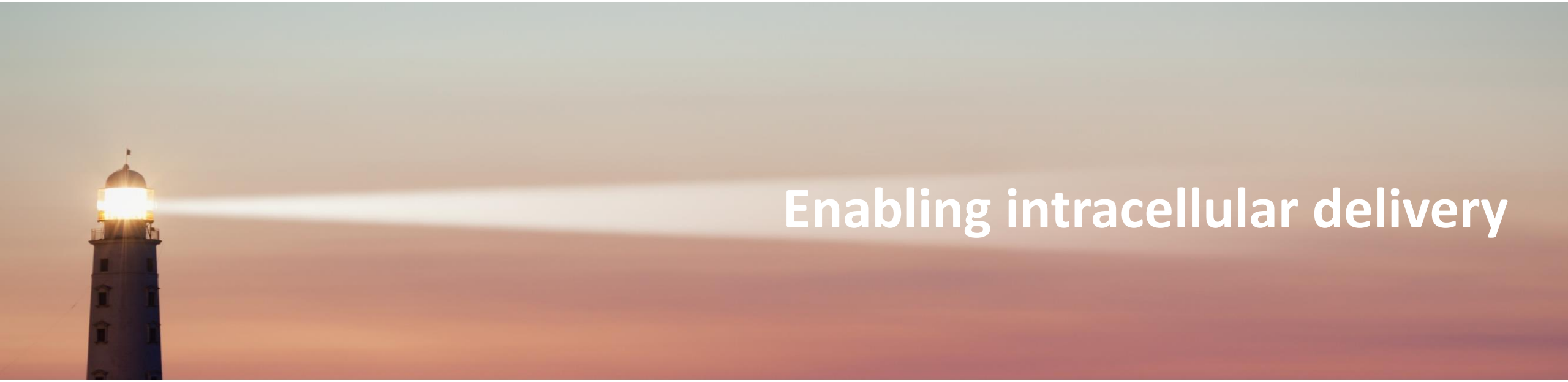
PCI Biotech



Q2 & 1H 2021 PRESENTATION

August 31, 2021

Per Walday, CEO

Ronny Skuggedal, CFO

PCI BIOTECH

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PCI BIOTECH

- Q&A session through teleconference and webcast console

This presentation will also be presented through a teleconference, **mainly facilitated for investors intending to ask questions verbally during the Q&A session**.

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A line mediator will provide information on how to ask questions.

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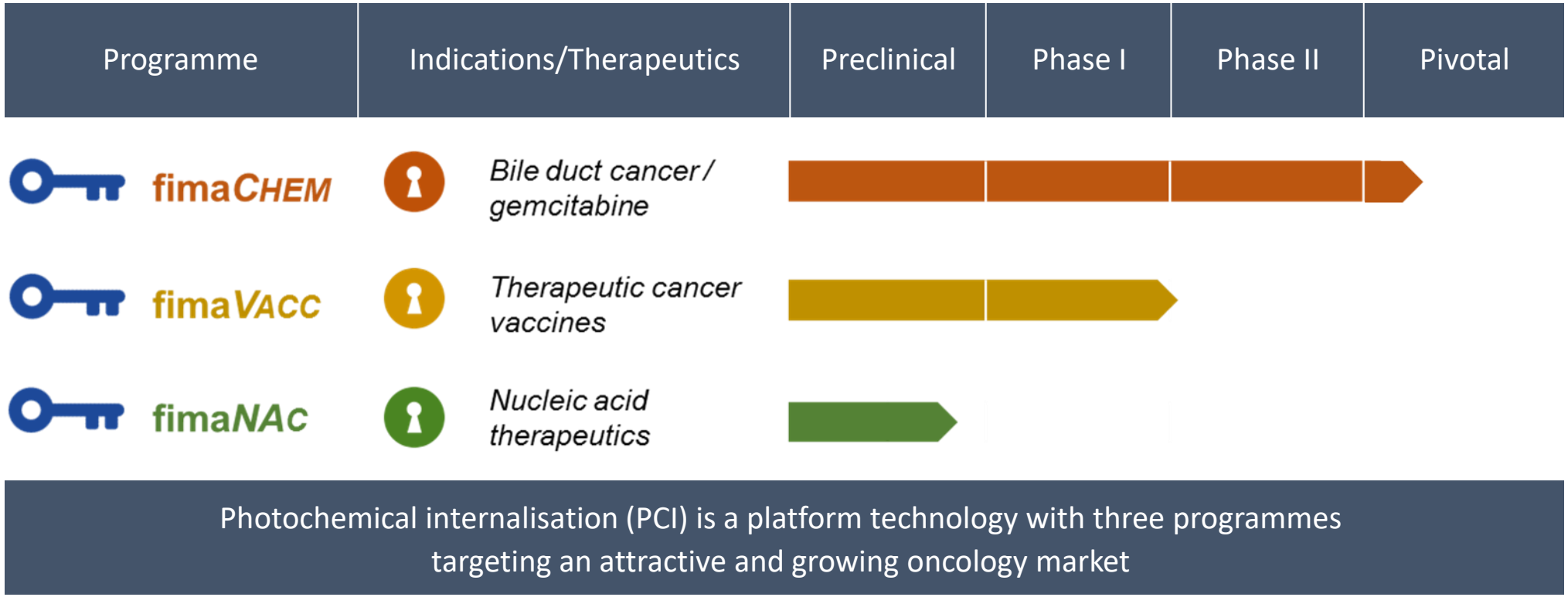
This information is also available in the Q2 Report press release and on the webpage https://www.pcibiotech.no/webcasts

Also possible to post questions through the webcast console.

