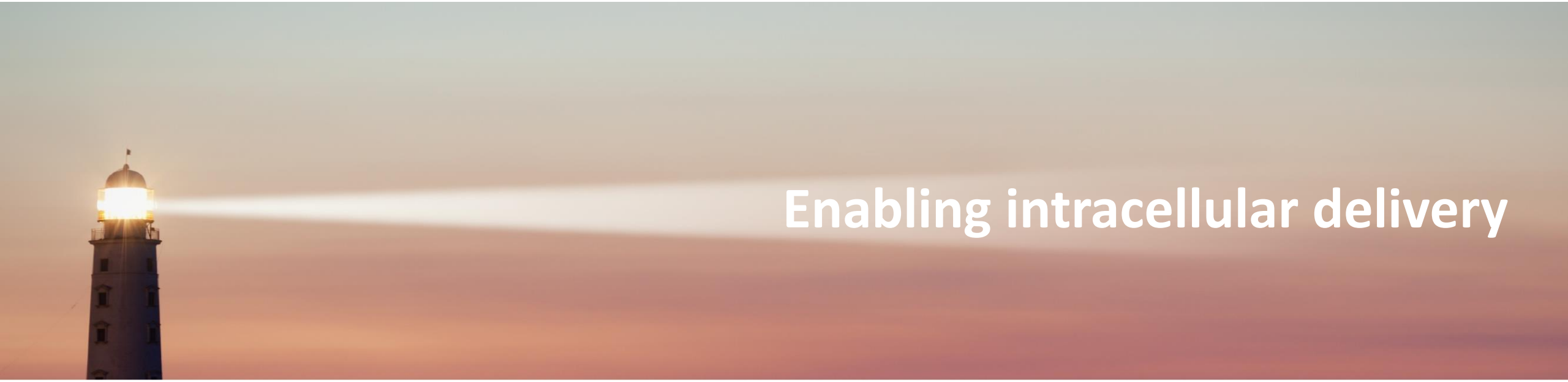
PCI Biotech



Q3 2020 PRESENTATION

November 11, 2020

Per Walday, CEO

Ronny Skuggedal, CFO

PCI BIOTECH

- Important notice and disclaimer

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PCI BIOTECH

- Q&A session through teleconference for verbal questions

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

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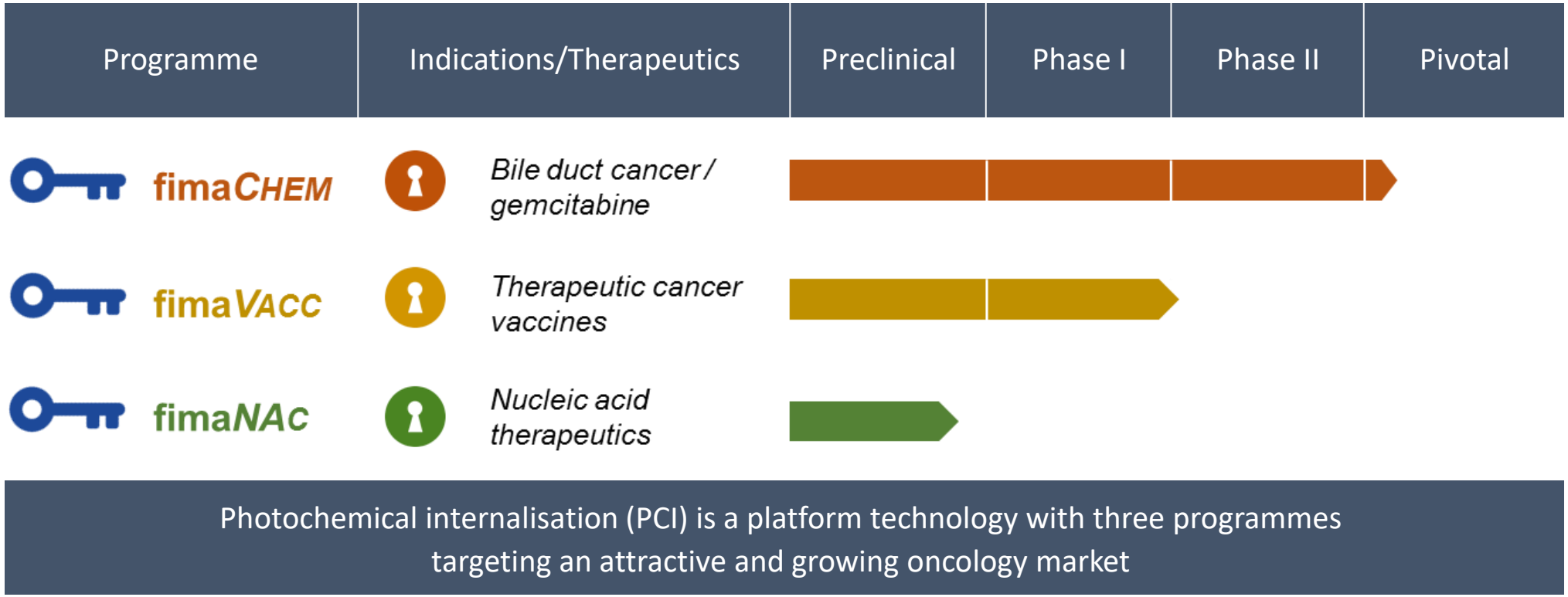
When prompted, provide the confirmation code or event title.
Confirmation Code: 2202572
Event title: PCI Biotech Holding ASA Q3 conference call

