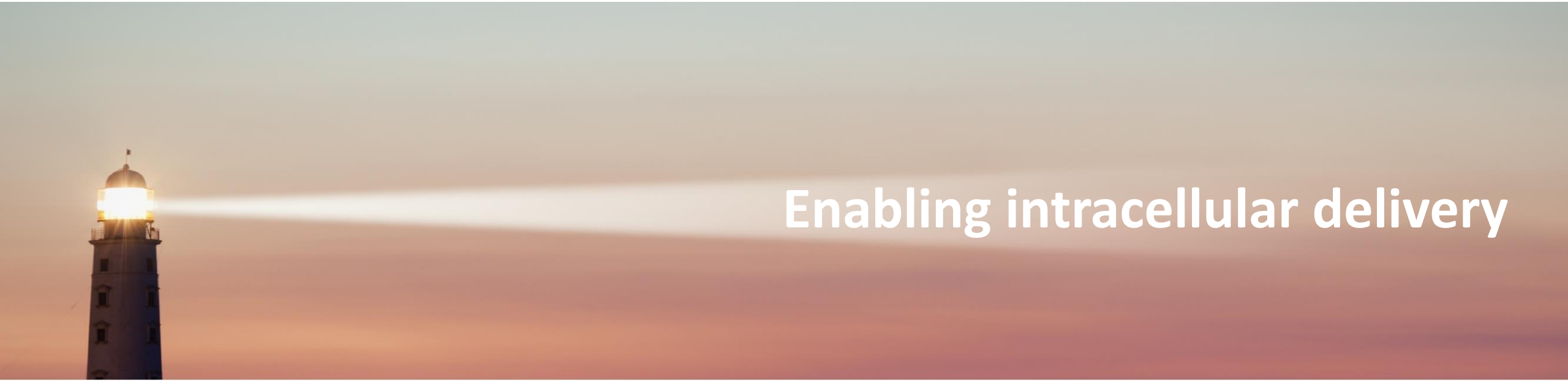
PCI Biotech



Q4 & Interim Full Year 2020 PRESENTATION

February 24, 2021

Per Walday, CEO

Ronny Skuggedal, CFO

PCI BIOTECH

- Important notice and disclaimer

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PCI BIOTECH

- Verbal Q&A session through teleconference

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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This information is also available in the Q4 Report press release and on the webpage https://www.pcibiotech.no/webcasts

PCI Biotech – enabling intracellular delivery

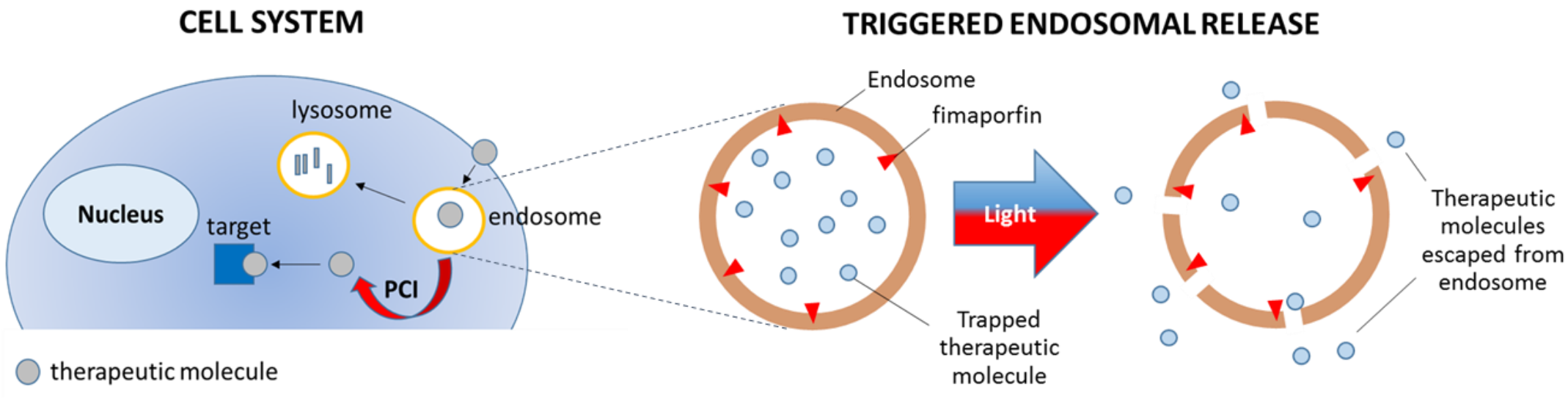
- A biotech company with an oncology focused pipeline

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

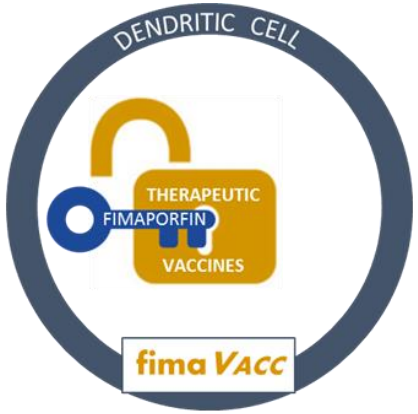


PCI Technology

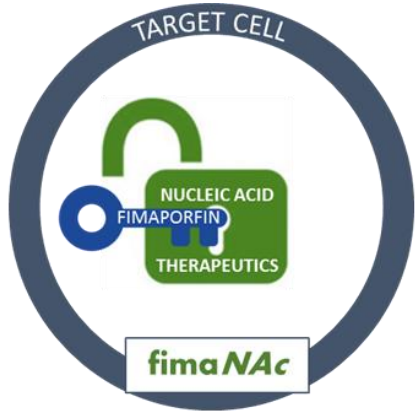
- Enabling drugs to reach intracellular therapeutic targets

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

2020 – Year in Review

- Focus on expanding and optimising RELEASE

fimaCHEM

- The RELEASE study has been significantly affected by the COVID-19 pandemic. The main focus during the year has therefore been on optimising and expanding the study, with the aim to recoup as much as possible of the delays inflicted by the pandemic. We are seeing increased screening and enrolment into the study, even though the pandemic is still affecting many countries. Our full focus is on effective execution of the RELEASE study.

fimaVACC

- Two important patents have been granted in the US, thereby further strengthening the foundation of this platform. The positive results of the successful Phase I study in healthy volunteers have been published in the high-impact immunology journal Frontiers in Immunology. The focus is now on utilising the Phase I results in partnering efforts and planning for a clinical proof-of-concept study.

