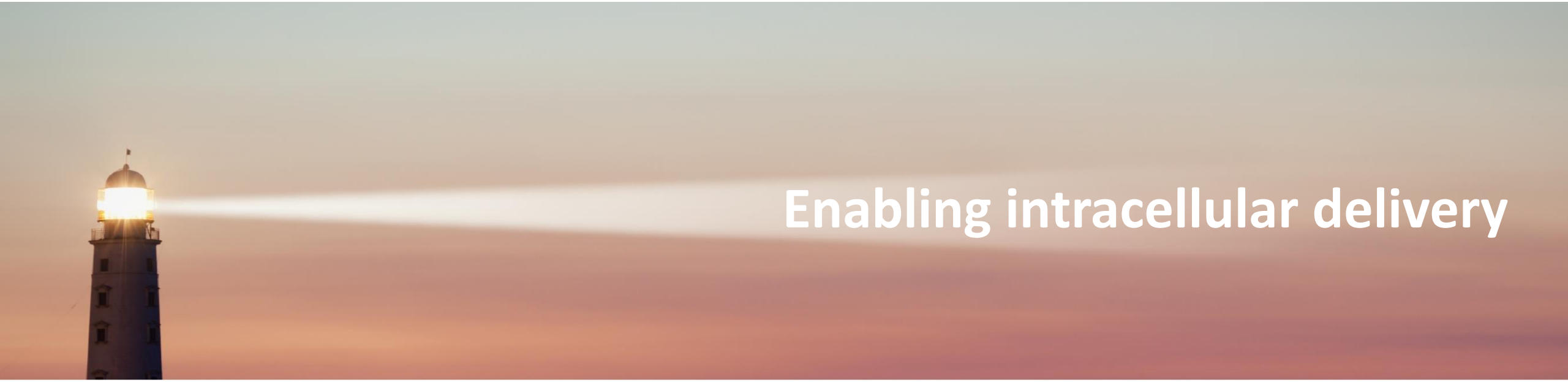
PCI Biotech



Q1 2021 PRESENTATION

May 7, 2021

Per Walday, CEO

Ronny Skuggedal, CFO

PCI BIOTECH

- Important notice and disclaimer

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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**.

If you plan to use this facility, please join the event 5-10 minutes prior to the scheduled start time.
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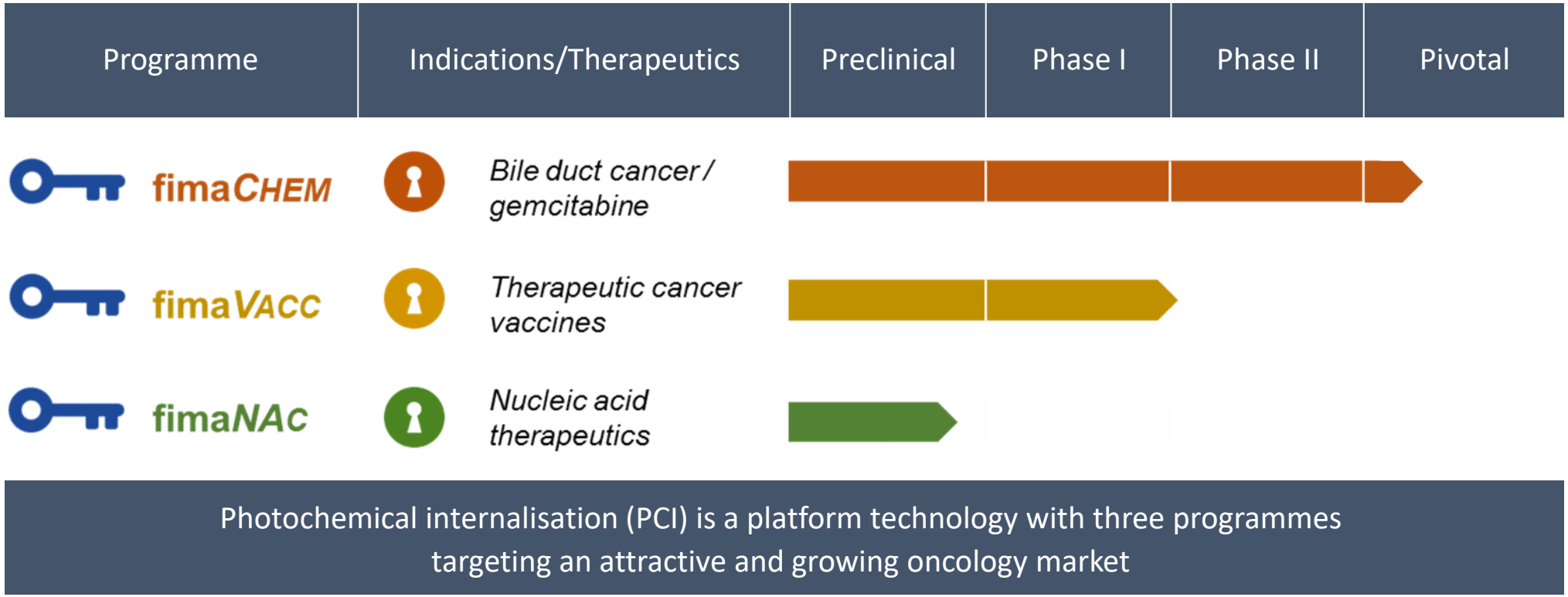
Confirmation Code: 5592549
Event title: PCI Biotech Q1 2021 Conference Call