PCI Biotech – enabling intracellular delivery

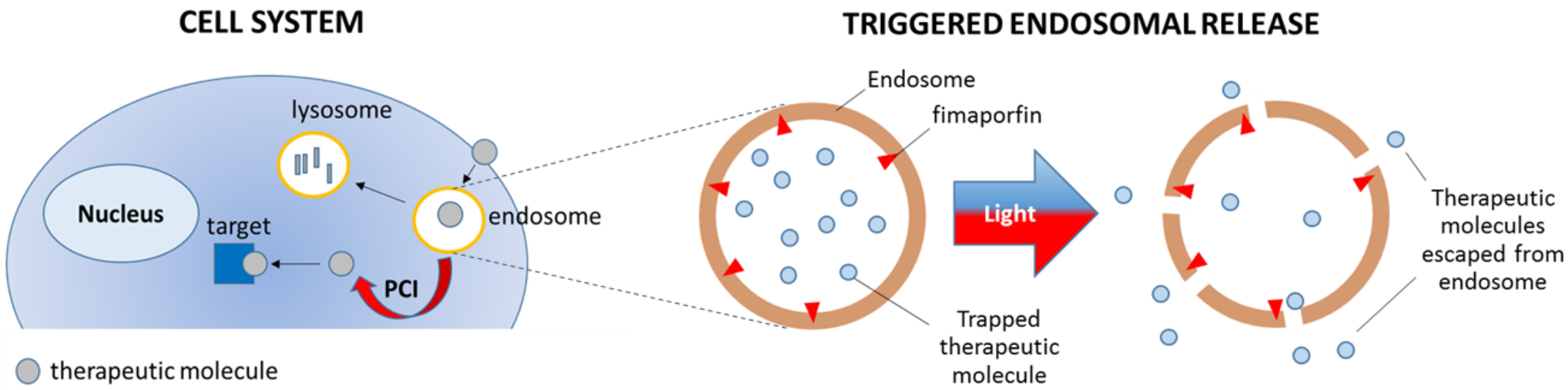
- A biotech company with an oncology focused pipeline



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

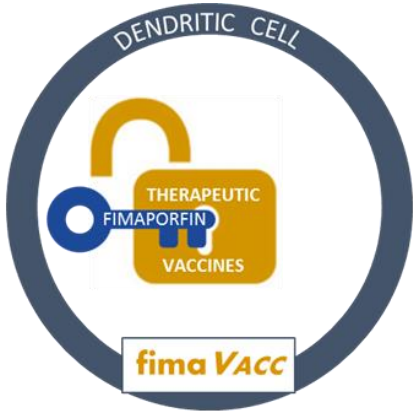


PCI Technology

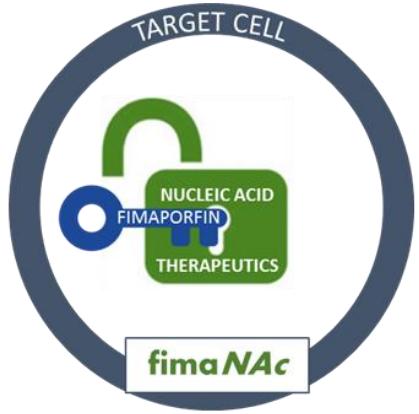
- Enabling drugs to reach intracellular therapeutic targets

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

1H 2021 HIGHLIGHTS

- fimaCHEM

RELEASE – revised timelines due to fluctuating patient recruitment in 2021

- The implementation of the amended protocol and the opening of Asian sites provided increased screening and enrolment to RELEASE in Q1
- Activity declined significantly in Q2 with only three patients included and the expected timeline for the interim analysis for potential accelerated approval is revised to 2H 2023
- Recruitment started stronger in Q3, with four patients enrolled in July

1H 2021 HIGHLIGHTS

- fimaCHEM

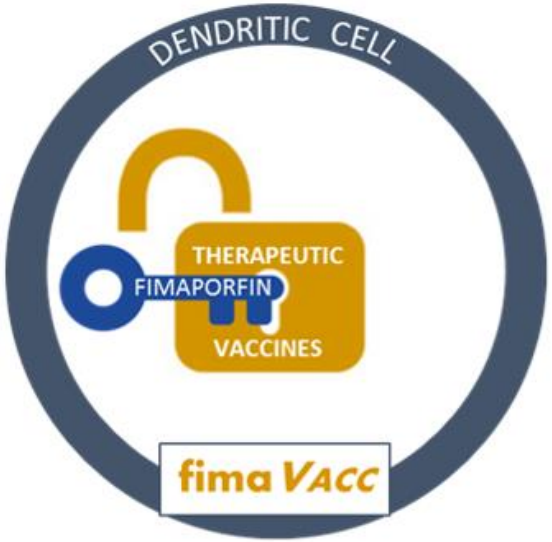
RELEASE – first US patient recruited and ODD granted in South Korea

