Q3 2019 PRESENTATION

November 27, 2019

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PCI BIOTECH

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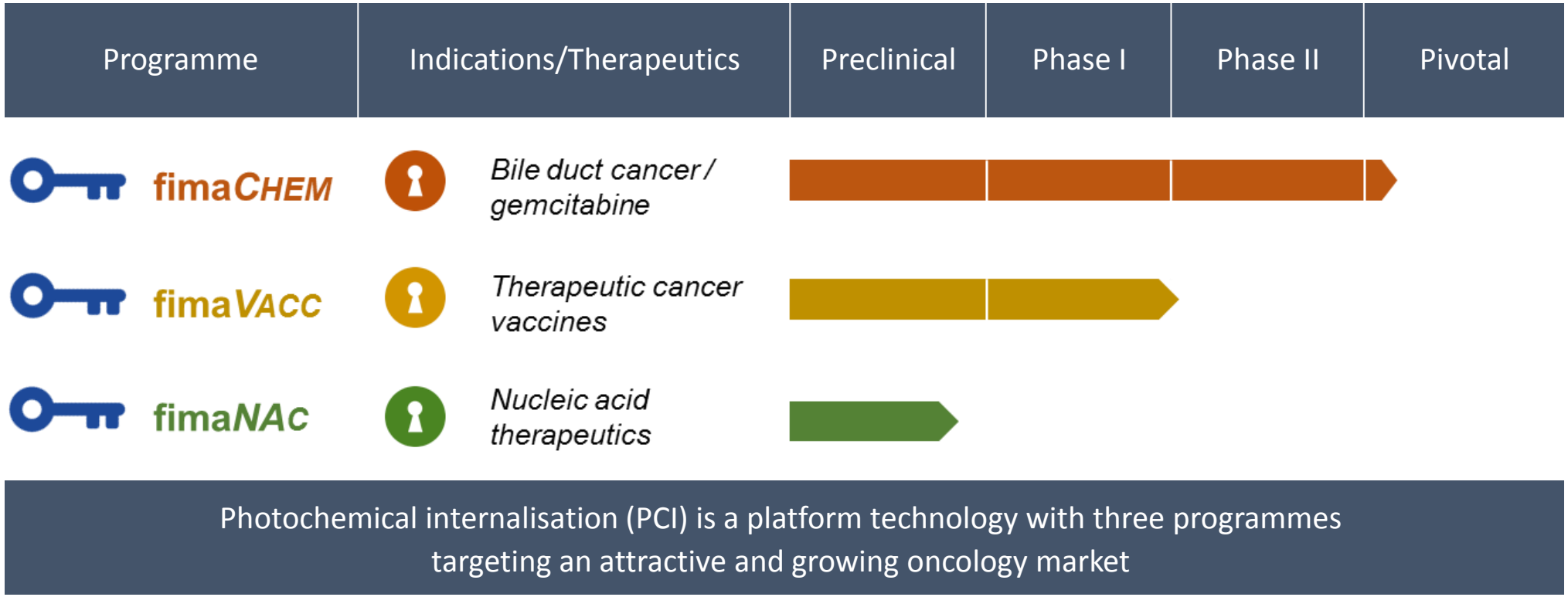
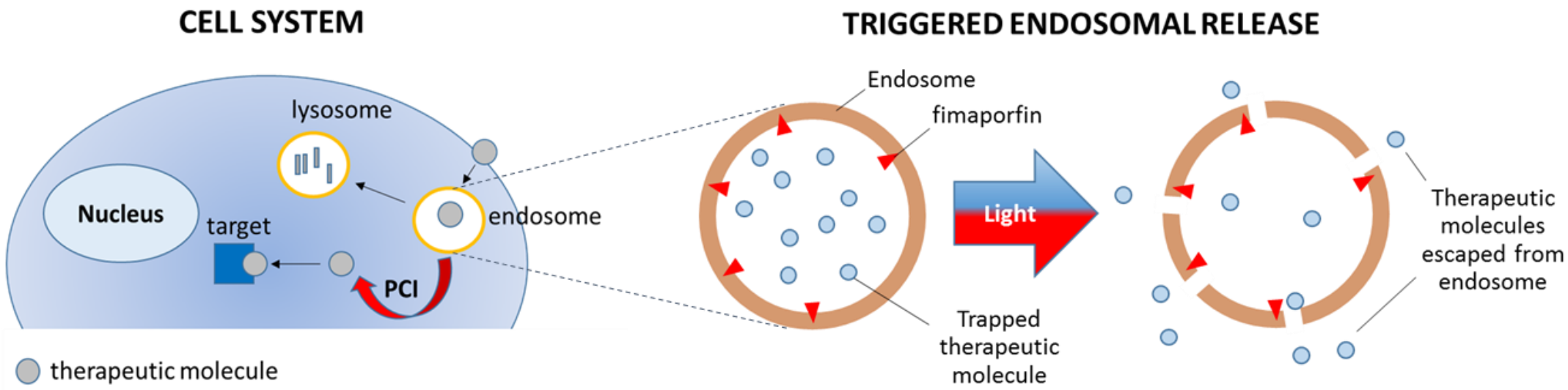
PCI BIOTECH – UNLOCKING THE POTENTIAL OF INNOVATIVE MEDICINES