This information is also available in the Q1 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

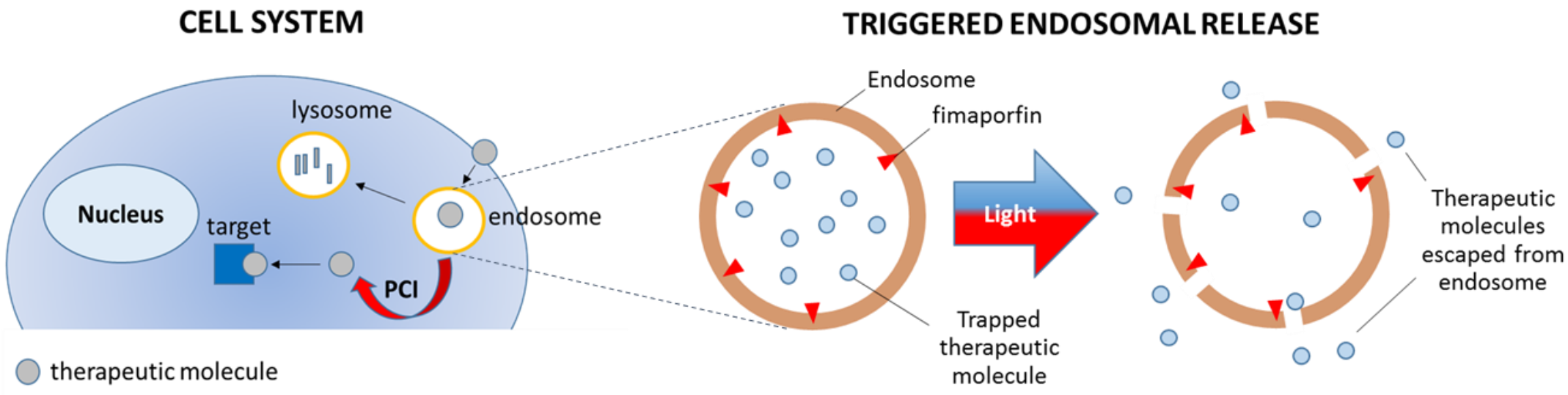
- A biotech company with an oncology focused pipeline



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

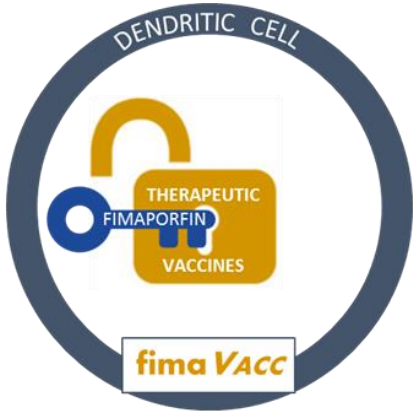


PCI Technology

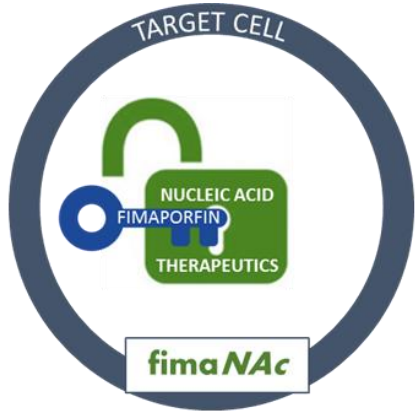
- Enabling drugs to reach intracellular therapeutic targets

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

Q1 2021 HIGHLIGHTS

- fimaCHEM

RELEASE – first patient included in US

- Increased screening and enrolment to RELEASE in Q1 after implementation of the amended protocol and the opening of Asian sites
- The full effect of these study optimisation initiatives is not expected until the Covid-19 situation improves further
- The first US patient was enrolled in the RELEASE study in April