- First US patient enrolled in the RELEASE study
- Orphan drug designation granted in South Korea for bile duct cancer treatment with fimaporfin in combination with gemcitabine
- Continued focus on enrolment of patients into the RELEASE study, with the emphasis going forward being on regular trial management, including overall performance evaluation and replacement of underperforming sites

1H 2021 HIGHLIGHTS

- **fima*VACC***

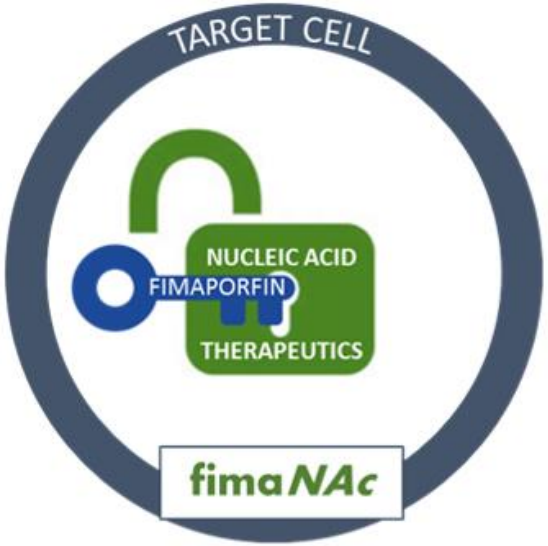
  - Successful Phase I vaccination proof of concept study published in the high impact immunology journal, Frontiers in Immunology, demonstrating that **fima*VACC*** enhances the immune response to peptide- and protein-based vaccines in healthy volunteers
  - US patent granted for the use of **fima*VACC*** in combination with immune checkpoint inhibitors



1H 2021 HIGHLIGHTS

- **fimaNAc**

  - Encouraging data on enhanced delivery of mRNA for various medical applications presented at the UK based 12th Annual RNA Therapeutics Virtual Conference
  - Established extensive research collaboration with the South Korean company OliX Pharmaceuticals, a leading developer of RNAi therapeutics



1H 2021 HIGHLIGHTS

- **Corporate**

  - Significantly strengthening the organisation with three highly skilled individuals; an experienced operational leader for RELEASE and two key employees within clinical science and business development focusing on **fima*VACC*** and **fima*NAc***

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

*Cholangiocarcinoma; CCA

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

fimaCHEM

- Orphan drug designation granted in South Korea

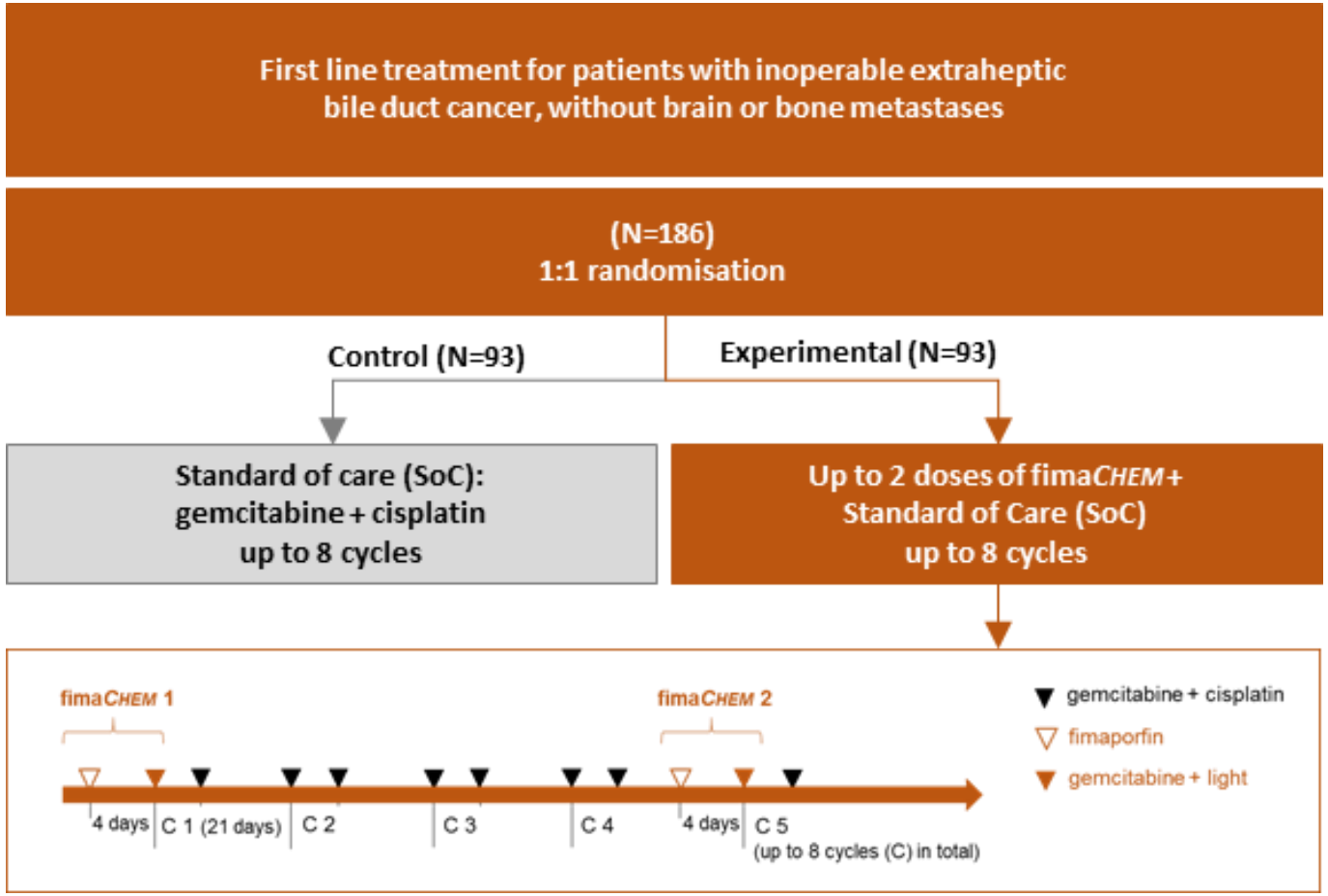
  - In May 2021, the Ministry of Food and Drug Safety (MFDS) in South Korea granted Orphan Drug Designation (ODD) to fimaporfin for combination treatment with gemcitabine in patients with inoperable locally advanced or metastatic bile duct cancer (cholangiocarcinoma)