An oncology company with three well differentiated assets



PCI TECHNOLOGY – MODE OF ACTION

- Enabling drugs to reach intracellular therapeutic targets

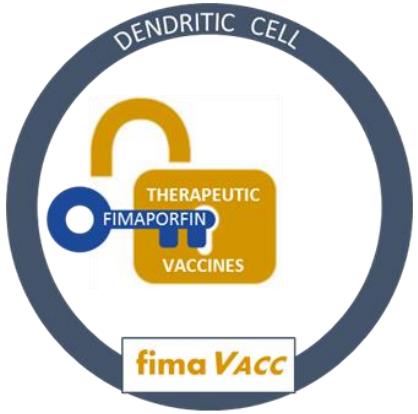


PCI TECHNOLOGY

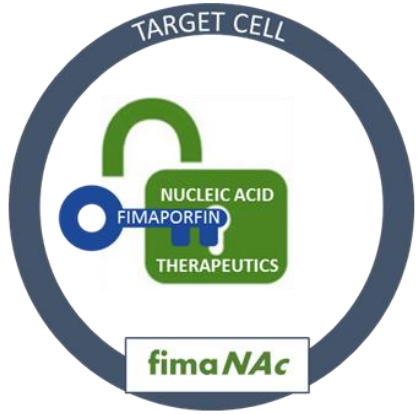
- Enabling drugs to reach intracellular therapeutic targets

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 HIGHLIGHTS

► fimaCHEM

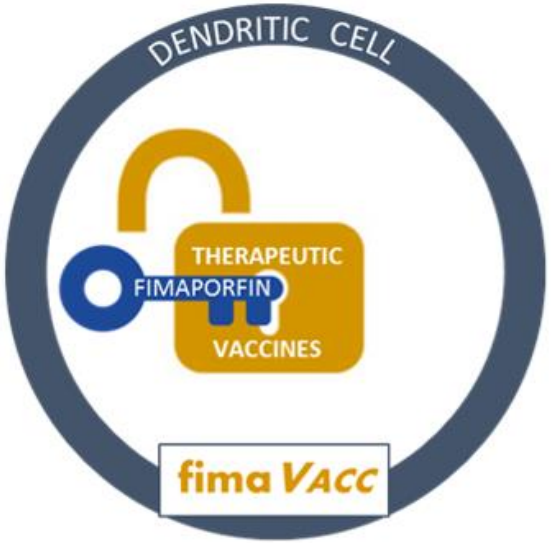
RELEASE – maintaining main milestones

- First patient enrolled in May 2019
- Regulatory and ethics approval in 10 of 11 EU countries + USA
- Opened 23 of total planned 40 sites
- First US clinical site opened only recently, enrolment of first US patient likely to slide into 2020
- ~10 sites behind schedule, expecting to catch up in early 2020
- Site selection ongoing in Asia with the aim to include sites in 2020

Q3 HIGHLIGHTS

▶ fimaVACC

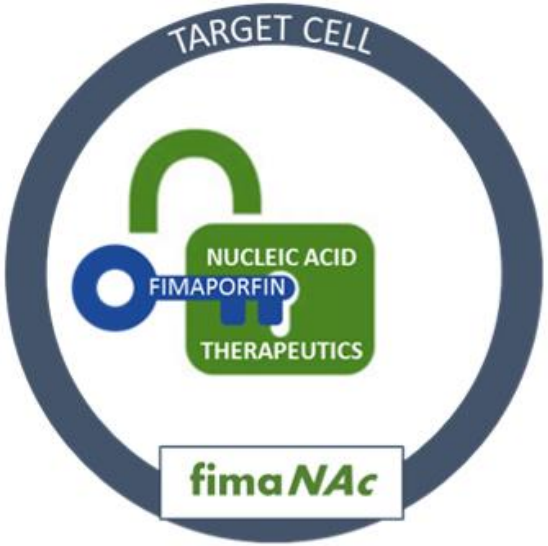
- Phase I results accepted for presentation at the ESMO Immuno-Oncology Congress
- Proof-of-Concept of the **fimaVACC** technology established with enhanced immune responses in healthy volunteers
- Publication of preclinical results in ‘Frontiers of Immunology’, a high-impact journal
- Parallel development strategies with direct partnering efforts and planning for clinical PoC in disease setting