Q1 2021 HIGHLIGHTS

- fimaCHEM

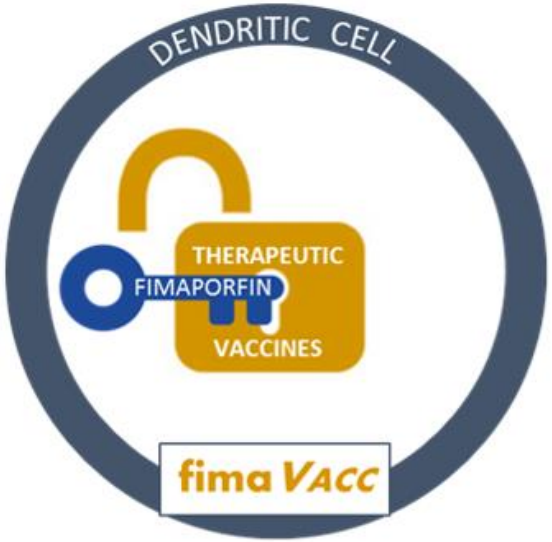
RELEASE – first patient included in US

- Continued focus on enrolment of patients into the RELEASE study, with the emphasis going forward being on regular trial management, including performance evaluation and replacement of underperforming sites
- The expected timeline for the planned interim analysis remains in the range from 2H 2022 to 1H 2023

Q1 2021 HIGHLIGHTS

- **fimaVACC**

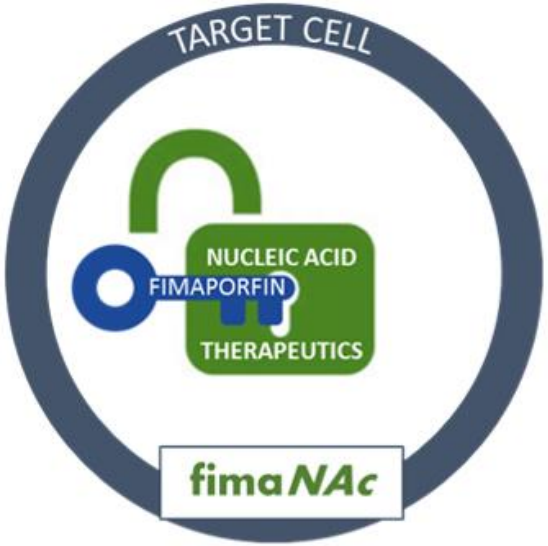
- Successful Phase I vaccination proof of concept study published in the high impact immunology journal, Frontiers in Immunology
- The published data demonstrates that **fimaVACC** enhances the immune response to peptide- and protein-based vaccines in healthy volunteers
- The focus going forward is utilising the Phase I results in partnering efforts and planning for clinical proof-of-concept in a disease setting



Q1 2021 HIGHLIGHTS

- **fimaNAc**

  - Encouraging data on enhanced delivery of mRNA for various medical applications was presented at the UK based 12th Annual RNA Therapeutics Virtual Conference in February 2021
  - In May 2021, PCI Biotech entered into an extensive research collaboration with the South Korean company OliX Pharmaceuticals, a leading developer of RNAi therapeutics



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- **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

fimaCHEM

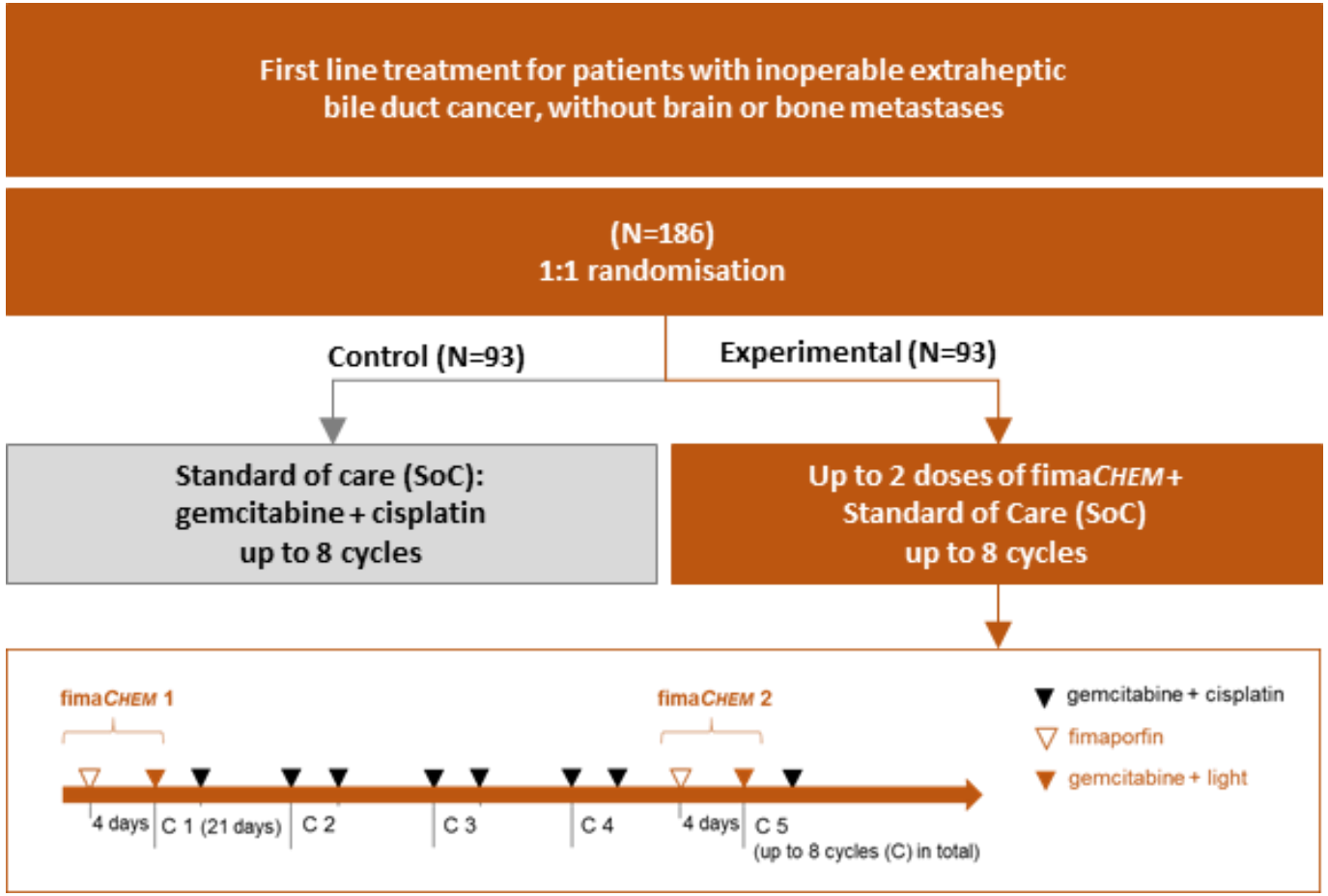
- Excellent fit with medical need and existing treatments