  - ODD in South Korea may under certain circumstances provide several benefits, including conditional approval, extended market exclusivity and exemptions from required data

  - ODD is now granted in three major markets, across all continents with sites for the pivotal RELEASE study with registration intent

BILE DUCT CANCER – RELEASE STUDY

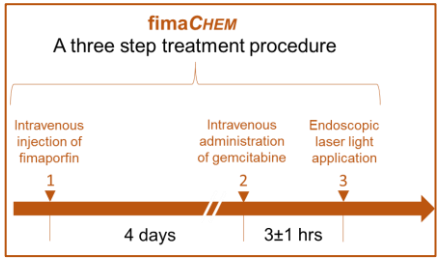
- Pivotal study with potential accelerated/conditional approval on interim analysis



- Rare disease
- Majority of cases are inoperable upon presentation
- Median overall survival of less than one year
- No approved treatment, limited development pipeline

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

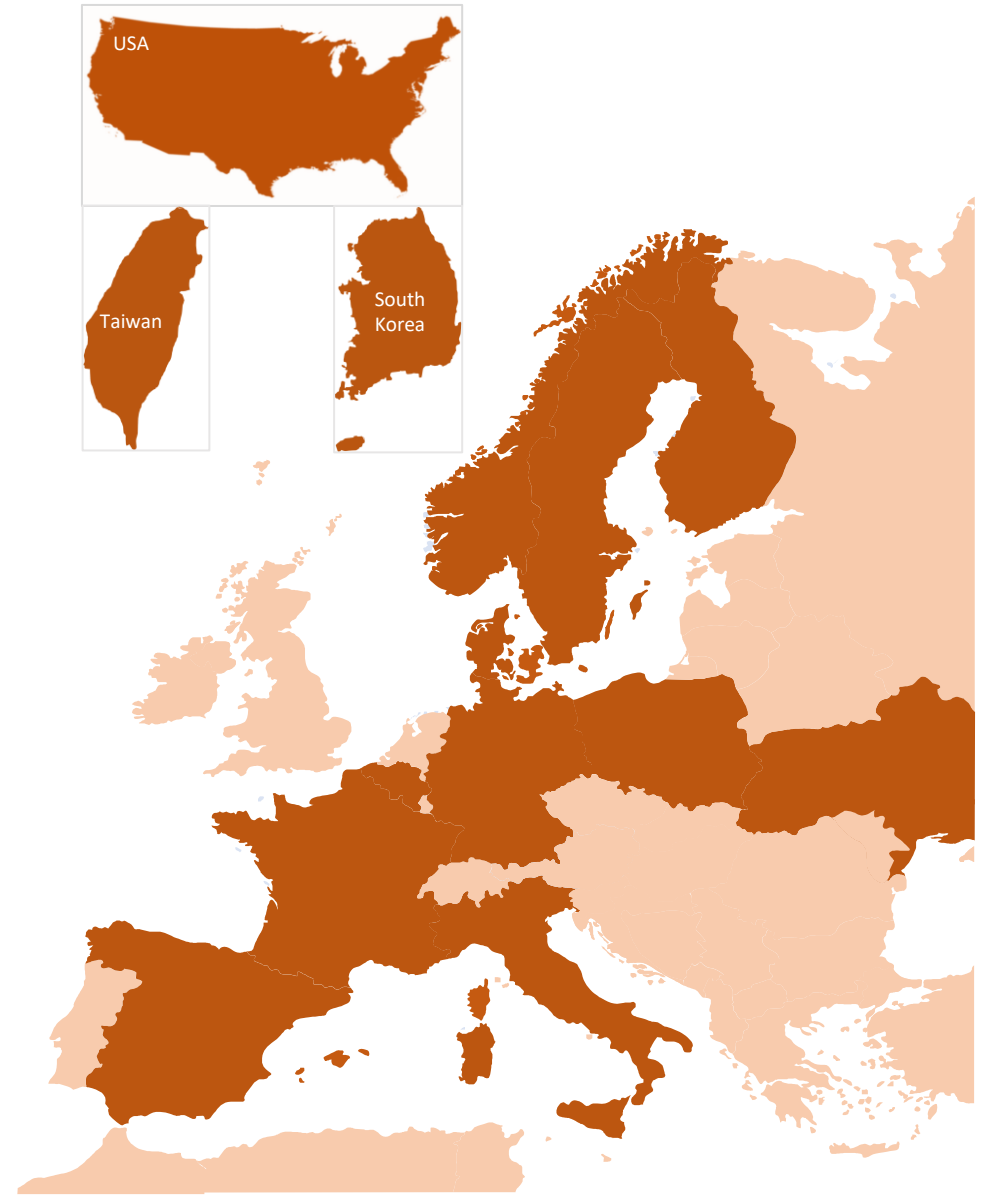
- **fimaCHEM** in addition to current Standard of Care