Q3 HIGHLIGHTS

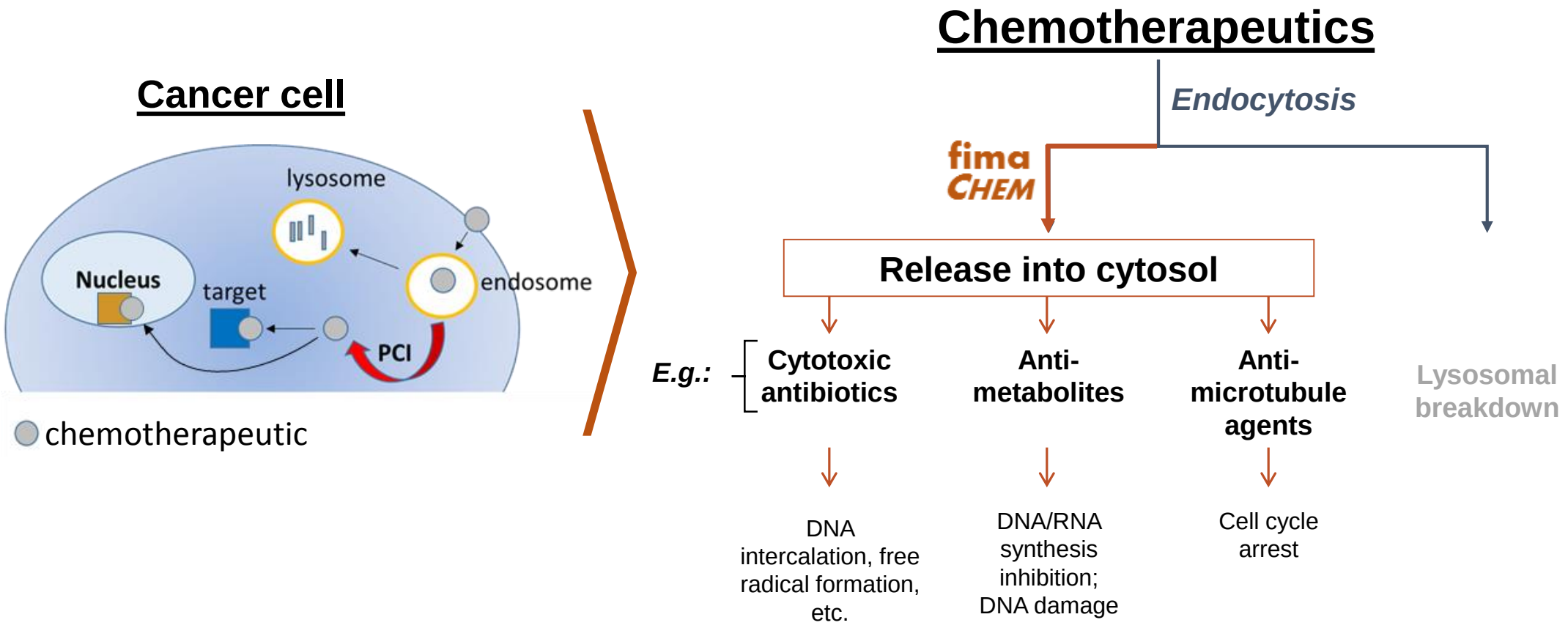
▶ fimaNAc

- Extended and expanded the AstraZeneca research collaboration through 2019
- Scope recently expanded to evaluate if synergies in oncology are transferrable to other disease areas
- Further potential partnership to be evaluated during 1H 2020
- Promising response on patent application for mRNA delivery, which is highly relevant for several collaboration partners



PCI TECHNOLOGY

► **fima*CHEM*** – mode of action



BILE DUCT CANCER – EXTRAHEPATIC INOPERABLE

- **fimaCHEM** – an excellent fit with medical need and existing treatments

High unmet medical need

- Only **11-12 months**[1] average survival for inoperable tumors
- Less than 1/3 of tumors are resectable at presentation
- No approved chemotherapies; gemcitabine and cisplatin are actively used and recommended
- Endoscopic stenting for palliative biliary drainage