This information is also available in the Q3 Report press release and on the webpage https://www.pcibiotech.no/webcasts

PCI Biotech – enabling intracellular delivery

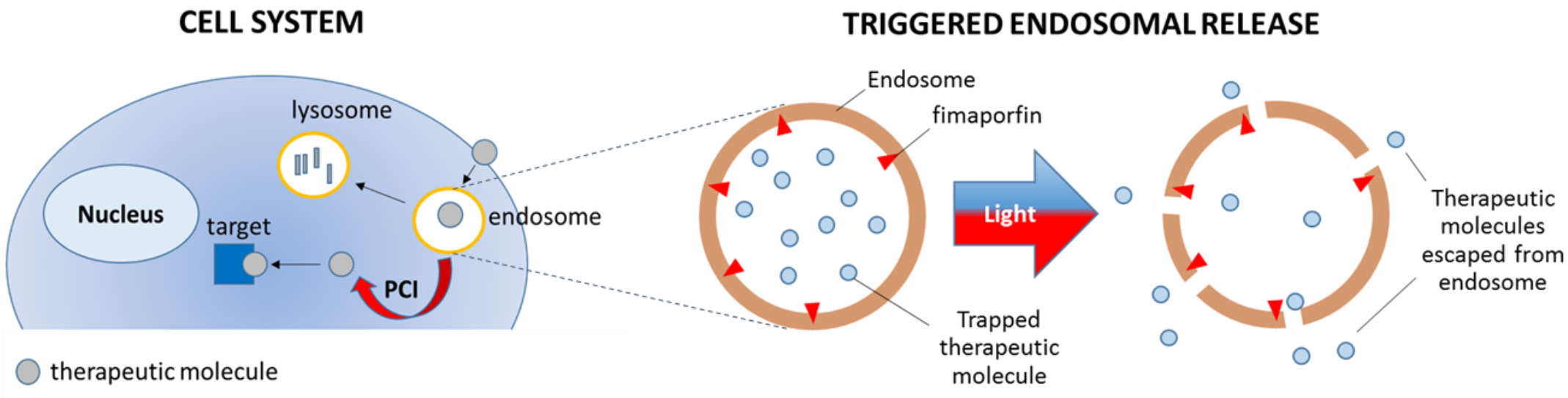
- A biotech company with an oncology focused pipeline



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

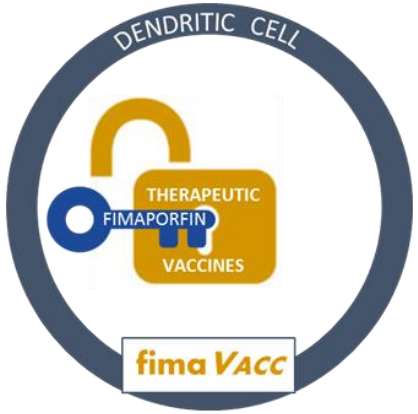


PCI Technology

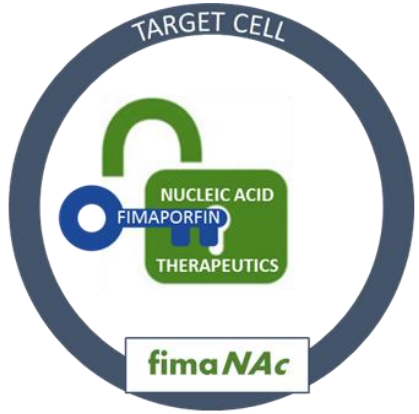
- Enabling drugs to reach intracellular therapeutic targets

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

Q3 2020 HIGHLIGHTS

- fimaCHEM

RELEASE – first patient included in Asia

- The first patient has been enrolled in the RELEASE study in South Korea, less than three months after opening of the first study site in Asia
- All the nine planned study sites in Asia are now open, with initial good screening activity
- The Asian clinical sites are located in South Korea and Taiwan, providing access to hospitals and KOL's in a commercially interesting region with higher prevalence of bile duct cancer

Q3 2020 HIGHLIGHTS

- fimaCHEM

RELEASE – initiatives to recoup delays

- Several initiatives are being 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
- Full approvals of the protocol amendment are received in 10 European countries, South Korea, Taiwan and US
- Seven sites are pending local ethic approvals and the focus is now on achieving the remaining approvals
- A total of 45 sites are open by end-October 2020 across EU, US and Asia and 38 of these sites are open under the new amended protocol