BILE DUCT CANCER – RELEASE STUDY

- Pivotal study status

  - 47 sites currently open for patient enrolment
    - 9 sites in Asia – first Asian patient enrolled Oct'20
    - 6 sites in the US – first US patient enrolled Apr'21
  - Several initiatives implemented autumn 2020 with the aim to recoup the COVID-19 caused delay – the most important being increased number of sites and protocol amendment to expand eligible patient population
  - Expansion to Asia has contributed significantly to patient recruitment
  - The initiatives resulted in increased screening and enrolment in Q1 2021, but this positive trend did unfortunately not continue into Q2, with only three patients included during that quarter
  - Q3 started stronger, with four patients included in July



BILE DUCT CANCER – RELEASE STUDY

- Pivotal study progress and timelines

- Focus going forward is on regular trial management, including overall performance evaluation with replacement of underperforming sites, and proactive management of study specific risks, such as retention of randomised patients and adherence to study procedures and eligibility criteria

- The previously communicated time range for interim readout was based on a recruitment plan with 14-18 patients per quarter going forward, which is above our best quarter to date (N=10)

- This plan was ambitious, and it also assumed no further recruitment impact by Covid-19, which is now considered unlikely

- On this basis, the company is now revising the expected timing of the planned interim analysis to 2H 2023

- Full focus on RELEASE – further strengthened the team with an experienced operational leader and evaluating all identified opportunities to optimise the overall performance of the study

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

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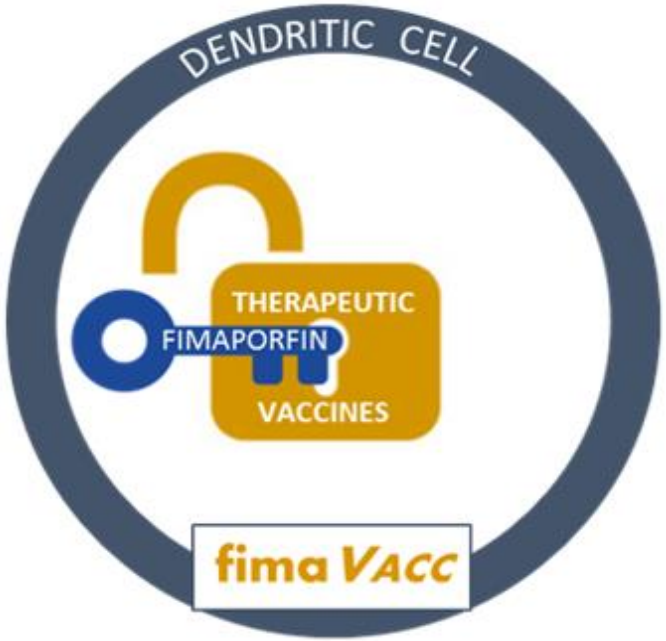
- **fima VACC** – aiming to enhance the effect of immunotherapeutics



Compelling preclinical results

- Particularly strong CD8 T-cell immune responses

Successfully translated into humans

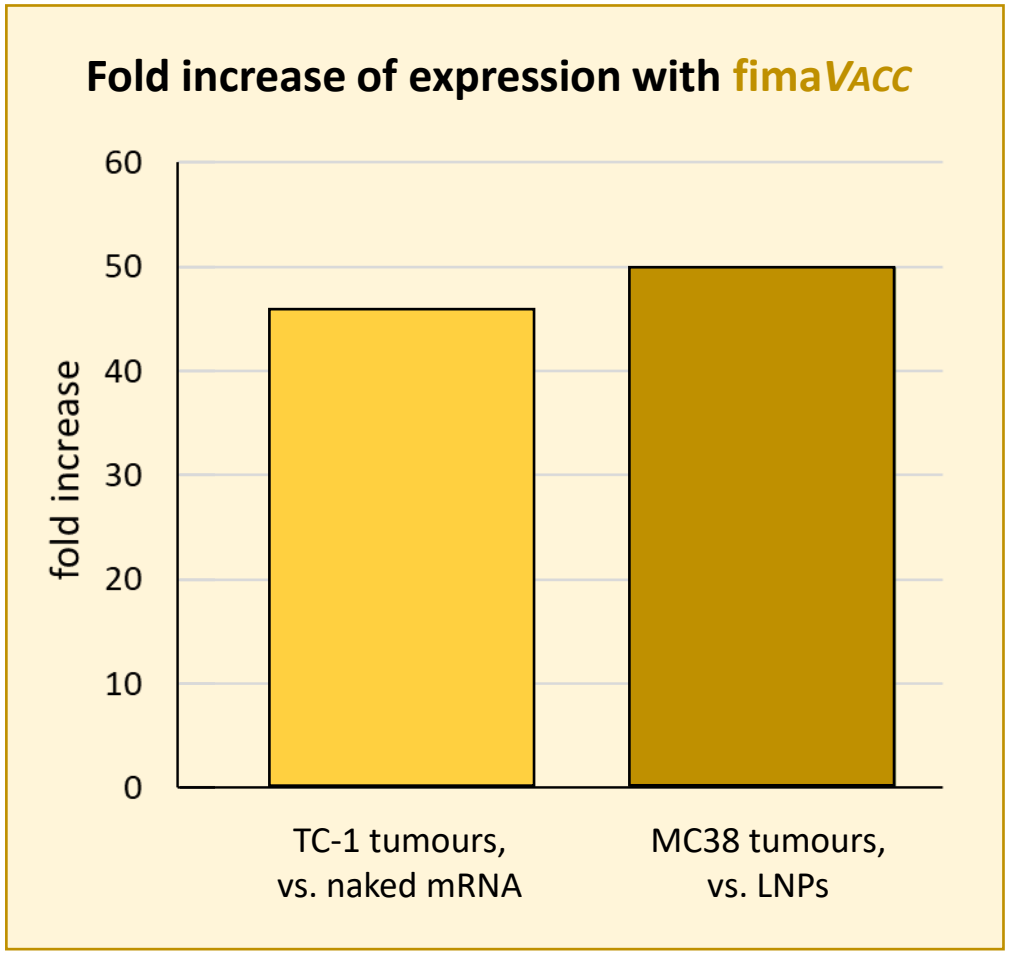
- Phase I study in healthy volunteers with peptide- and protein-based vaccines