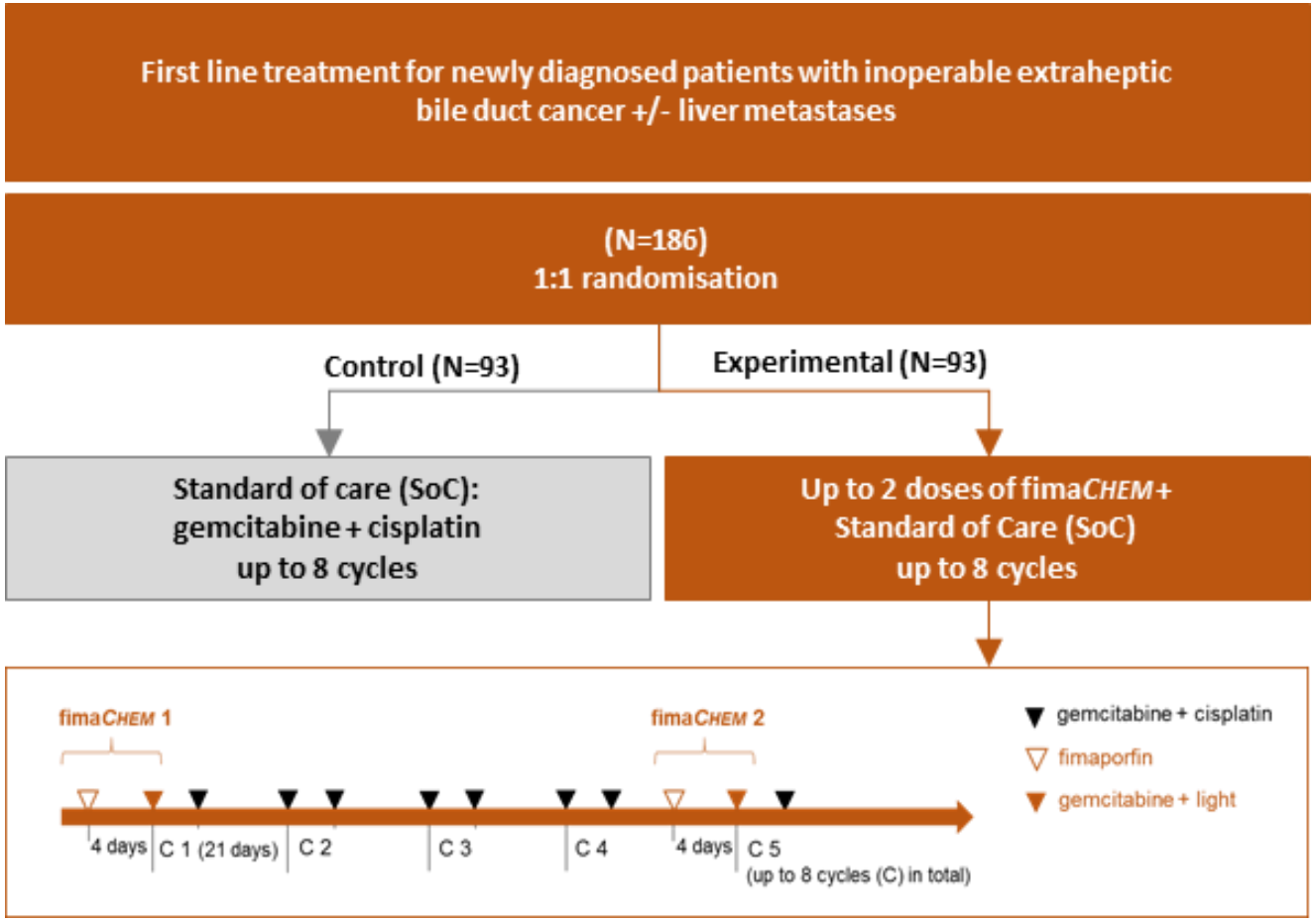
fimaCHEM advantages

- mOS[2] of **21.7 months** at selected dose (cohort IV) in Phase I dose-escalation
- Potentially offers clear benefit for majority of target patient cases
- Enhances recommended first-line chemotherapy and boosts effect where it is most needed
- Easy illumination through standard endoscopic methods

[1] New England Journal of Medicine 2010;362:1273-81
[2] Median overall survival

BILE DUCT CANCER – RELEASE STUDY

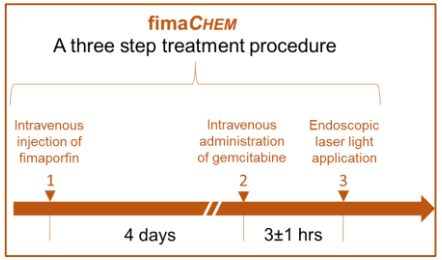
- Pivotal study with potential accelerated/conditional approval on interim analysis



- Rare disease (1-2 cases per 100,000 in EU and US)
- Majority of cases are inoperable upon presentation
- Median overall survival of less than one year
- No approved treatment, limited development pipeline