  - **Efficacy:** mOS[1] of **22.8 months** at selected dose (cohort IV) in Phase I dose-escalation (vs. **11-12 months**[2] with 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 and boosts effect locally, where it is most needed (no direct competition)
  - **Protection:** EU and US Orphan Drug designation offers 7 to 10 years exclusivity
  - **Competition:** Precision/gene/small molecules in clinical development are mainly Second line or iCCA targeted
  - **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 – RELEASE STUDY

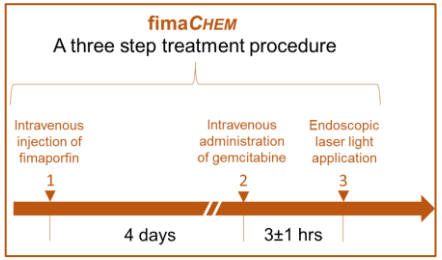
- Pivotal study with potential accelerated/conditional approval on interim analysis



- 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

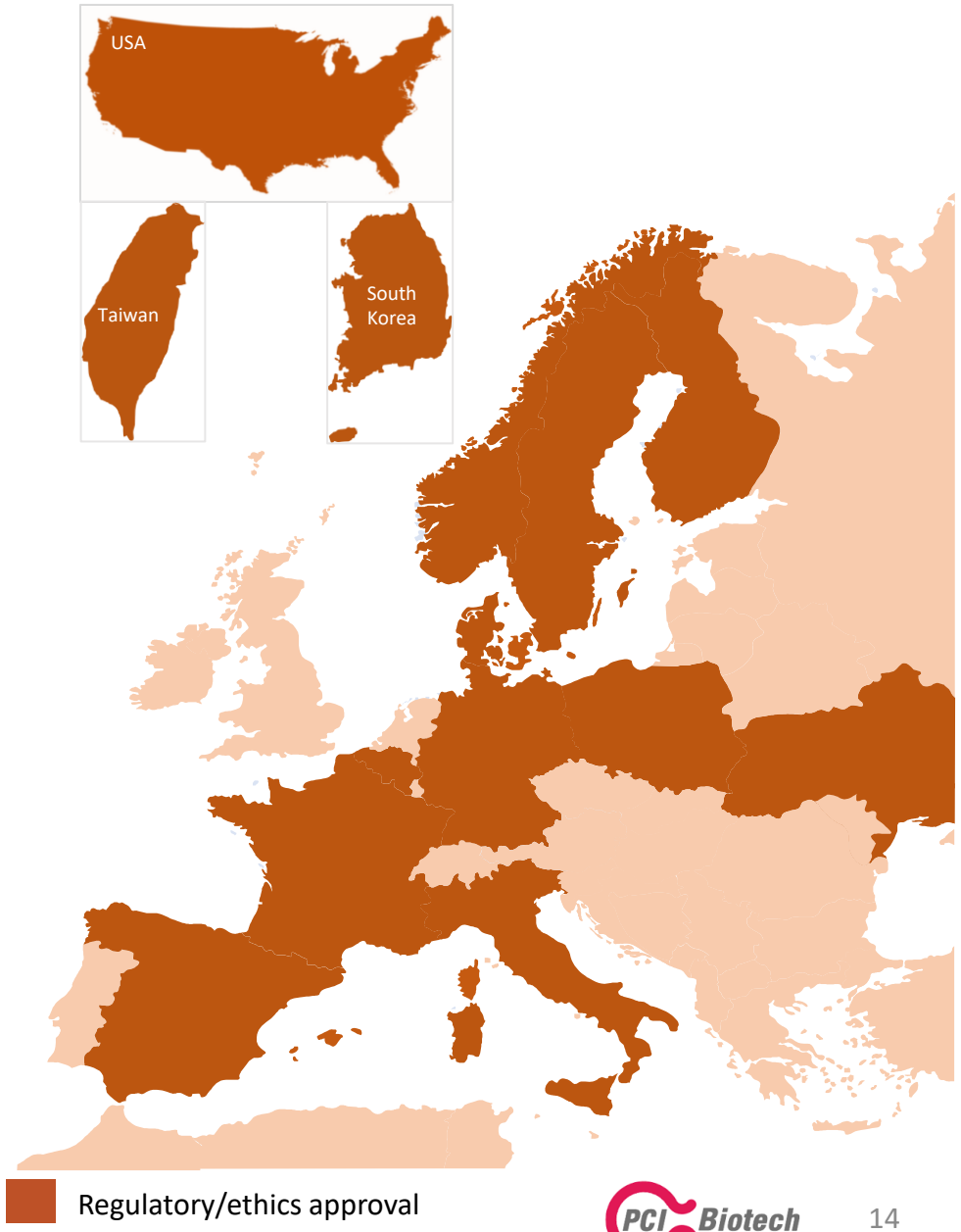
- **fimaCHEM** in addition to current Standard of Care