Q3 2020 HIGHLIGHTS

- fimaCHEM

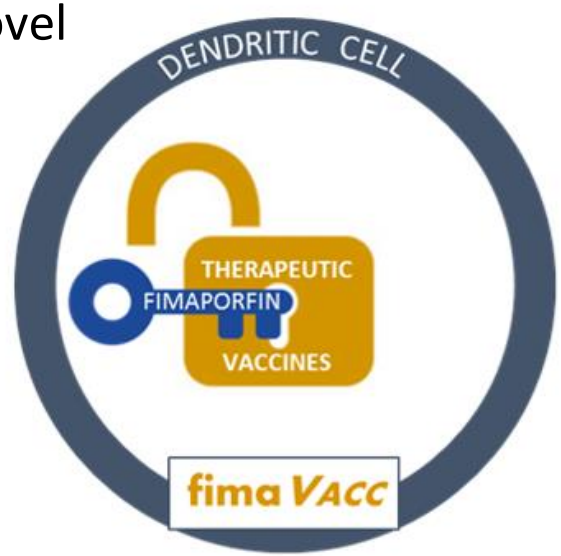
RELEASE – effect of the COVID-19 pandemic

- The consequences of the COVID-19 pandemic and the new recruitment initiatives for the RELEASE study cannot yet be fully established
- The second wave of the pandemic is currently sweeping over many countries, but we are seeing early indications of increased screening activity after implementation of the new amended protocol and the opening of Asian sites
- The situation is less clear in the US and implementation of the new amendment by local ethics is still pending at most sites – first patient enrolled may slide into 2021
- The company continues to have full focus on enrolment of patients into the RELEASE study – the expected timeline for the planned interim analysis is retained as a range from 2H 2022 to 1H 2023

Q3 2020 HIGHLIGHTS

- **fima VACC**

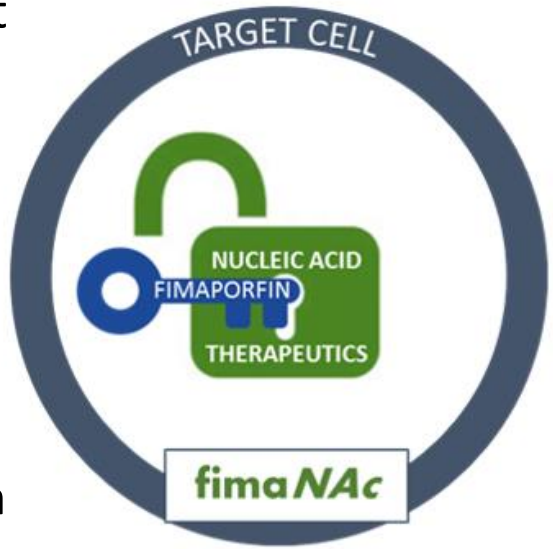
- A new research collaboration is established with DCprime to explore novel cancer vaccination concepts
- DCprime is a clinical stage, privately held cancer immunotherapy focused company and the companies will perform an extensive evaluation of technology compatibility and synergy based on preclinical studies
- The results will be evaluated and explored for the potential for further development and partnership



Q3 2020 HIGHLIGHTS

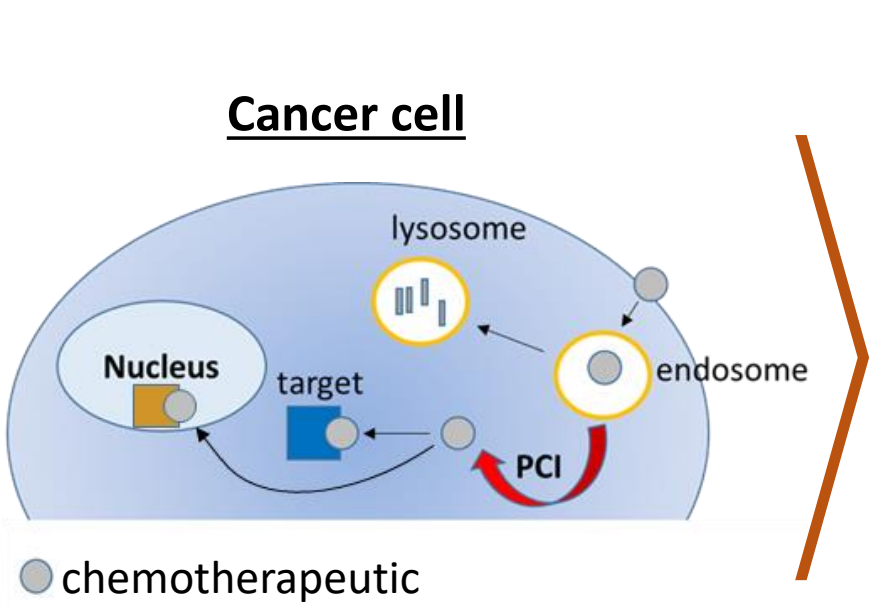
- **fima*NAc***

  - 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 continued to be 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 needs
  - The companies will work together to publish the preclinical results from this collaboration