- Approximately 40 clinical sites
- 11 European countries + USA
- Site selection ongoing in Asia (S Korea and Taiwan)

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



Bile Duct Cancer – Release Study

- Pivotal study progressing as planned

- Regulatory and ethics approvals progressing according to plan – approvals received for USA and 10 of 11 planned European countries by mid-November
- 23 of planned 40 sites open for patient enrolment
- First US clinic opened only recently, with first US patient likely to slide into 2020
- Current lag in opening of sites does not affect the main milestones
- Site selection ongoing for start-up in 2020 in Asia, where bile duct cancer is more prevalent

BILE DUCT CANCER – RELEASE STUDY

► Endpoints, milestones and timelines

Endpoints:

Interim analysis: Primary Endpoint: Progression free survival (PFS) Secondary endpoint: Objective Response Rate (ORR)	• Orphan drug designation in Europe and USA • Potentially accelerated/conditional 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

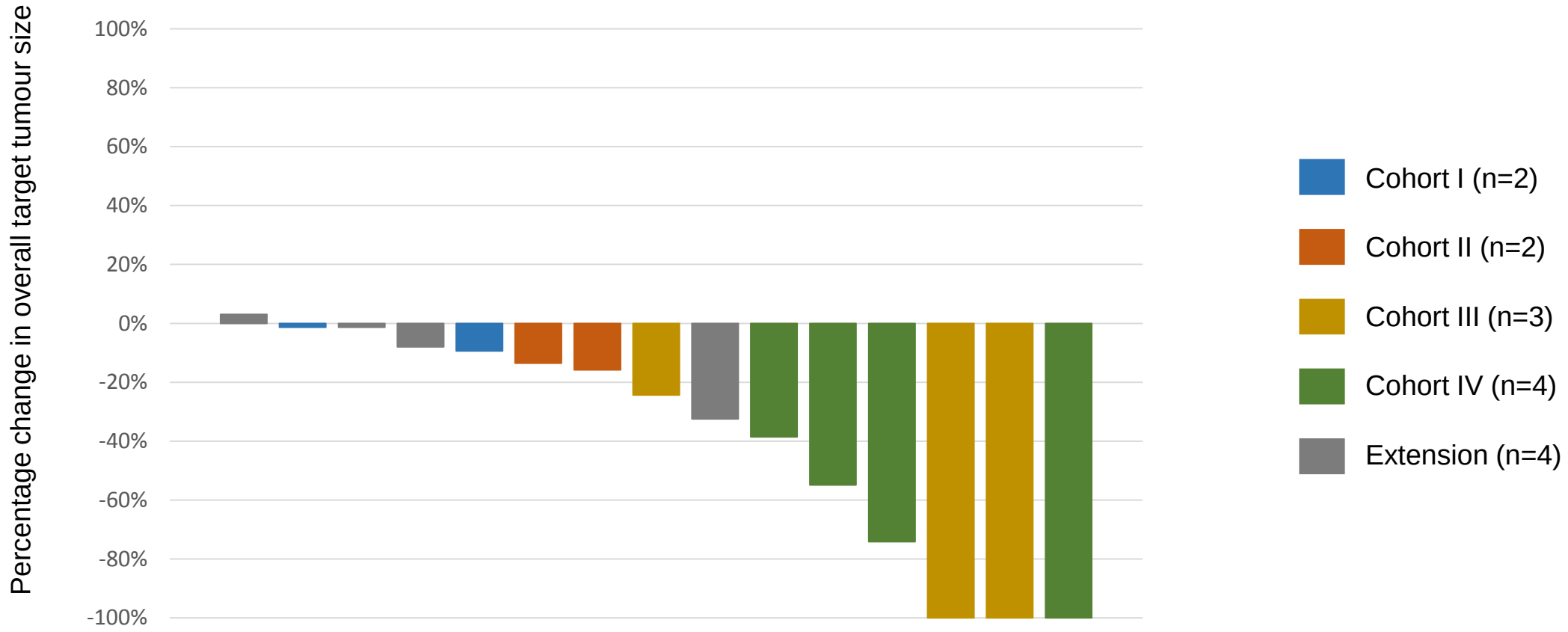
Milestones and timelines:

First patient enrolled in Europe in May 2019	• First patient in the US may slide into 1H 2020
Seamless safety review by IDMC when 8 patients have undergone two fimaCHEM treatments	• IDMC = Independent Data Monitoring Committee
Event driven interim analysis after 60 progression free survival (PFS) events	• Interim analysis expected approximately 36 months after inclusion of first patient in May 2019
Timing and format for study conclusion may be impacted by outcome of Interim analysis	• Final analysis expected approximately 50 months after inclusion of first patient in May 2019