Bile Duct Cancer – Release Study

- Pivotal study status

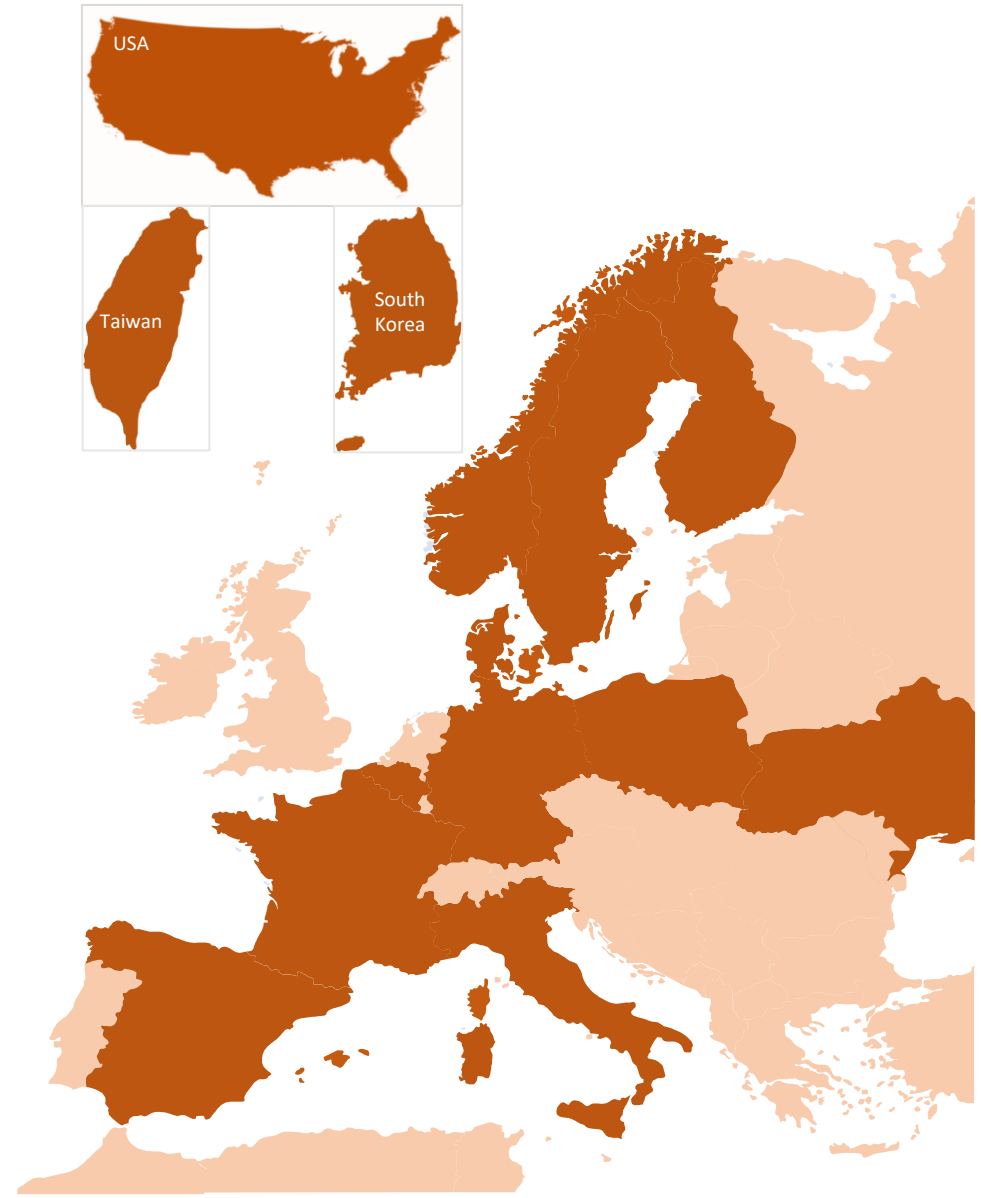
  - Open sites in South Korea, Taiwan, USA and 11 European countries
  - 46 sites currently open for patient enrolment – plan to have approximately 50
  - 9 sites open in Asia – first Asian patient enrolled Oct'20
  - 6 sites open in the US – first US patient enrolled Apr'21
  - Several initiatives implemented 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