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

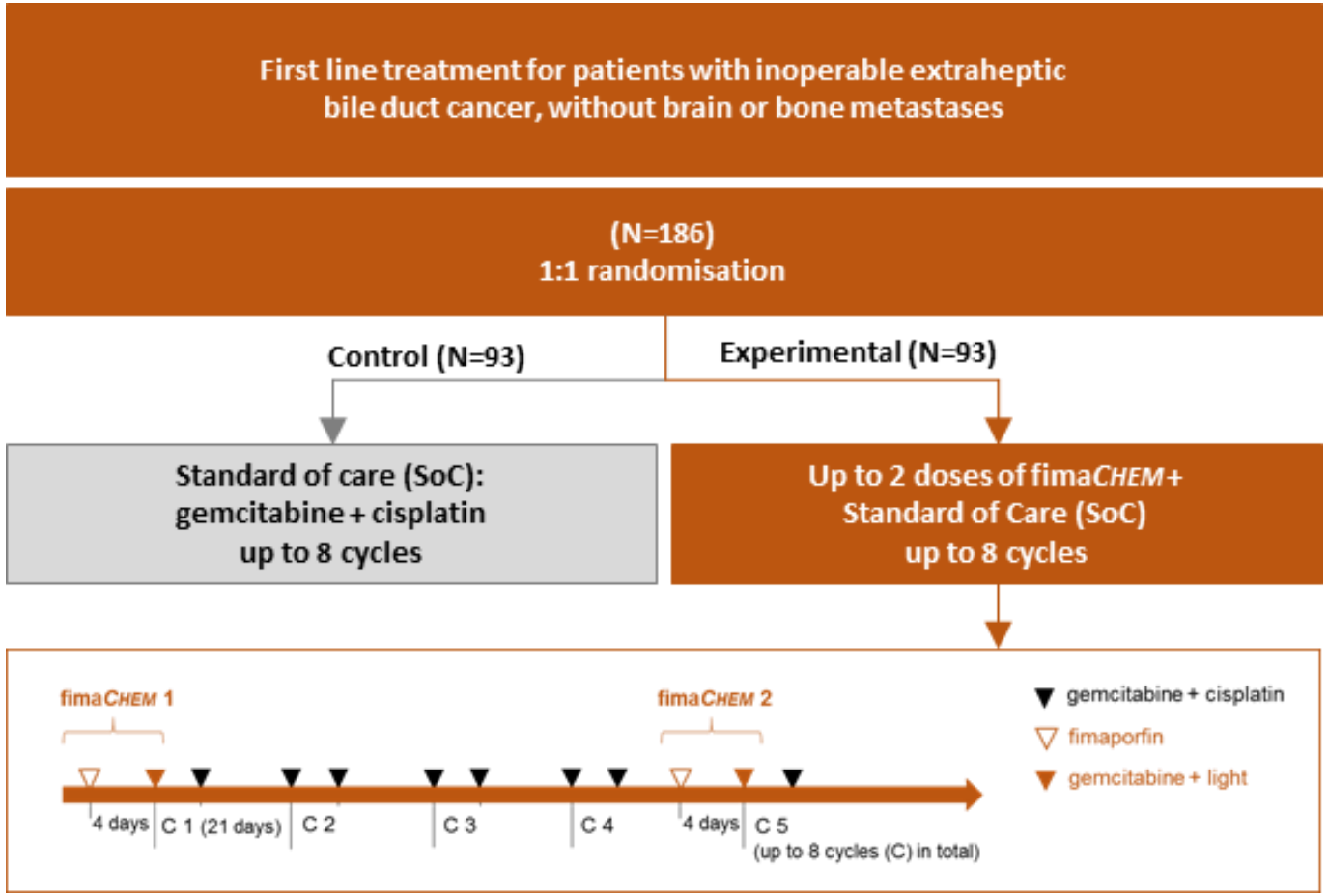
- Excellent fit with medical need and existing treatments

  - **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

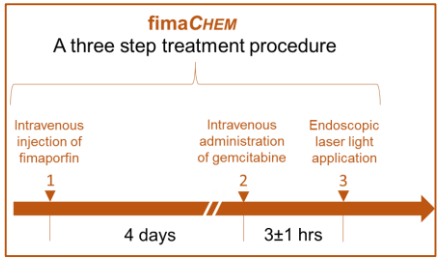
- Pivotal study with potential accelerated/conditional approval on interim analysis



- 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
- 12 European countries, 2 Asian countries + USA