Versatile vaccination platform

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

INTRATUMOURAL IMMUNOTHERAPY WITH NAKED MRNA

- Encouraging preclinical results



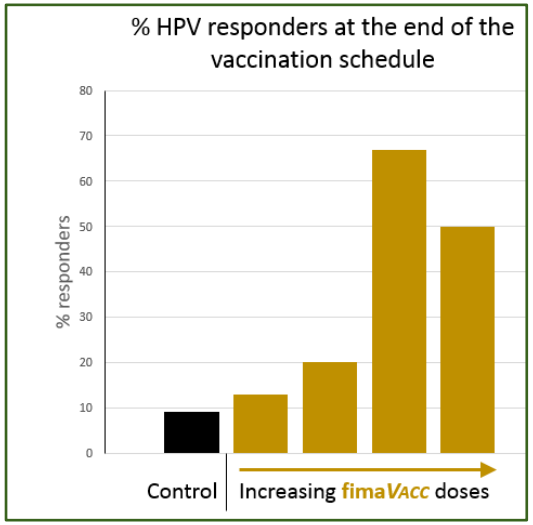
- Intratumoural immunotherapy with **fimaVACC**
  - Systemic therapeutic effects can be achieved
  - For use with mRNA encoding antigens and/or immuno-stimulating factors
  - Expression confined to tumour – may be important to avoid potential side effects
    - **fimaVACC** substantially better than LNPs
  - Potential inherent adjuvant effect of **fimaVACC**
    - Modulation of tumour microenvironment

PROGRESS OF THE fimaVACC PROGRAMME

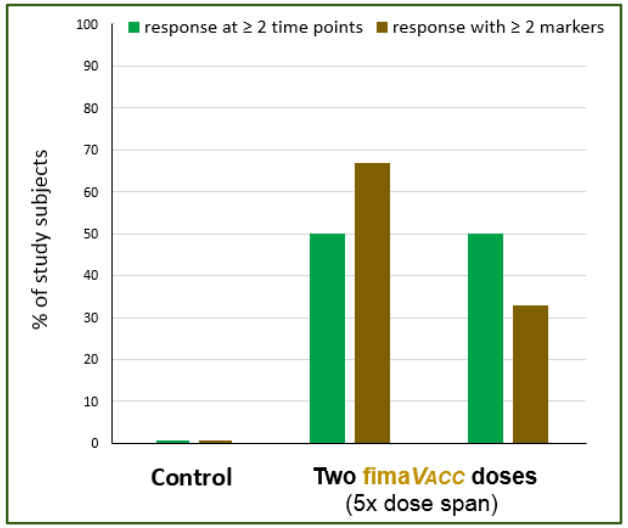
- Successful clinical proof-of-concept with protein/peptide-based vaccines

- Phase I study provided successful clinical proof-of-concept for fimaVACC
  - Overall objective to determine the safety, tolerability and immune response of fimaVACC
  - Proof of concept and efficacy in terms of intradermal dosing in humans achieved

Overall T-cell response



CD8+ T-cell response



fimaVACC provides:

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

PROGRESS OF THE fimaVACC PROGRAMME

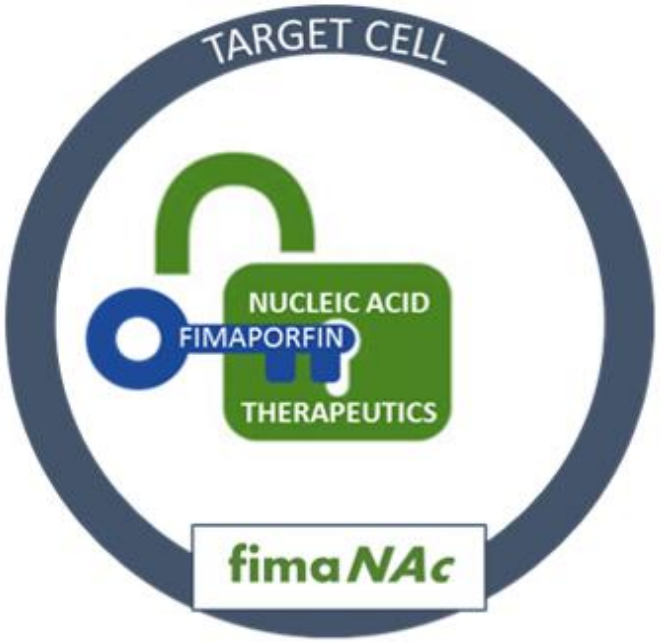
- Growing robust evidence, with Phase I study published

  - The full Phase I study results were published early January 2021 in Frontiers in Immunology, a high impact immunology journal
  - In June 2021, a new US patent was granted covering the use of fimaVACC in combination with immune checkpoint inhibitors
  - The RELEASE focus during the pandemic has unfortunately reduced available resources for fimaVACC – the company has strong confidence in the commercial potential and has strengthened the organisation with two highly skilled people within clinical science and business development, to drive the preparation for a potential clinical proof-of-concept study for therapeutic vaccination in a relevant cancer disease

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

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

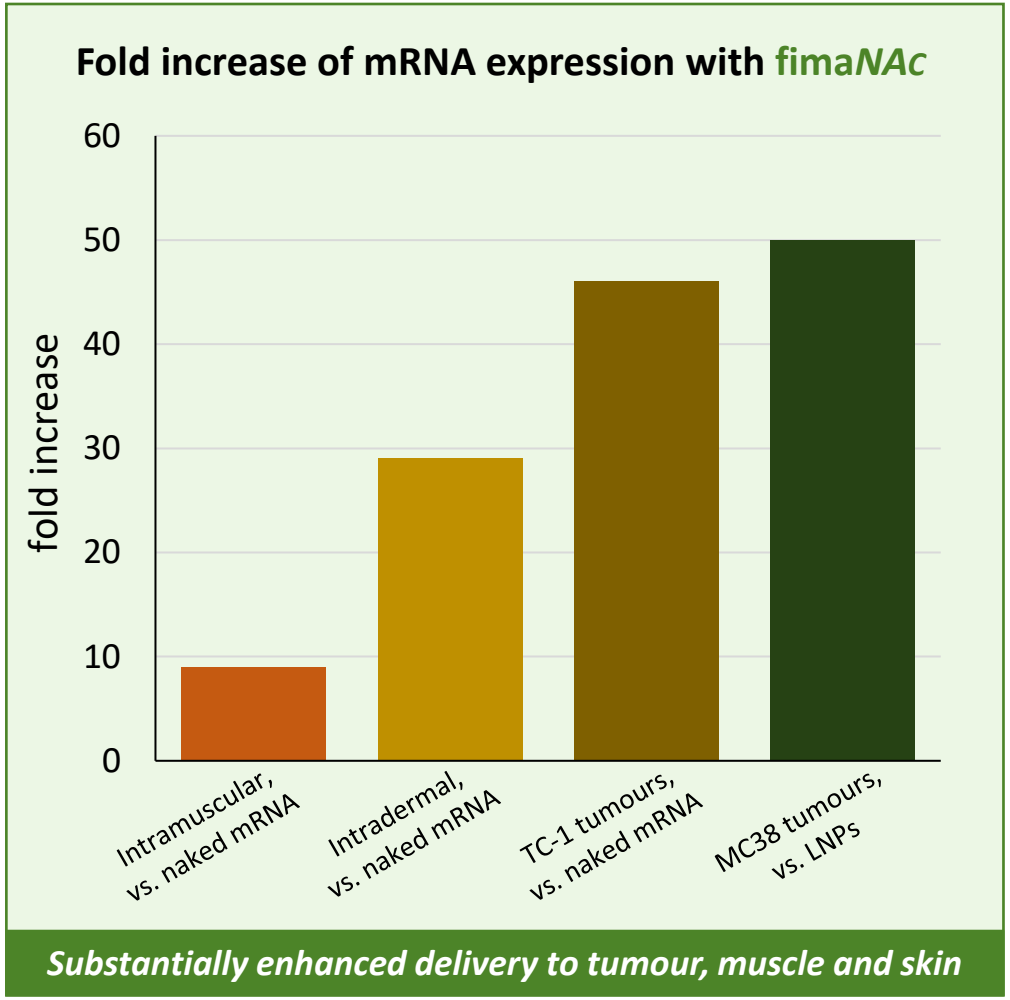
- Intracellular delivery of sufficiently high payloads remain a major obstacle for many applications

Collaborations with several players in the field

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

NAKED MRNA DELIVERY WITH fimaNAc – DIFFERENT APPLICATIONS

- Encouraging collaborative results presented at an international conference on RNA therapeutics



- Local delivery technology
  - mRNAs and fimaporfin can be mixed and administered as one injection, with illumination in the same procedure
  - mRNA expression spatially restricted to illuminated area
- Clinically proven platform technology
  - fimaVACC and fimaCHEM using the same platform – ample safety data in humans
- Applications where a local effect is desired
  - Skin, muscles, tumours, eye, joints, lymph nodes
- Substantial enhancement in tumour, muscle and skin
- Actively centre internal research efforts towards the most attractive applications