fimaNAc

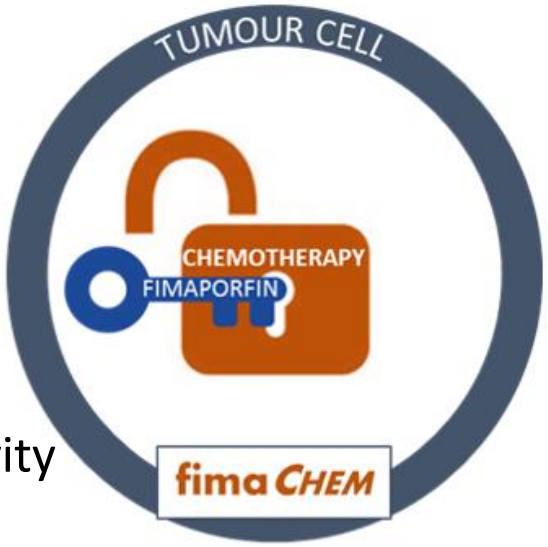
- The collaboration with AZ that ended in 2020 provided strong data for the platform, which were recently presented at an international meeting on RNA therapeutics. Recent vaccination successes has created a lot of attention to this class of drugs, and we will now centre our efforts on the most attractive opportunities.

Q4 2020 HIGHLIGHTS

- fimaCHEM

RELEASE – first patient included in Asia and patent granted in Europe

- The first patient has been enrolled in the RELEASE study in South Korea
- All the nine planned study sites in Asia are now open, with initial good screening and enrolment activity
- European patent for treatment of bile duct cancer granted, providing extended protection several years beyond the potential market exclusivity offered by the orphan drug designation



Q4 2020 HIGHLIGHTS

- fimaCHEM

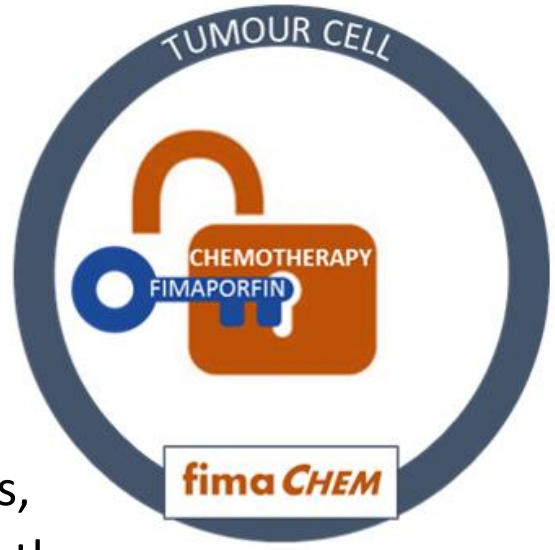
RELEASE – initiatives to recoup delays, and case report series published

- Several initiatives have been implemented in the RELEASE study to recoup long-term recruitment projections
- Besides going into Asia, the most important initiative is the protocol amendment made to expand the eligible patient population
- A total of 47 RELEASE study sites are open by end-January 2021 across EU, US and Asia and all are operating under the amended protocol
- A case report series from the Phase I study was in November published in Endoscopy International Open, providing detailed descriptions of treatment effects in three select patients at the dose chosen for the RELEASE study

Q4 2020 Highlights

- fimaCHEM

RELEASE – effect of the COVID-19 pandemic

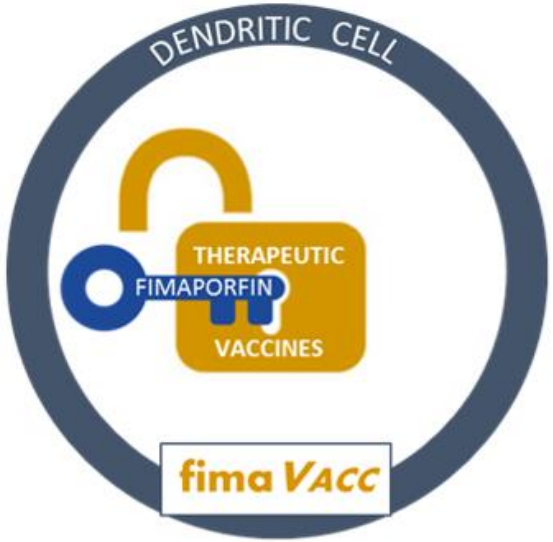


- The second wave of the COVID-19 pandemic is still having a severe impact in many countries
- The consequences of COVID-19 and the new recruitment initiatives for the RELEASE study cannot yet be fully established
- We are seeing indications of increased screening and enrolment after implementation of the amended protocol and the opening of Asian sites, although we do not expect to see the full effect of these initiatives until the COVID-19 situation improves
- The company continues to have full focus on enrolment of patients into the RELEASE study – the expected timeline for the planned interim analysis remains in the range from 2H 2022 to 1H 2023

Q4 2020 HIGHLIGHTS

- **fimaVACC**

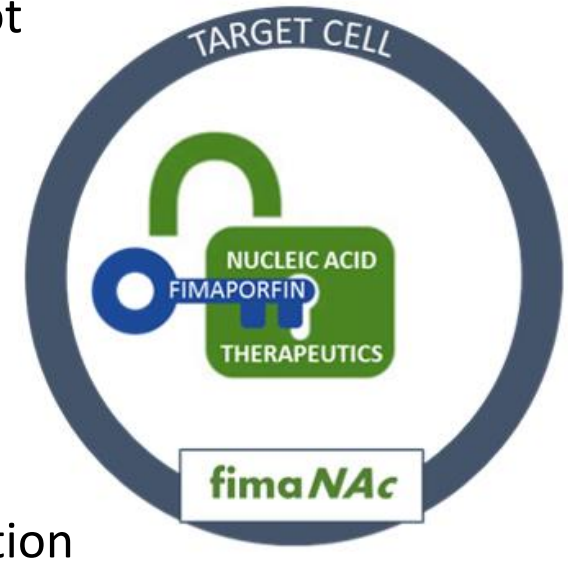
  - Successful Phase I vaccination proof of concept study published in the high impact immunology journal *Frontiers in Immunology*
  - The publication provides detailed data from the Phase I study in healthy volunteers, demonstrating that **fimaVACC** enhances the immune response to peptide- and protein-based vaccines in healthy volunteers