BILE DUCT CANCER – CLINICAL PHASE I STUDY

- Dominated by significant target tumour reduction in the first 6 months

- Best Overall Response – all patients in all cohorts with measurable disease follow-up (n=15)



BILE DUCT CANCER – PHASE I DOSE-ESCALATION STUDY

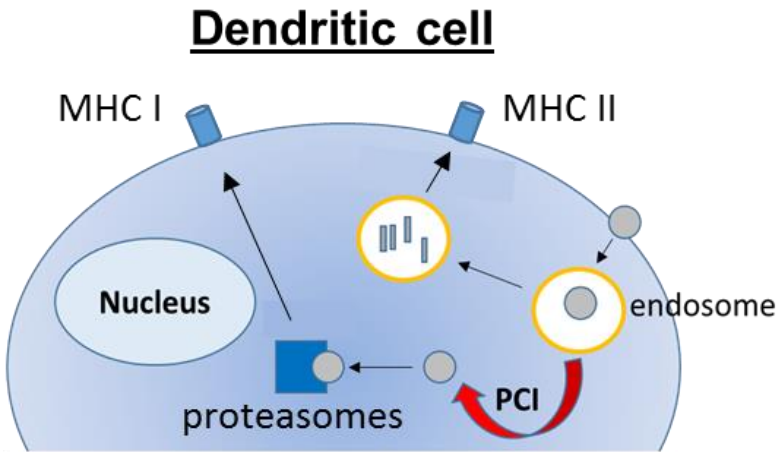
► Positive early signs of efficacy – median Overall Survival of 21.7 months at selected dose

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)	21.7 months	14.4 months

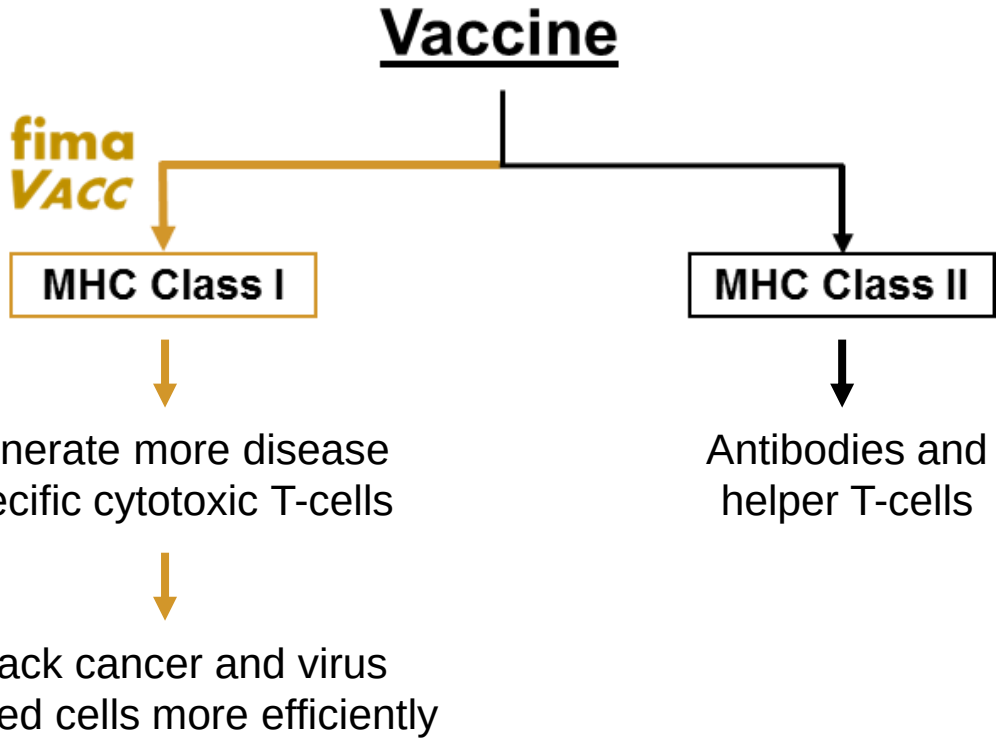
- Cohort IV dose has been selected for the pivotal RELEASE study
- Half of the patients in Cohort IV survived >30 months
- One patient in Cohort IV still alive by mid-November, 44 months after treatment
- Encouraging Phase I results paved the way for a pivotal trial, with interim analysis
- Safety of two treatments provided in a Phase I Extension