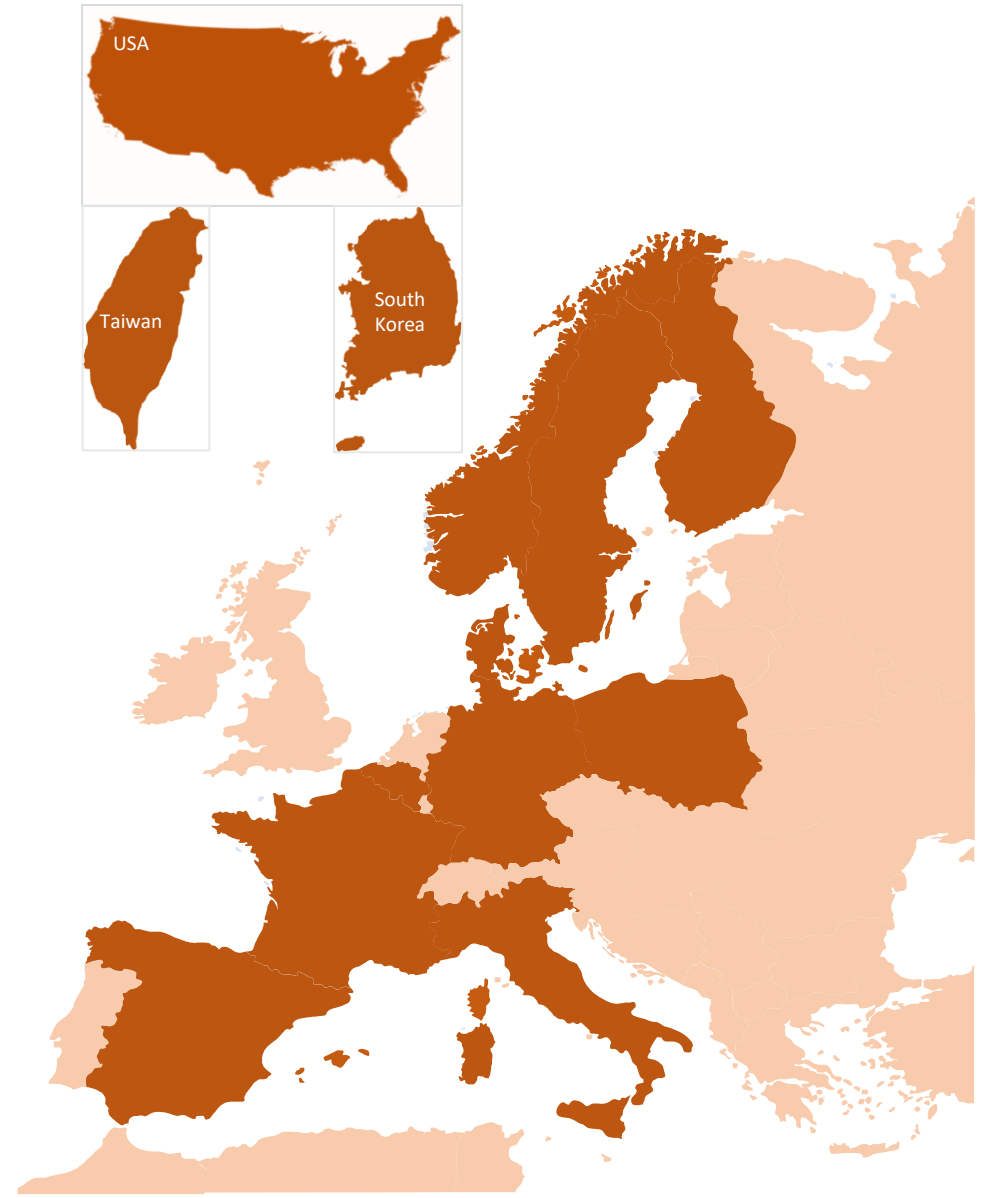
- **fimaCHEM** in addition to current Standard of Care