Q4 2020 HIGHLIGHTS

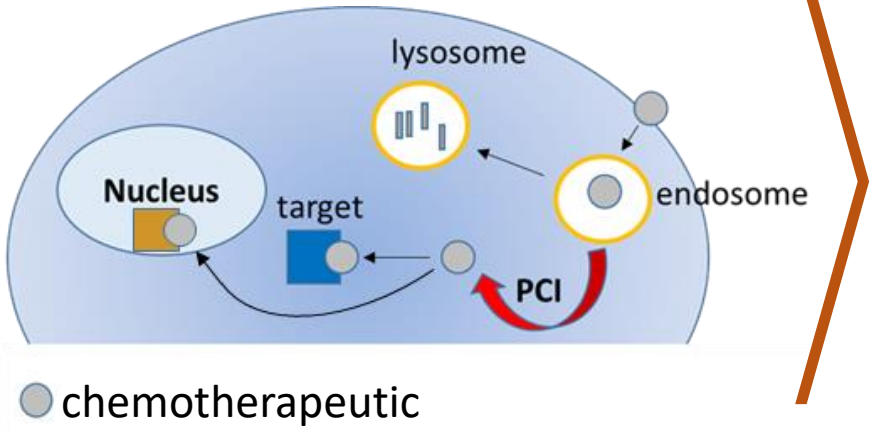
- **fima*NAc***

- In October 2020 PCI Biotech was informed that AstraZeneca elected not to enter into a definitive agreement for the **fima*NAc*** technology
- Encouraging preclinical results have been achieved with the **fima*NAc*** platform in this collaboration and the decision not to enter into a definitive agreement is primarily based on a strategic evaluation by AstraZeneca of their current development priorities
- PCI Biotech presented the encouraging mRNA data from this collaboration in February 2021 at the UK based 12th Annual RNA Therapeutics Virtual Conference



PCI TECHNOLOGY

- **fima CHEM** – mode of action



Chemotherapeutics

fima CHEM

Endocytosis

Release of the trapped chemotherapeutic into the cytosol, thereby enabling it to reach its target and induce the intended therapeutic effect

Lysosomal breakdown

fimaCHEM

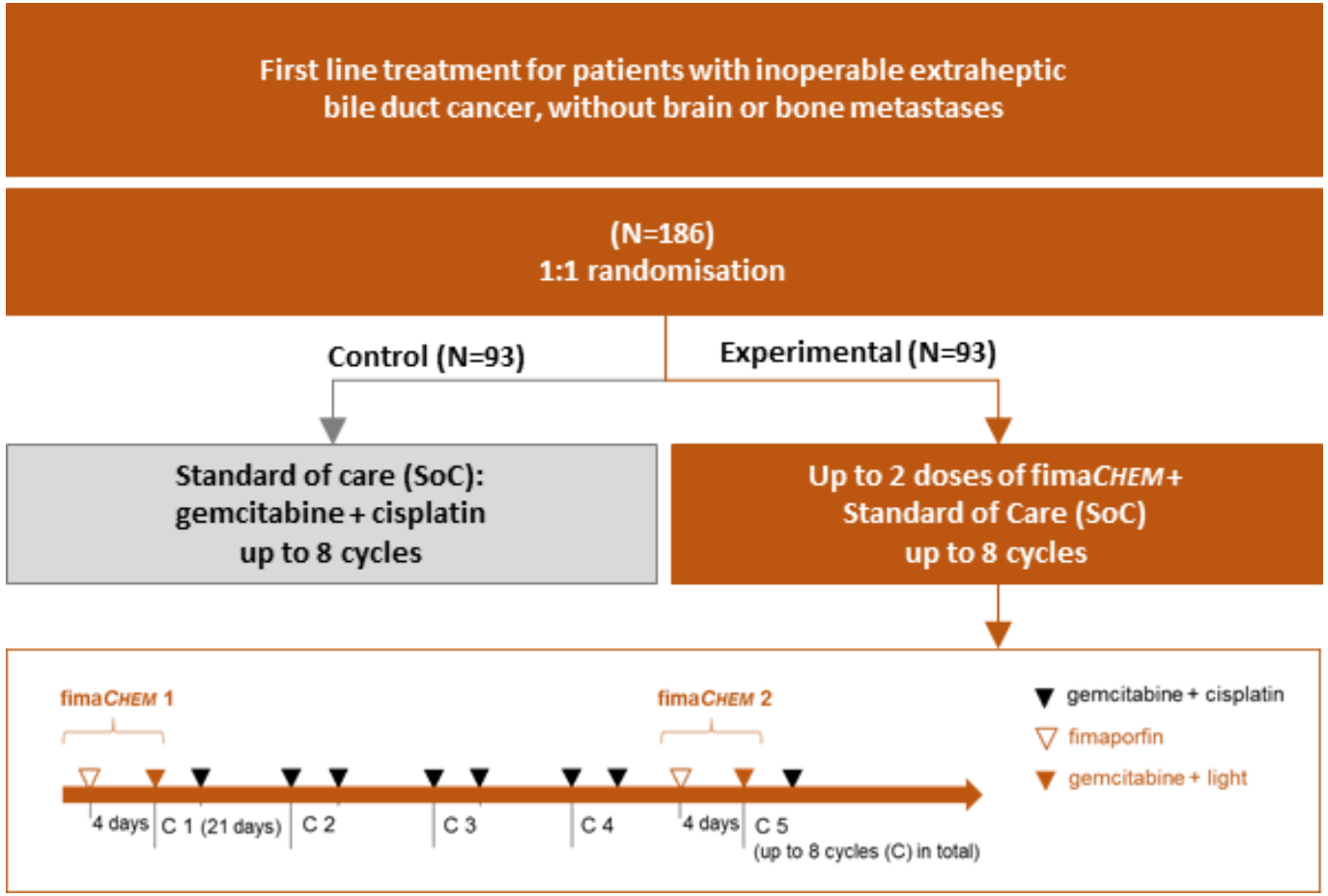
- Excellent fit with medical need and existing treatments

  - **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

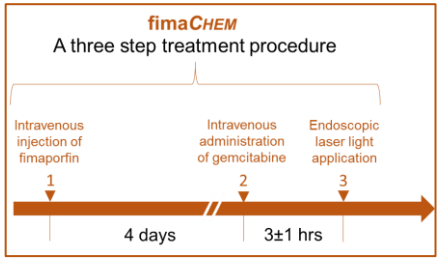
- Pivotal study with potential accelerated/conditional approval on interim analysis