Research Collaboration

- Collaboration established with OliX Pharmaceuticals

- In May 2021, PCI Biotech entered into an extensive research collaboration with the South Korean company OliX Pharmaceuticals, a leading developer of RNAi therapeutics
- OliX Pharmaceuticals and PCI Biotech will combine their know-how and technology platforms to explore synergies and further partnership
- The partnership is governed by a research collaboration agreement, under which the collaborators will perform an extensive evaluation of technology compatibility and synergy based on preclinical studies
- The companies will evaluate results achieved from this research collaboration to explore the potential for further development and partnership

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

OliX Pharmaceuticals

eTheRNA

IMMUNICUM

APOSENSE

imv IMMUNOVACCINE

FINANCE

- Key financial figures

- Fluctuations in exchange rate, effects on bank deposits and net financial result
- BIA grant for **fima*VACC*** ended Q2 2021, with NOK 13.4 million accumulated funding
- Solid cash position, partly placed in Euro, with an expected financial runway into 2H 2022

(figures in NOK 1,000)	Q2 2021	Q2 2020	1H 2021	1H 2020	FY 2020
Other income (public grants)	2 310	1 919	3 898	3 838	7 368
Operating results	-19 083	-22 252	-40 254	-38 226	-82 121
Net financial result	*937*	*-6 745*	*-1 665*	*13 656*	*9 881*
Net profit/loss	-18 146	-28 997	-41 919	-24 570	-72 239

(figures in NOK 1,000)	Q2 2021	Q2 2020	1H 2021	1H 2020	FY 2020
Cash & cash equivalents	147 732	231 370	147 732	231 370	187 967
Cash flow from operating activities	-14 958	-16 556	-37 843	-38 927	-77 391

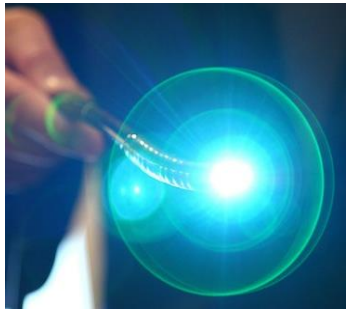
PROGRESSING THE PCI-TECHNOLOGY PIPELINE

- Strengthened the organisation with recruitment of three key senior employees

fimaCHEM

Progressing development in bile duct cancer towards marketing authorisation application

- RELEASE study with interim read for potential accelerated approval ongoing across three continents
- Implemented improved trial design and several initiatives to optimise execution during the pandemic
- Recruitment increased in 2021 with good contribution from Asia, but is still fluctuating
- IDMC safety review of two treatments expected 2H 2021
- Timelines for expected interim read revised to 2H 2023



fimaVACC

Successful study in healthy volunteers with enhanced immune responses published

- Phase I results published in high-impact immunology journal: Frontiers in Immunology
- US patent granted for use in combination with immune checkpoint inhibitors
- Available for licensing and plan for clinical proof of concept in a disease setting

fimaNAC

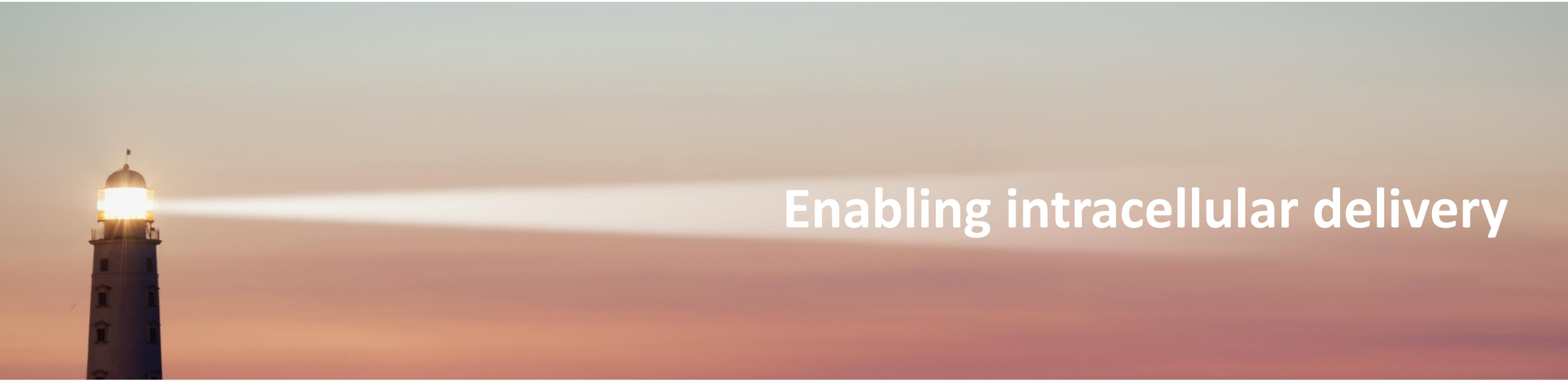
Providing an intracellular delivery solution for nucleic acid therapeutics

- Presented encouraging mRNA data and established a new extensive research collaboration in RNAi
- Actively centre internal research efforts towards the most attractive applications

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 extrahepatic 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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