PCI TECHNOLOGY

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



Vaccine antigen



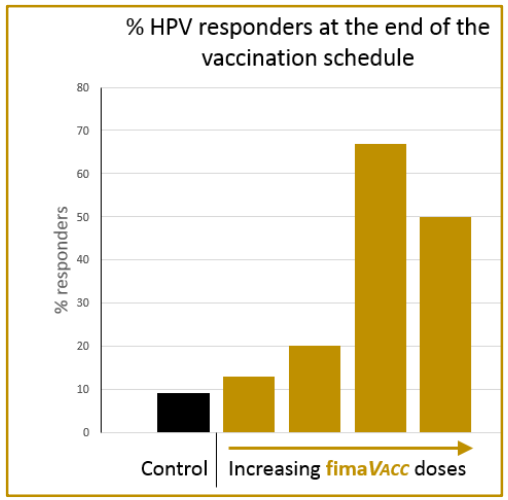
SOLID PROGRESS OF THE fimaVACC PROGRAMME IN 2019

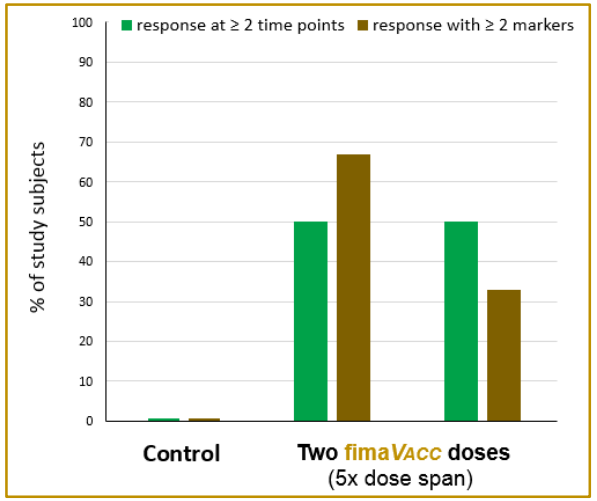
- Successful clinical proof-of-concept

- 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
  - Positive overall characterisation of tolerability, with efficacy seen across a wide tolerable dose span

SUCCESSFUL CLINICAL PROOF-OF-CONCEPT

- Phase I study in healthy volunteers shows enhanced immune responses





fimaVACC provides:

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

- Results show that 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**

SOLID PROGRESS OF THE fimaVACC PROGRAMME

- Next steps

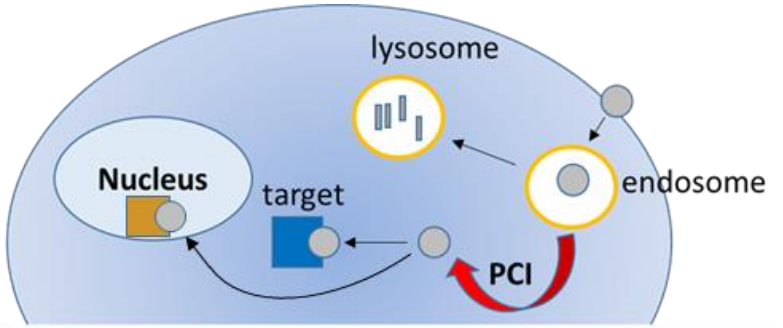
- Study results presentation – ESMO Immuno-Oncology Congress in Dec 2019
- Assessing publication in scientific journal
- Phase I results to be used in direct partnering efforts and plan for clinical proof-of-concept in disease setting

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

fima NAc

Release into cytosol

Lysosomal breakdown

E.g.:

siRNA
miRNA

↓

Knockdown of gene expression

mRNA
DNA

↓

Therapeutic protein production

RESEARCH COLLABORATIONS

- Six collaborations established with key players in nucleic acid therapeutics

fimaNAc

- Astra Zeneca collaboration extended to end of 2019 – scope expanded to evaluate whether synergies established in oncology are transferrable to other disease areas – additional 6 months period for determination of potential next steps
- Promising response on patent application for mRNA delivery, which is highly relevant for several collaboration partners

AstraZeneca

IMV IMMUNOVACCINE

BAVARIAN NORDIC

eTheRNA

Phio PHARMACEUTICALS

BIONTECH

FINANCE

- Key financial figures

- Other income in line with previous year

- Operating result impacted by planned start-up activities and initiation of the RELEASE study

(figures in NOK 1,000)	Q3 2019	Q3 2018	YTD 2019	YTD 2018	FY 2018
Other income (public grants)	2 425	2 238	7 275	6 613	9,585
Operating results	-18 495	-8 386	-63 474	-30 241	-44 519

(figures in NOK 1,000)	Q3 2019	Q3 2018	YTD 2019	YTD 2018	FY 2018
Net change cash and cash equivalents*	-17 288	-7 869	-64 993	-30 253	298 537
Cash and cash equivalents	284 332	20 536	284 332	20 536	349 326