BILE DUCT CANCER – RELEASE STUDY

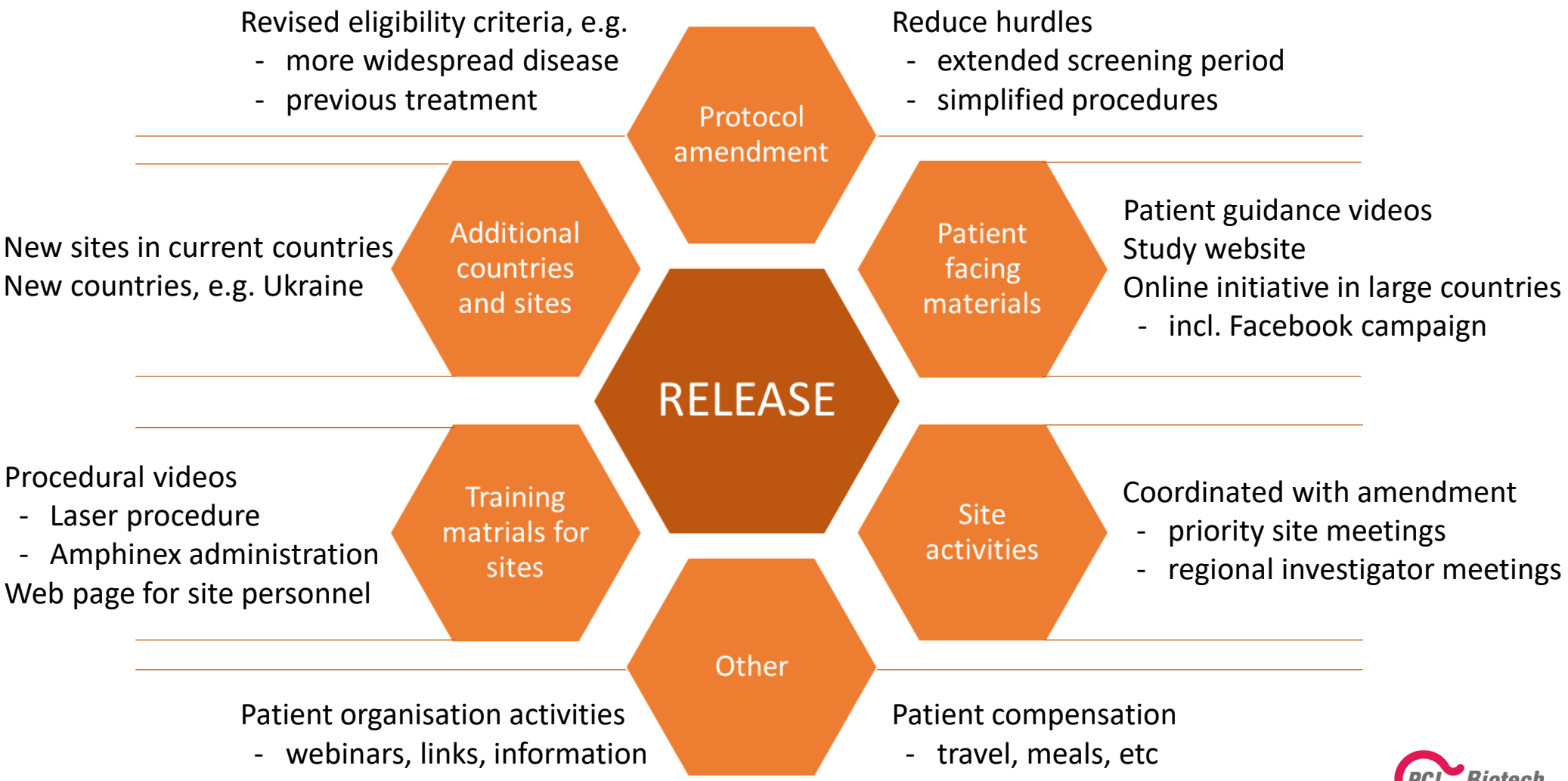
- Pivotal study progress

  - Regulatory and ethics received for South Korea, Taiwan, USA and 10 of 12 planned European countries
  - 45 sites open for patient enrolment – 30 in Europe
  - 9 sites recently opened in Asia – first Asian patient enrolled
  - 6 sites open in the US – awaiting first US patient
  - Screening in the RELEASE study affected by the COVID-19 pandemic
  - Several initiatives implemented with the aim to recoup the COVID-19 caused delay



BILE DUCT CANCER – RELEASE STUDY

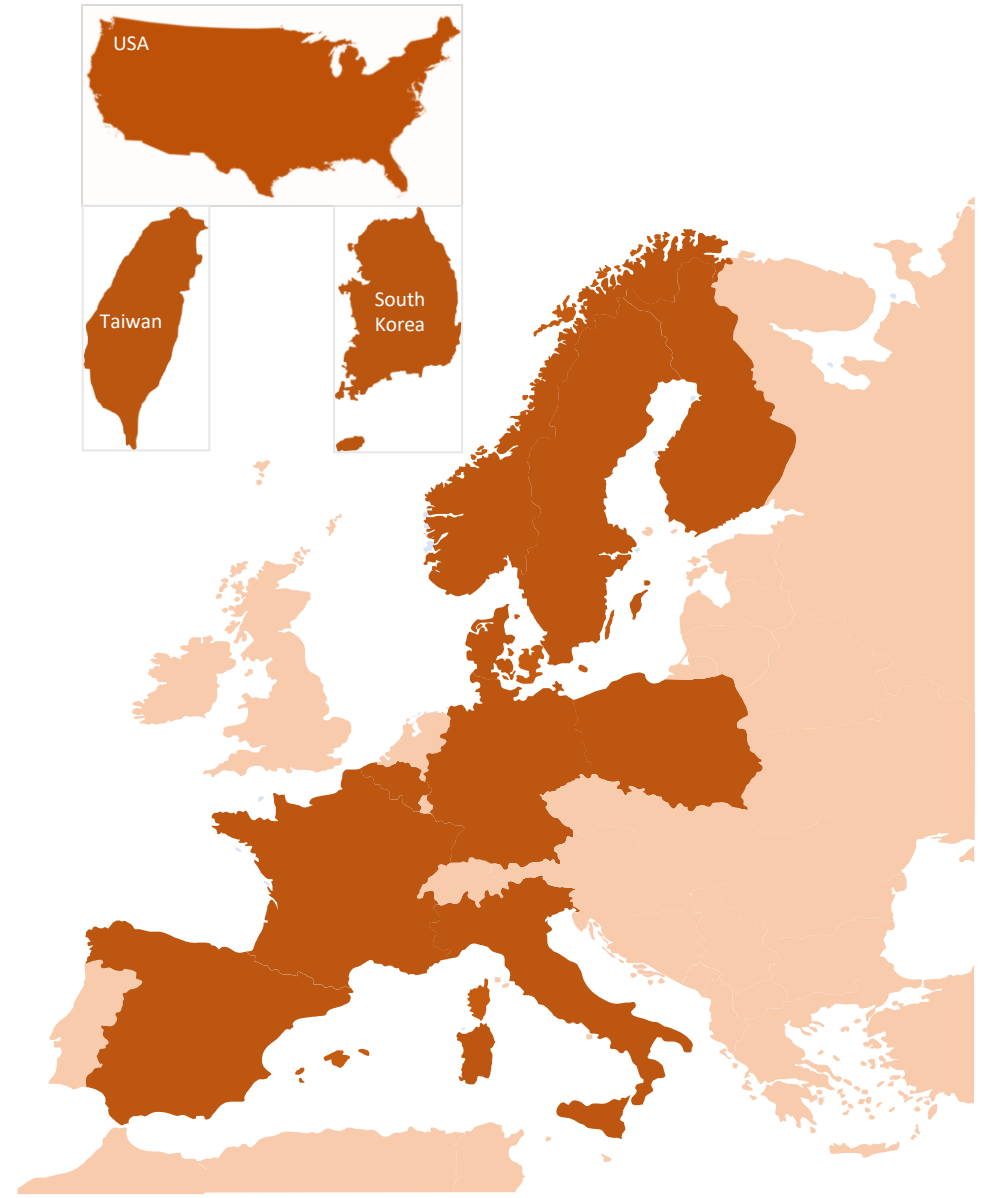
- Several initiatives to enhance recruitment – based on KOL and site feedback