BILE DUCT CANCER – RELEASE STUDY

- Pivotal study progress

- Increased screening and enrolment in Q1 2021, but the full effect of these measures are not expected until the COVID-19 situation improves
- Focus going forward is on regular trial management, including performance evaluation and potential replacement of underperforming sites, as well as monitoring of study specific risks, such as retention of randomised patients and adherence to study procedures and eligibility criteria
- The expected timing of the planned interim analysis remains in the range from 2H 2022 to 1H 2023



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 – 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

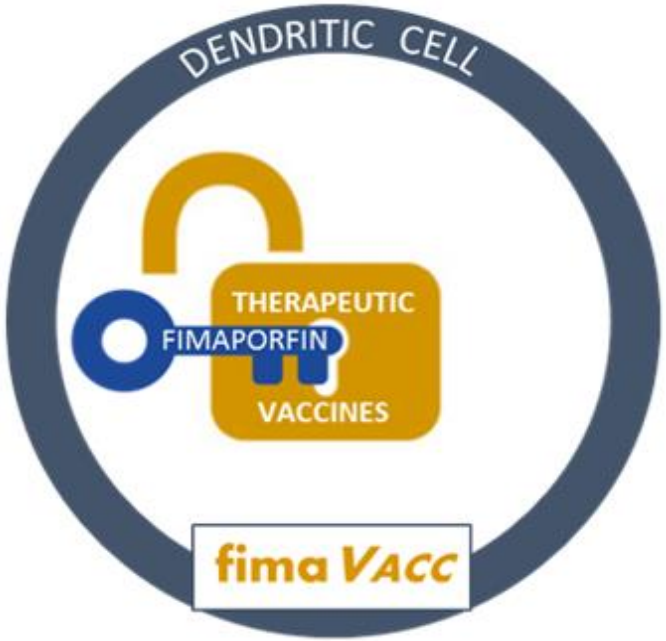
Milestones and timelines:

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 2022 – 1H 2023
Timing and format for study conclusion may be impacted by outcome of Interim analysis	• Final analysis expected approximately 1H 2024

*IDMC = Independent Data Monitoring Committee

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

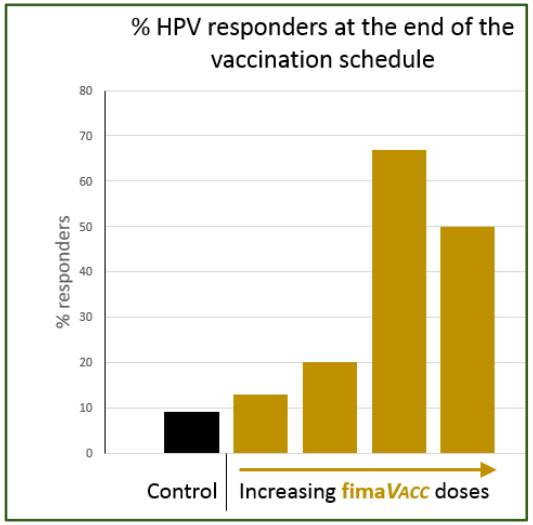
- Can potentially be used with several modalities, including nucleic acid based technologies