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

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

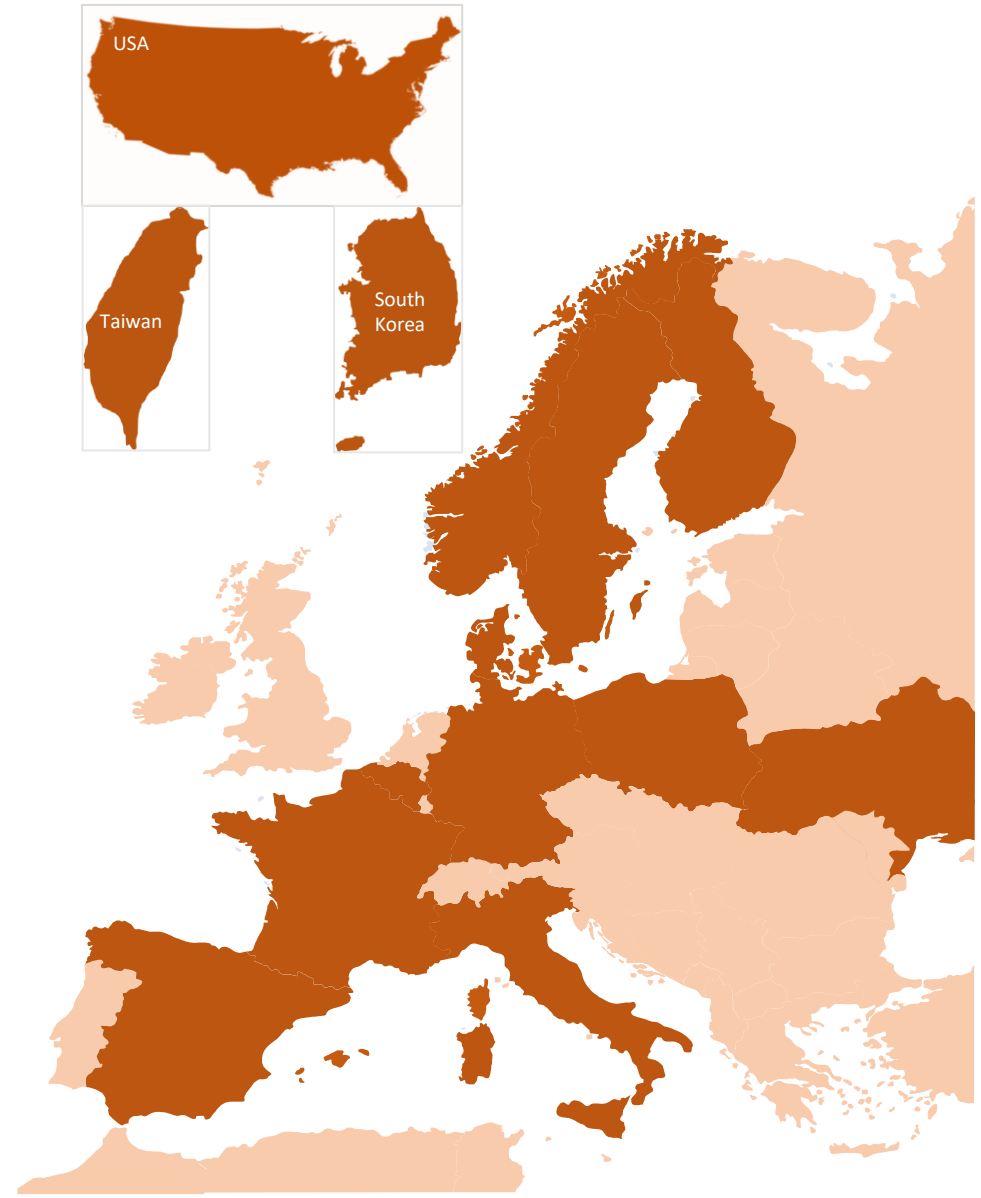
- **fimaCHEM** in addition to current Standard of Care



BILE DUCT CANCER – RELEASE STUDY

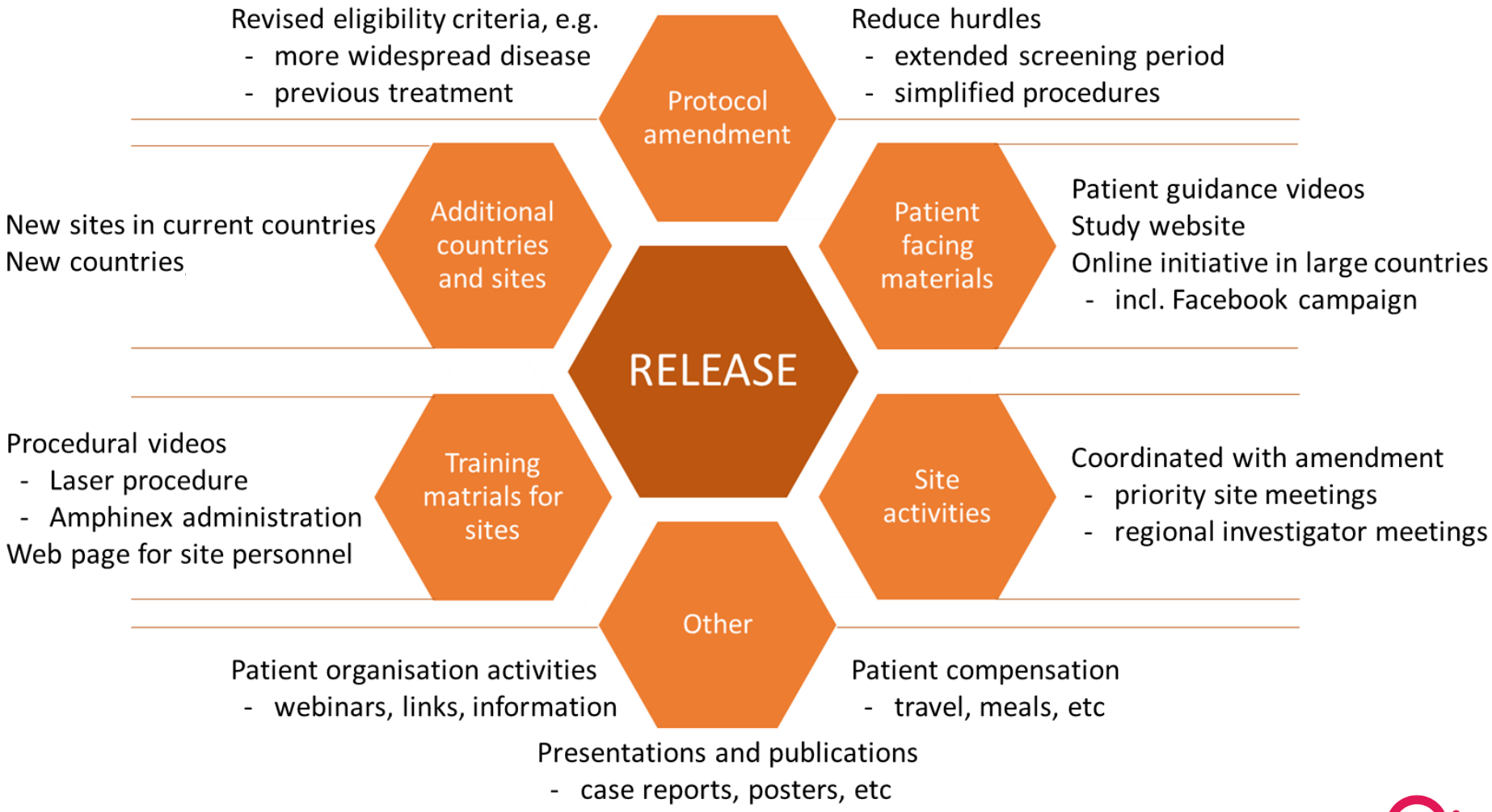
- Pivotal study status

  - Open sites in South Korea, Taiwan, USA and 11 European countries
  - Ukraine has been added to the country mix, replacing UK due to approval delays and trial competition
  - 47 sites open for patient enrolment
  - 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 affected by COVID-19
  - Several initiatives implemented with the aim to recoup the COVID-19 caused delay