BILE DUCT CANCER – RELEASE STUDY

- Pivotal study progress

  - Most important initiatives are the increase in number of sites and the protocol amendment
  - Number of sites increased from 40 to >50
  - Protocol amendment approved in all current countries and 38 of 45 open sites screen under the amended protocol
  - We are in the second wave of the pandemic – despite this we are seeing early indications of increased screening activity after implementation of the new amended protocol and the opening of Asian sites
  - The expected timing of the planned interim analysis is retained as a range from 2H 2022 to 1H 2023



BILE DUCT CANCER – RELEASE STUDY

- Endpoints, milestones and timelines

Endpoints:

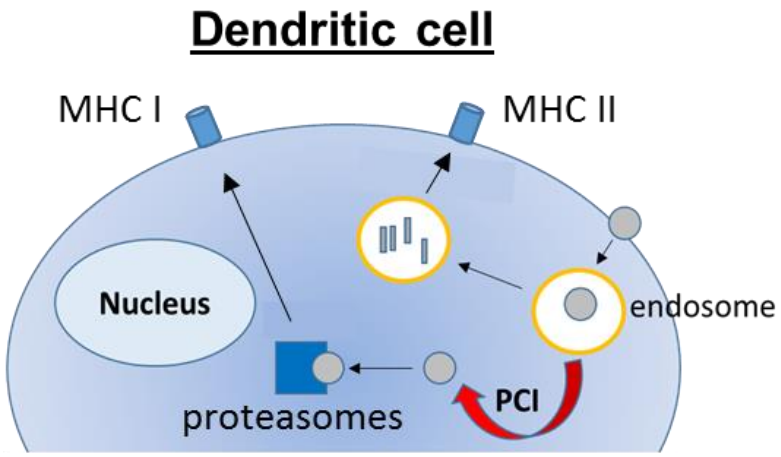
Interim analysis: Primary Endpoint: Objective Response Rate (ORR) Secondary endpoint: Overall Survival (OS)	• Orphan drug designation in EU & USA – potential accelerated approval
Final analysis: Primary endpoint: Progression Free Survival (PFS) Secondary endpoint: Overall Survival (OS)	• Single randomised 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 may slide into 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 (tbd pending further development of the COVID-19 pandemic)
Timing and format for study conclusion may be impacted by outcome of Interim analysis	• Final analysis expected approximately 1H 2024 (tbd pending further development of the COVID-19 pandemic)

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

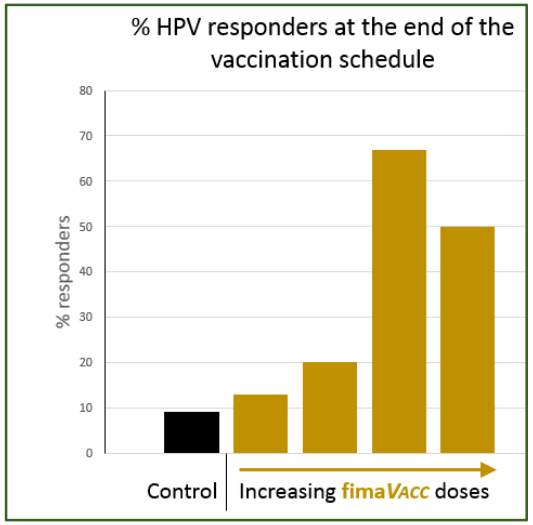
Antibodies and helper T-cells

PROGRESS OF THE fimaVACC PROGRAMME

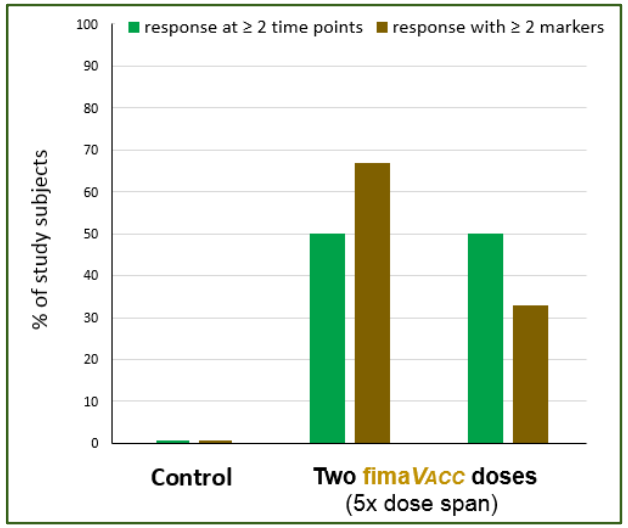
- Successful clinical proof-of-concept

- 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***

NEW RESEARCH COLLABORATION

- Established with DCprime

- A new research collaboration was established in September this year with DCprime to explore the combination of PCI with their proprietary technologies
- DCprime is a privately held, clinical stage cancer immunotherapy company developing novel vaccination technologies
- The collaborators will perform an extensive evaluation of technology compatibility and synergy based on preclinical studies
- The collaboration pursues the development of completely novel cancer vaccination concepts based on tumour-independent antigens (TIAs)
- The companies will evaluate results achieved from this research collaboration and then explore the potential for further development and partnership