PROGRESS OF THE fimaVACC PROGRAMME

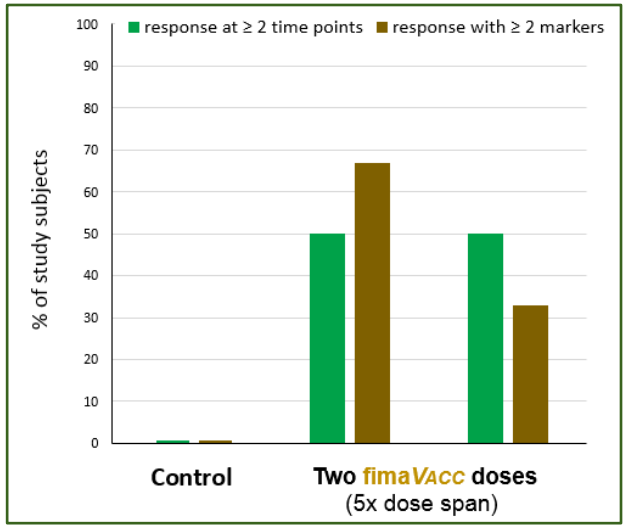
- Successful clinical proof-of-concept

- 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

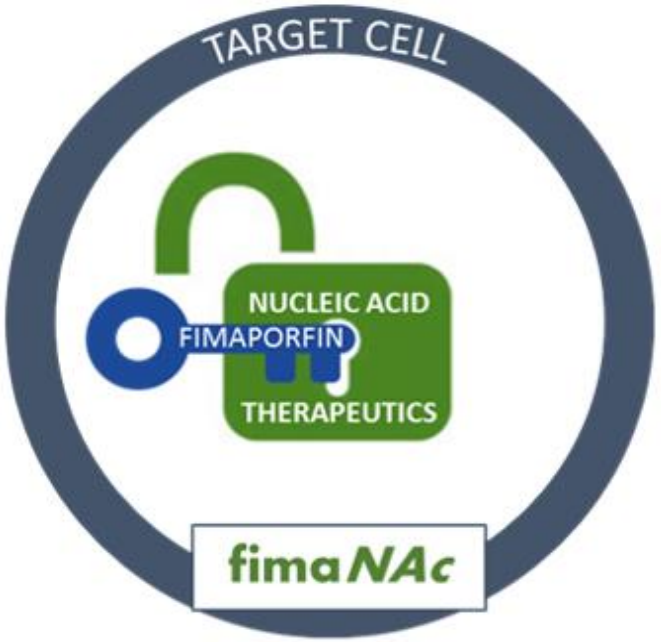
- Growing robust evidence, with Phase I study published

  - 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
  - Actively exploring and preparing 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

Research Collaborations

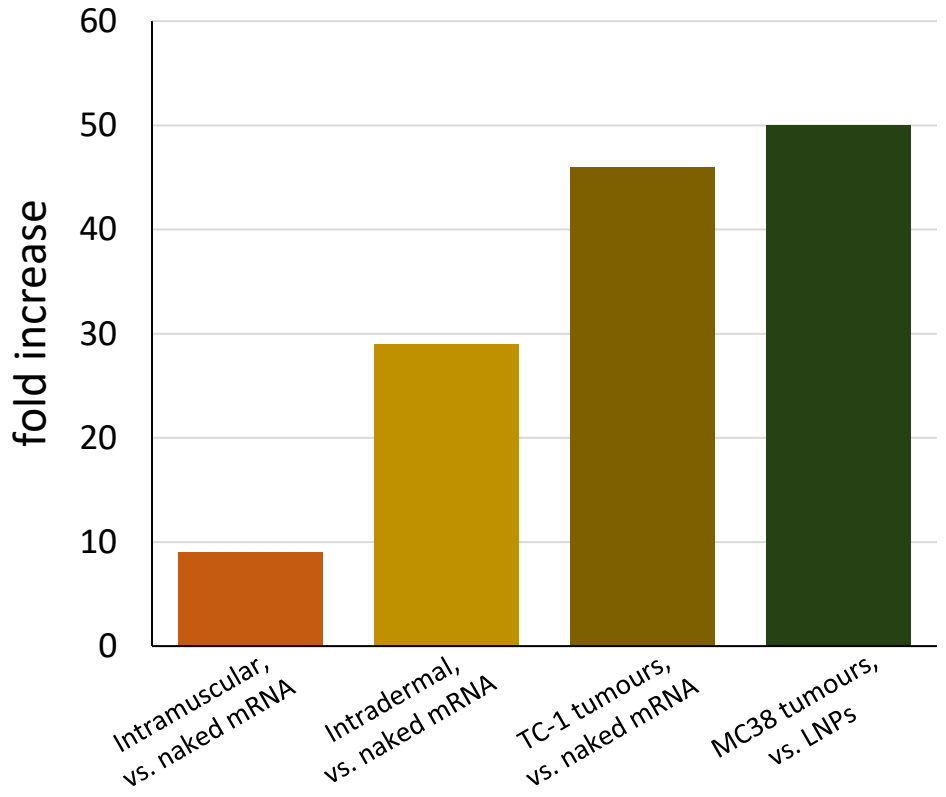
- Collaborations provide important knowhow and encouraging results

- Currently five collaborations within delivery of nucleic acid therapeutics, spanning across different classes of drugs and therapeutic applications
- The collaborations provide valuable scientific knowhow and encouraging results, some of which were recently presented at an international conference on RNA therapeutics
- Strong potential for further development of **fima*NAc***, not least within the emerging field of mRNA where the success of vaccines against COVID-19 has created a lot of attention
- Actively centre our efforts towards the most attractive **fima*NAc*** opportunities