BILE DUCT CANCER – RELEASE STUDY

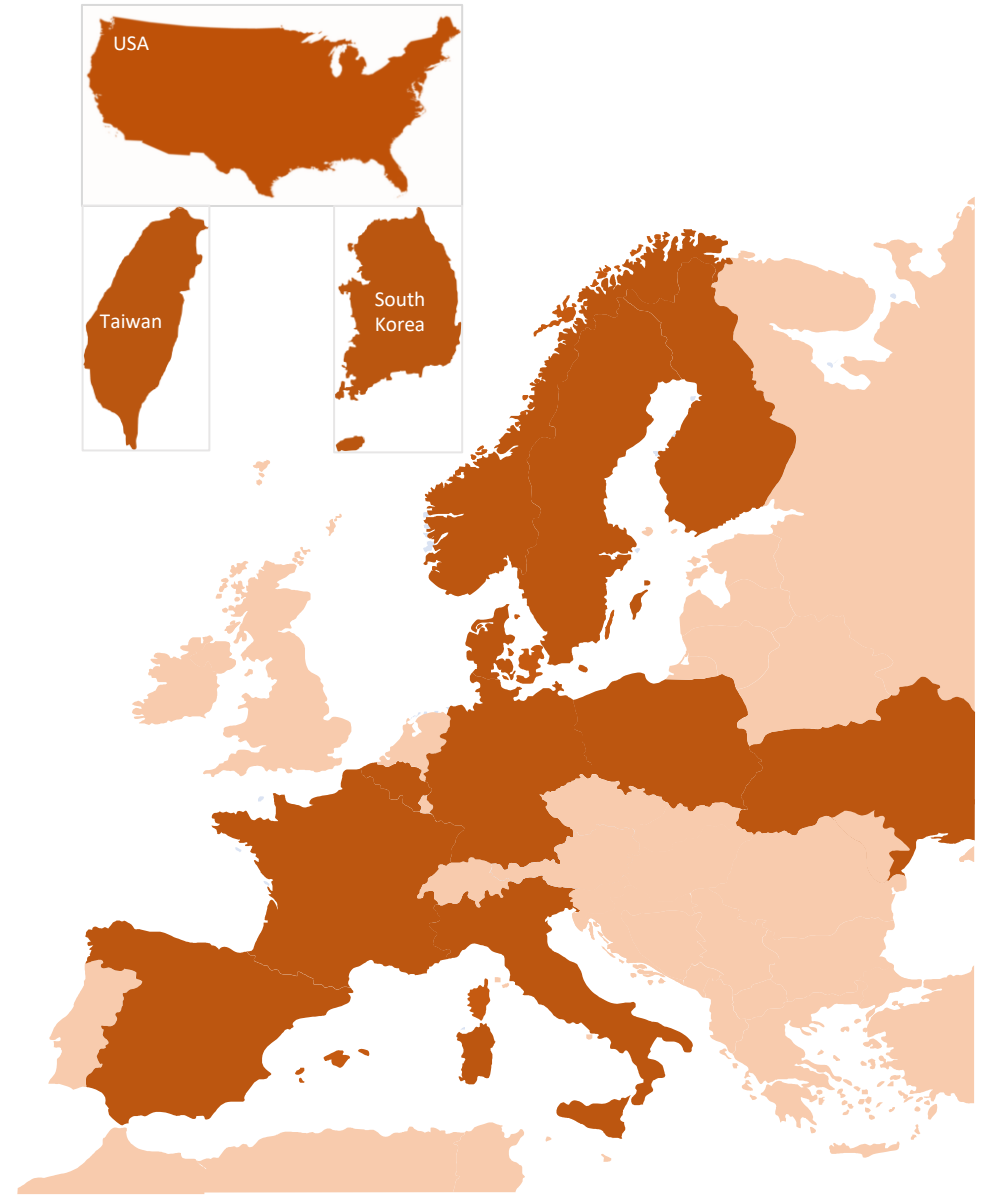
- Several initiatives to enhance recruitment – based on KOL and site feedback



Bile Duct Cancer – Release Study

- Pivotal study progress

- Most important initiatives are the increase in number of sites and the protocol amendment
- Number of planned sites increased to >50
- Protocol amendment approved in all countries, and all sites screen under the amended protocol
- Early indications of increased screening and enrolment after implementation, 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 sites
- 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:

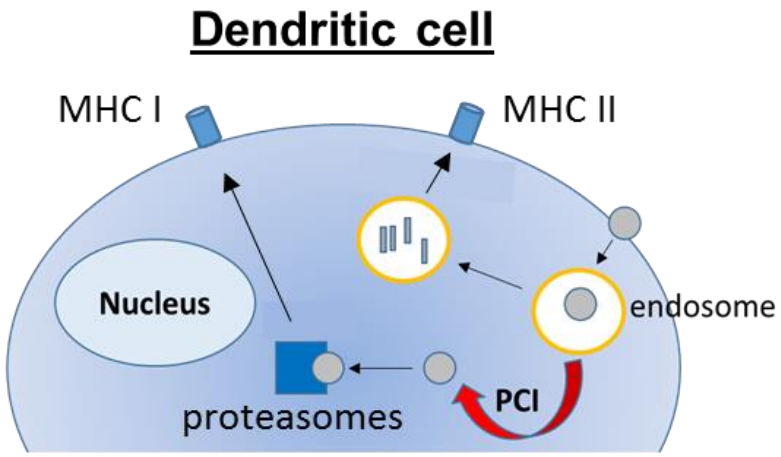
Interim analysis: Primary Endpoint: Objective Response Rate (ORR) Secondary endpoint: Overall Survival (OS)	• Orphan drug designation in EU & USA – potential accelerated approval
Final analysis: Primary endpoint: Progression Free Survival (PFS) Secondary endpoint: Overall Survival (OS)	• Single randomised trial considered sufficient based on interaction with US and EU regulatory authorities

Milestones and timelines:

First patients enrolled in Europe in May 2019 and in Asia in October 2020	• First patient in the US expected 1H 2021
Seamless safety review by IDMC when 8 patients have undergone two fimaCHEM treatments	• IDMC = Independent Data Monitoring Committee
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

PCI TECHNOLOGY

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



Vaccine

Endocytosis

fima VACC

MHC Class I

Generate more disease specific cytotoxic (CD8) T-cells

Attack cancer and virus infected cells more efficiently

MHC Class II

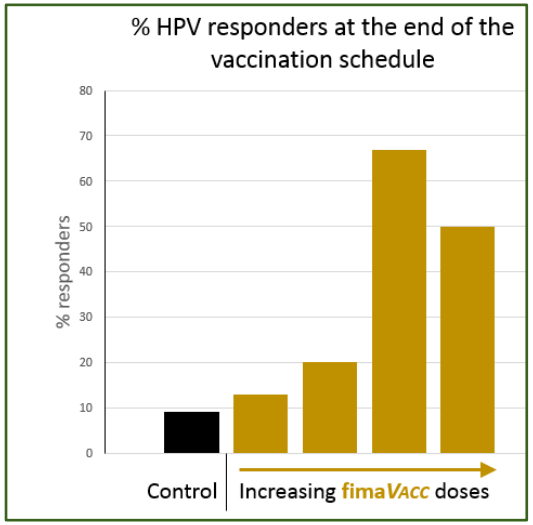
Antibodies and helper T-cells

PROGRESS OF THE fimaVACC PROGRAMME

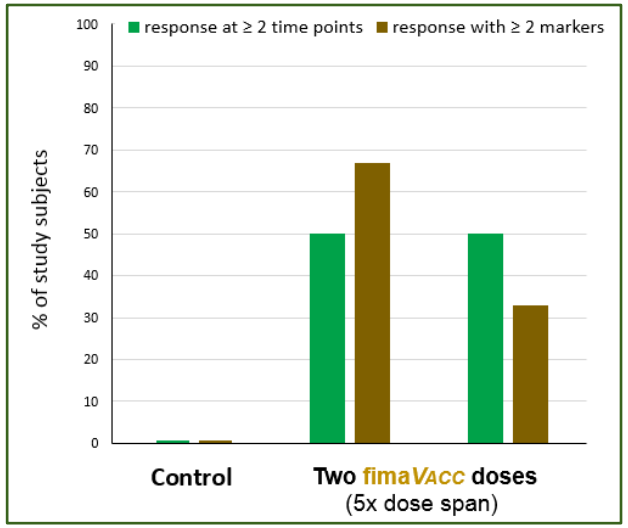
- Successful clinical proof-of-concept

- 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

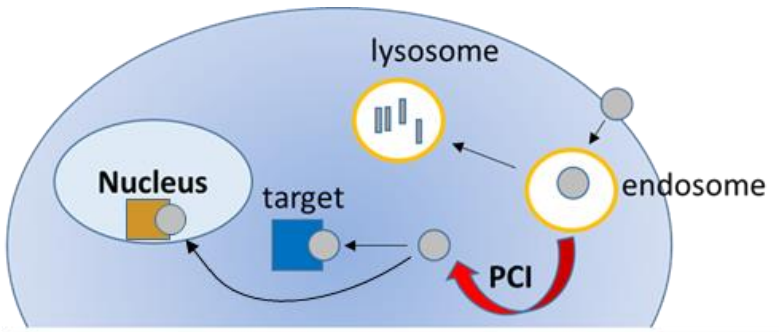
  - Next step: moving to Phase II with a partner or by ourselves (proof-of-concept in a disease setting)

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

PCI TECHNOLOGY

- **fimaNAc** – mode of action

Target cell



Nucleic acid therapeutic

Nucleic acid therapeutic

Endocytosis

fimaNAc

Endosomal release of nucleic acid therapeutics into the cytosol enables access to the gene related processes needed for therapeutic effects, such as protein production and knockdown of gene expression

Lysosomal breakdown

Research Collaborations

- Collaboration with AstraZeneca produced encouraging results

  - In October 2020, PCI Biotech was informed that AstraZeneca elected not to enter into a definitive agreement for the **fimaNAc** technology – a decision that was primarily based on a strategic evaluation by AstraZeneca of their current development priorities

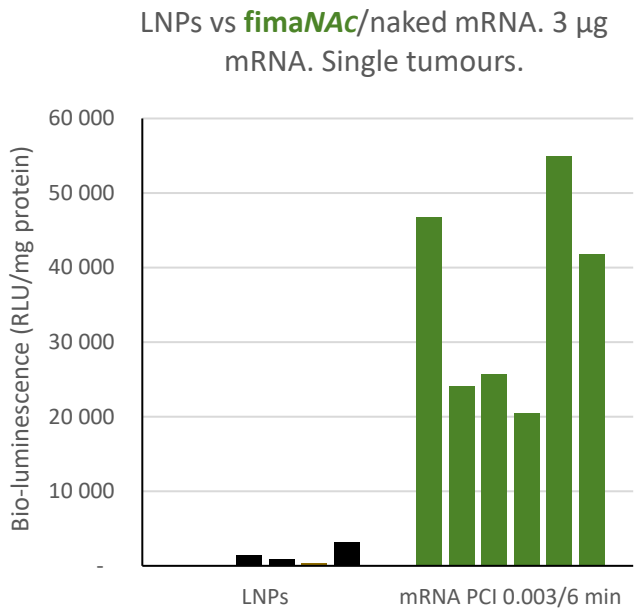
  - The collaboration provided valuable scientific knowhow and encouraging results, which were recently presented at an international conference on RNA therapeutics
    (*see next 4 slides for excerpt*)

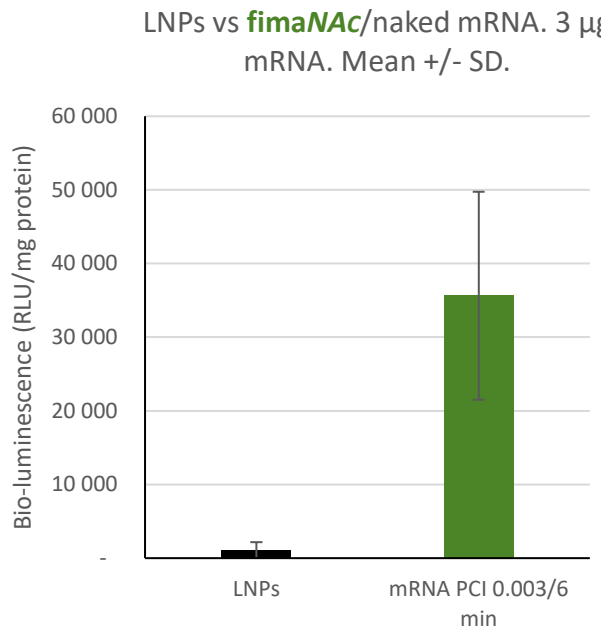
  - Strong potential for further development of **fimaNAc**, not least within the emerging field of mRNA where the success of vaccines against COVID-19 has created a lot of attention