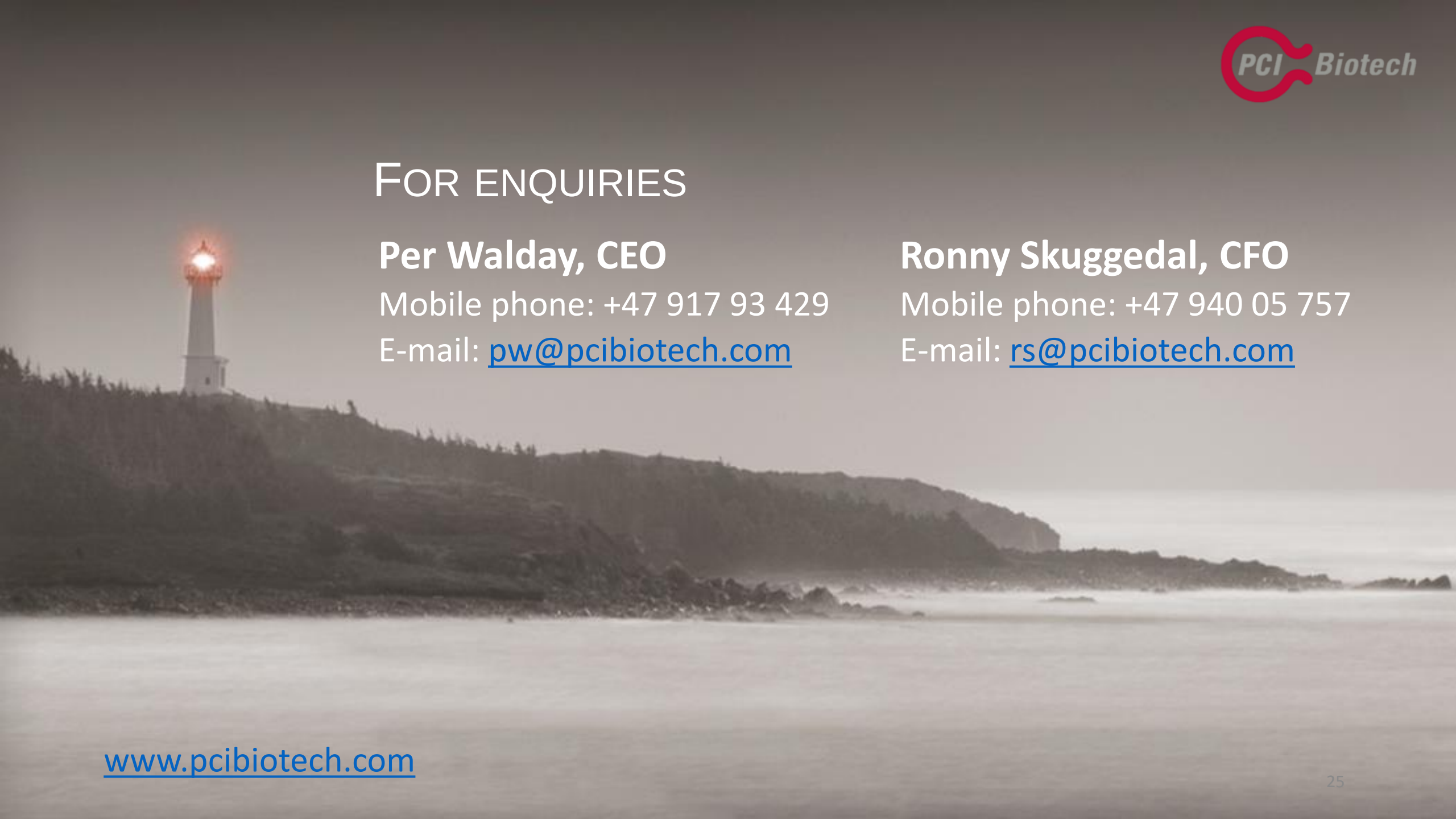
*Including effects from exchange rate fluctuation on bank deposits in EURO from October 2018

KEY ACHIEVEMENTS & NEAR-TERM MILESTONES

1H 2019	✓ fimaVACC	Completion of Phase I immune analyses
1H 2019	✓ fimaCHEM	Safety of repeated treatment confirmed
1H 2019	✓ fimaCHEM	First patient enrolled in the RELEASE study
2H 2019	✓ fimaVACC	Phase I results presented at key conference
1H 2020	✓ fimaVACC	Phase I results published in scientific journal
1H 2020	✓ fimaCHEM	First US patient enrolled in the RELEASE study
2H 2020	✓ fimaCHEM	First Asian 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



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