NAKED MRNA DELIVERY WITH fimaNAc – DIFFERENT APPLICATIONS

- Enhanced delivery to skin and muscle – best effect seen for intratumoural delivery

Fold increase of mRNA expression with fimaNAc



- Intratumoural immunotherapy
  - Systemic therapeutic effects can also be achieved
  - mRNA encoding antigens and immuno-stimulating factors
  - To avoid side effects of potent effector molecules it may be very important to confine mRNA expression to tumour
    - fimaNAc substantially better than LNPs
  - The photochemical treatment can also have an immunological adjuvant effect
    - Modulation of tumour microenvironment

NAKED MRNA DELIVERY WITH fimaNAc – SUMMARY

- Local delivery technology
  - mRNAs and fimaporfin can be mixed in aqueous solution and administered as one injection without local or systemic side effects
  - mRNA administration and illumination can be done in the same procedure
  - mRNA expression spatially restricted to illuminated area
- Clinically proven platform technology
  - The clinical fimaVACC and fimaCHEM programmes are using the same platform technology
  - Ample safety data in humans both for systemic and local administration
- Applications where a local effect is desired
  - Skin, muscles, tumours, eye, joints, lymph nodes
- Substantially enhanced delivery to tumour, muscle and skin
  - Clearly improved characteristics compared to LNPs demonstrated in tumour

Research Collaborations

- 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 nucleic acid therapeutics

fimaNAc

- Currently five active collaborations
- 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

DC PRIME

APOSENSE

imv IMMUNOVACCINE

FINANCE

- Key financial figures
  - Fluctuations in exchange rate, effects on bank deposits and net financial result
  - Solid cash position, partly placed in Euro

(figures in NOK 1,000)	Q1 2021	Q1 2020	FY 2020
Other income (public grants)	1 588	1 919	7 368
Operating results	-21 171	-15 974	-82 121
Net financial result	*-2 602*	*20 401*	*9 881*
Net profit/loss	-23 773	4 427	-72 239

(figures in NOK 1,000)	Q1 2021	Q1 2020	FY 2020
Net change in cash during the period	-20 960	-22 940	-81 662
Exchange rate effect on cash in foreign currency	*-2 709*	*19 917*	*8 526*
Cash and cash equivalents	164 298	258 080	187 967

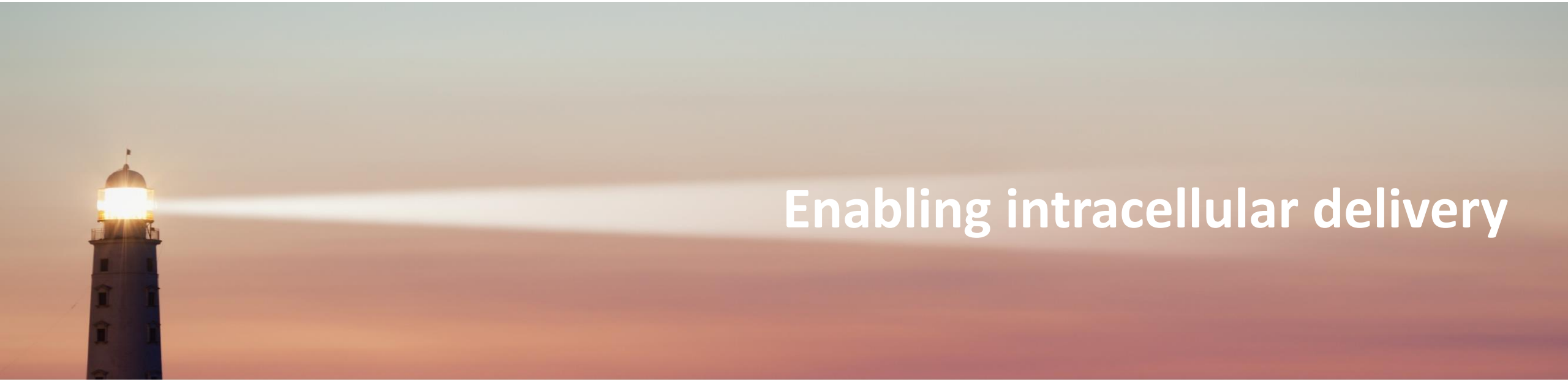
Recent Key Achievements & Near-Term Milestones

2H 2020	✓ fimaCHEM	First Asian patient enrolled in the RELEASE study
2H 2020	✓ fimaCHEM	Optimised protocol and procedures implemented at all sites
1H 2021	✓ fimaVACC	Phase I results published in high-impact immunology journal
1H 2021	✓ fimaNAc	Results from AZ collaboration presented at scientific conference
1H 2021	✓ fimaCHEM	First US patient enrolled in the RELEASE study
2H 2021	✓ fimaCHEM	Safety of two treatments reviewed by IDMC

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

PCI Biotech



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