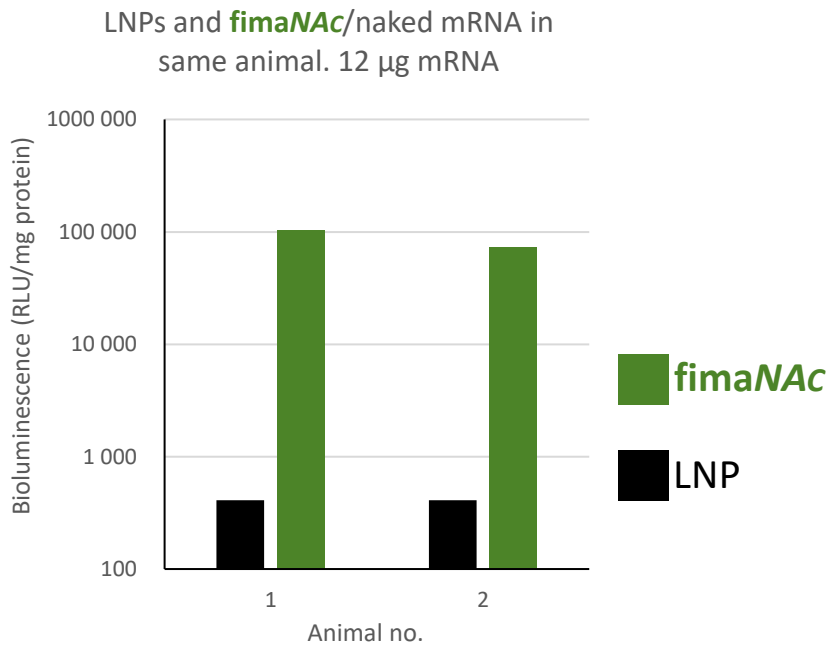
  - Will now actively centre our efforts towards the most attractive **fimaNAc** opportunities

Intratumoural Delivery with fimaNAc is Convincingly Superior to LNPs

- Consistently improves delivery to MC38 tumours compared to what is achieved with LNPs





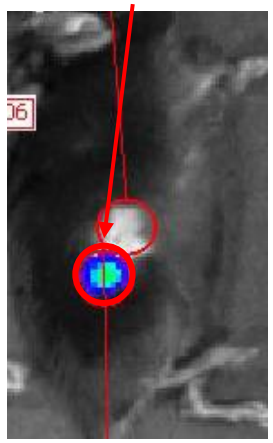


- fimaNAc with 3 µg mRNA increased luciferase activity about 35 times as compared to the LNPs
- In animals where one tumour was treated with fimaNAc and one with LNPs (12 µg mRNA) the observed fold increase was about 200 times (right panel)

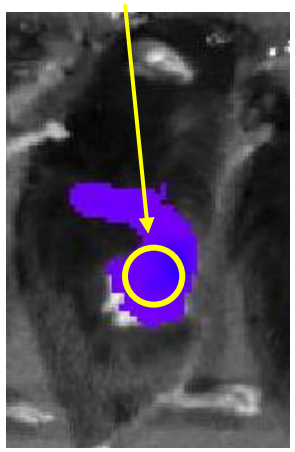
Preventing Undesirable Off-Target Delivery

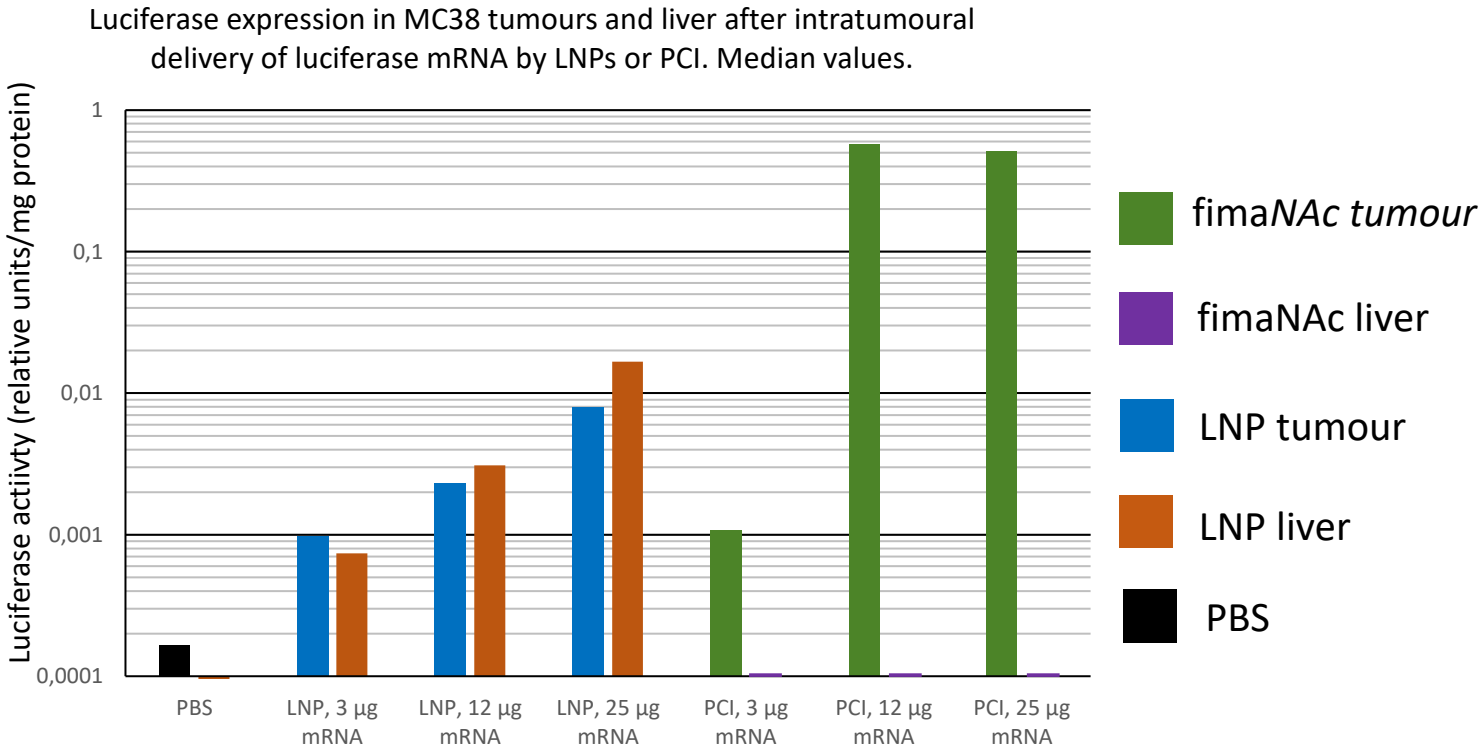
- With **fimaNAc**, mRNA expression is confined to tumour tissue

