi.org/10.3389/fimmu.2020.576756>

PCI TECHNOLOGY

- ▶ **fimaNAC** – mode of action



Nucleic acid therapeutic



RESEARCH COLLABORATIONS

- ▶ Collaborations within nucleic acid therapeutics

- ▶ Research collaborations to explore synergies with partner products
- ▶ Four current research collaborations
- ▶ PCI Biotech continues to pursue new value-adding collaborative opportunities

fimaNAC



DCPRIME



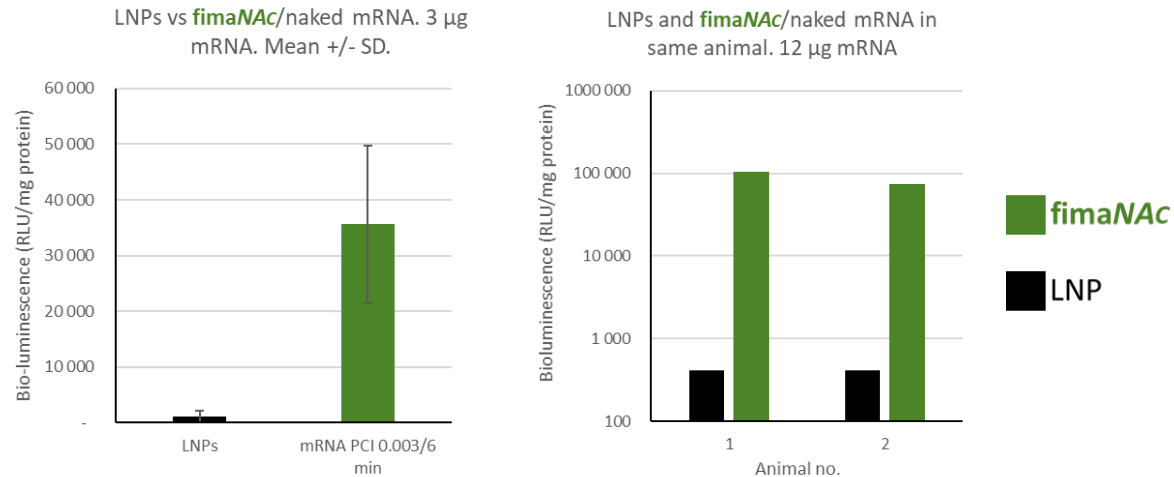
IMVTM
IMMUNOVACCINE

- ▶ Encouraging mRNA results recently presented at international RNA conference*

INTRATUMOURAL DELIVERY WITH **fimaNAC** IS CONVINCINGLY SUPERIOR TO LNPs

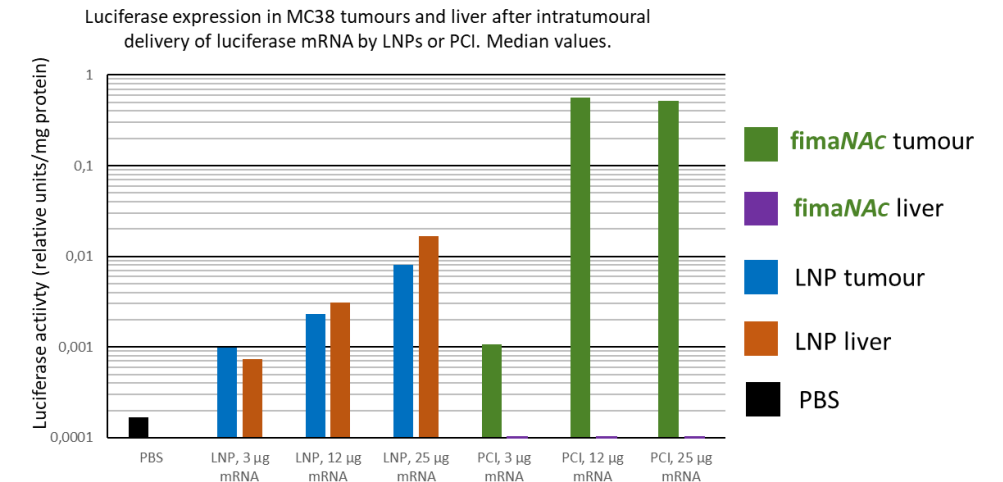
- ▶ Substantially higher and more targeted mRNA delivery to tumours compared to LNPs

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

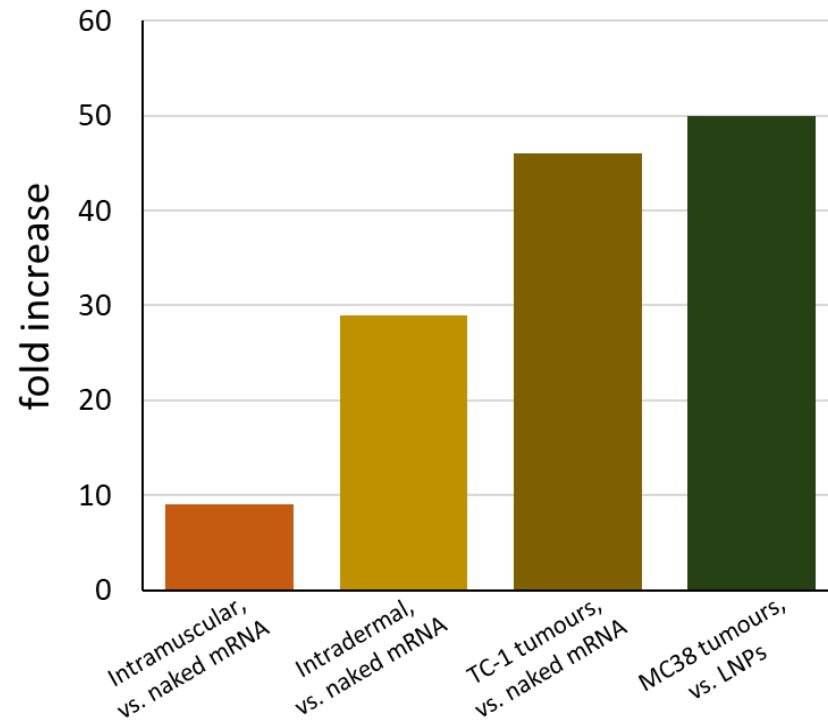


- ▶ **fimaNAC** -mediated delivery confined to tumour
- ▶ LNPs seem to leak out of the tumour leading to unwanted expression in the liver

NAKED MRNA DELIVERY WITH **fimaNAc** – DIFFERENT APPLICATIONS

- ▶ Substantially enhanced delivery to tumour, muscle and skin

Fold increase of mRNA expression with **fimaNAc**



- ▶ 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 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
 - 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 (EU & US) 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

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