PROGRESS OF THE fimaVACC PROGRAMME

- Growing robust evidence

  - Positive clinical study results presented at ESMO Immuno-Oncology Congress in December 2019 – publication in process in scientific journal

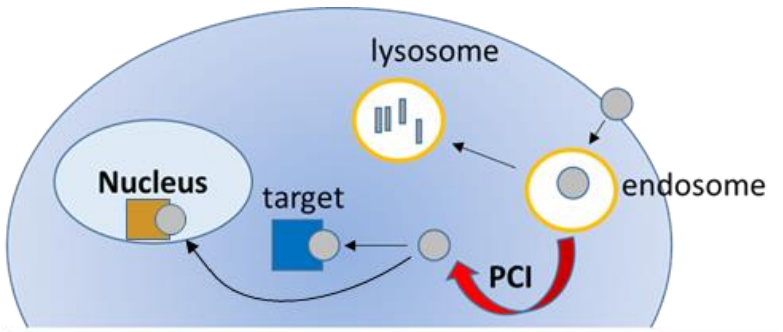
  - Next step: moving to Phase II with a partner or by ourselves (proof-of-concept in a disease setting)

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 not moving into a definitive agreement

  - The experimental phase of the preclinical research collaboration with AstraZeneca ended in 2019, and was followed by an evaluation period until end of 2020 for AstraZeneca to determine whether to move the collaboration into a definitive agreement
  - In October 2020, PCI Biotech was informed that AstraZeneca elected not to enter into a definitive agreement for the **fimaNAc** technology
  - Encouraging results have been achieved in this collaboration and the decision not to enter into a definitive agreement was primarily based on a strategic evaluation by AstraZeneca of their current development needs and priorities
  - The collaboration has provided us with valuable scientific knowhow from working with a big biopharma company over the last 5 years and the companies will together publish the results from this collaboration
  - PCI Biotech see strong potential for further development of **fimaNAc**, not least within the emerging field of mRNA

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) slightly 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)	Q3 2020	Q3 2019	YTD 2020	YTD 2019	FY 2019
Other income (public grants)	1 963	2 425	5 801	7 275	9 392
Operating results	-22 534	-18 495	-60 760	-63 474	-88 804
Net financial result	*1 329*	*4 224*	*14 985*	*135*	*58*
Net profit/loss	-21 204	-14 271	-45 775	-63 339	-88 746

(figures in NOK 1,000)	Q3 2020	Q3 2019	YTD 2020	YTD 2019	FY 2019
Net change in cash during the period	-22 294	-21 133	-64 753	-63 988	-86 574
Exchange rate effect on cash in foreign currency	*1 156*	*3 845*	*13 882*	*-1 005*	*-1 649*
Cash and cash equivalents	210 233	284 332	210 233	284 332	261 103

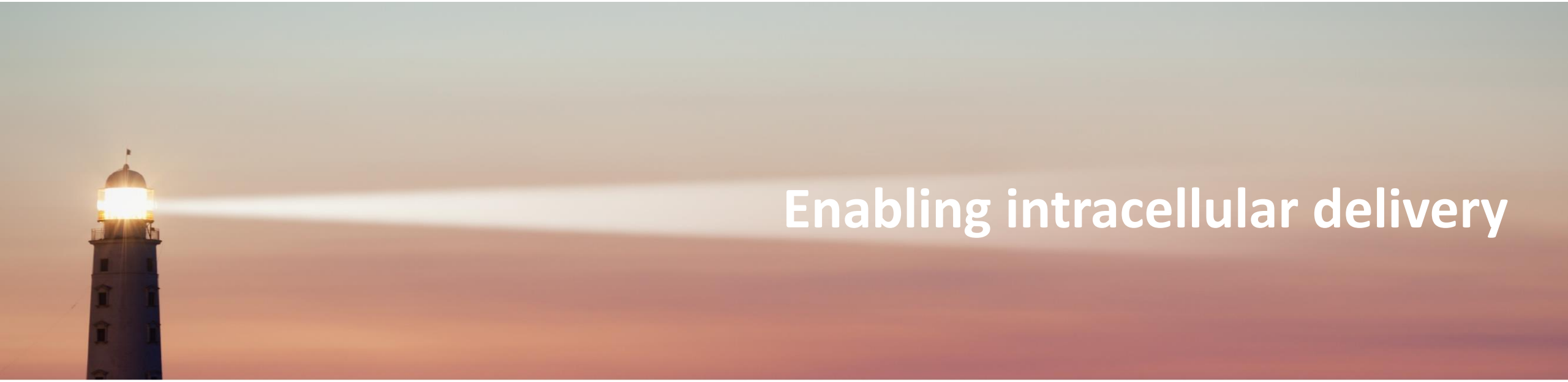
Recent Key Achievements & Near-Term Milestones

2H 2019	✓ fimaVACC	Phase I results presented at key conference
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	✓ fimaVACC	Phase I results accepted for publication in scientific journal
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