fimaNAc with naked mRNA



LNPs



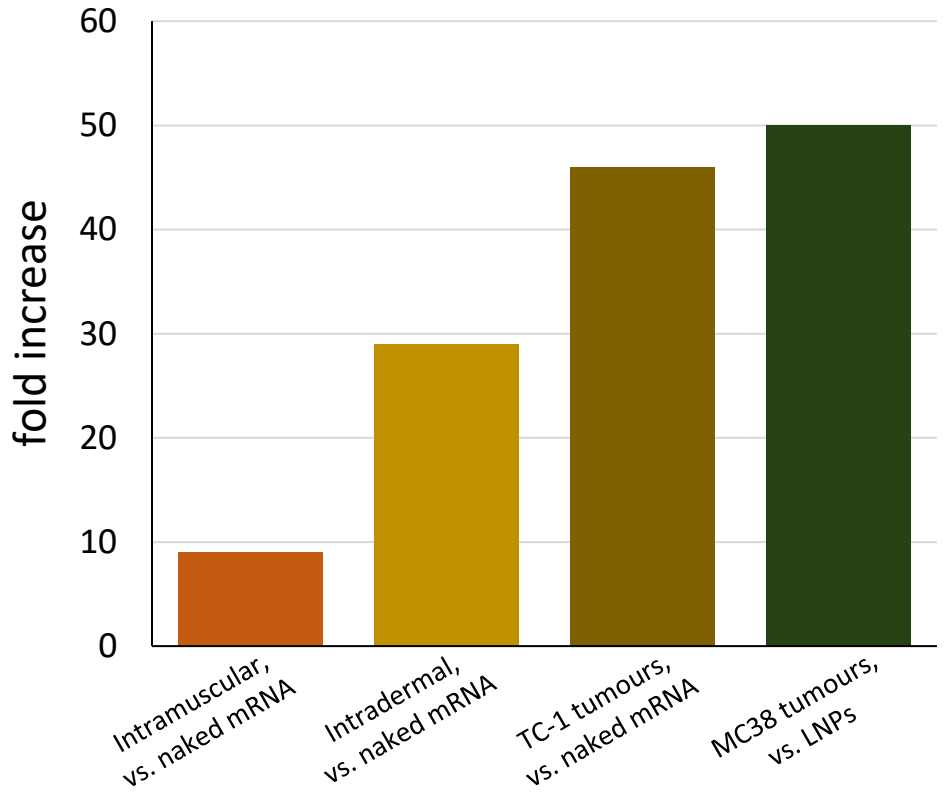


- With **fimaNAc** -mediated delivery of naked mRNA, expression is confined to the tumour
- LNPs seem to leak out of the tumour leading to unwanted expression in the liver, with similar expression levels as in the tumour

NAKED MRNA DELIVERY WITH fimaNAc – DIFFERENT APPLICATIONS

- 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 of fimaporfin
- 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

- Collaborations within nucleic acid therapeutics

fimaNAc

- Currently four active collaborations
- The recently established collaboration with DCprime spans both **fimaNAc** and **fimaVACC**
- PCI Biotech continues to pursue new and value-adding collaborative opportunities

eTheRNA

DC PRIME

APOSENSE

IMV IMMUNOVACCINE

FINANCE

- Key financial figures
  - Other income (public grants) impacted by tax scheme- and project modifications
  - Solid cash position, partly placed in Euro
  - Fluctuations in exchange rate effects on bank deposits

(figures in NOK 1,000)	Q4 2020	Q4 2019	FY 2020	FY 2019
Other income (public grants)	1 567	2 097	7 368	9 392
Operating results	-21 361	-25 350	-82 121	-88 804
Net financial result	*-5 104*	*-78*	*9 881*	*58*
Net profit/loss	-26 464	-25 427	-72 239	-88 746

(figures in NOK 1,000)	Q4 2020	Q4 2019	FY 2020	FY 2019
Net change in cash during the period	-16 910	-22 585	-81 662	-86 574
Exchange rate effect on cash in foreign currency	*-5 356*	*-644*	*8 526*	*-1 649*
Cash and cash equivalents	187 967	261 103	187 967	261 103

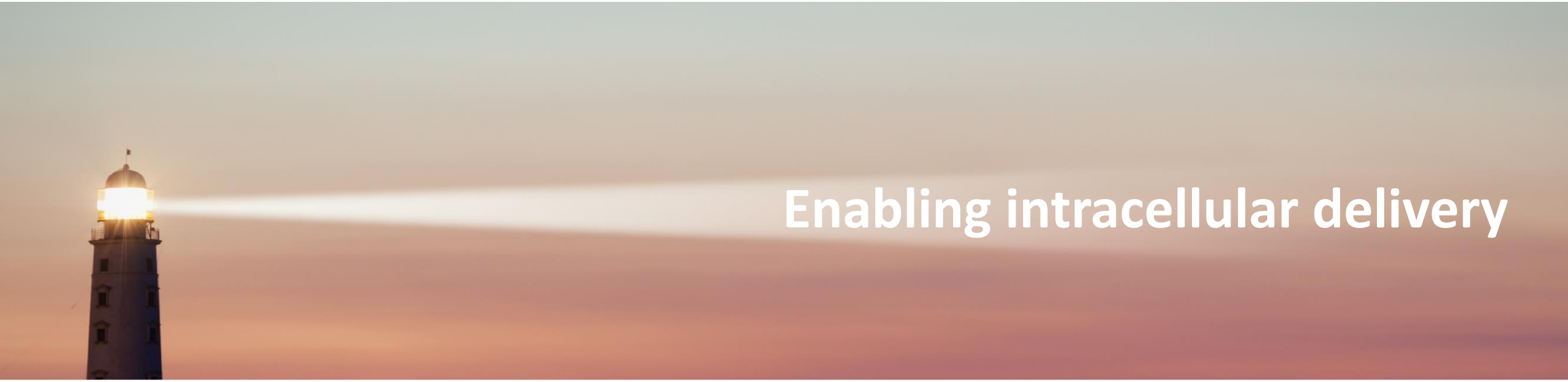
Recent Key Achievements & Near-Term Milestones

1H 2020	✓ fimaVACC	Two important patents granted in the US
1H 2020	✓ fimaCHEM	Expanding RELEASE to Asia by first country approval
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

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



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