Q1 2020 PRESENTATION

May 6, 2020

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PCI Biotech

PCI BIOTECH

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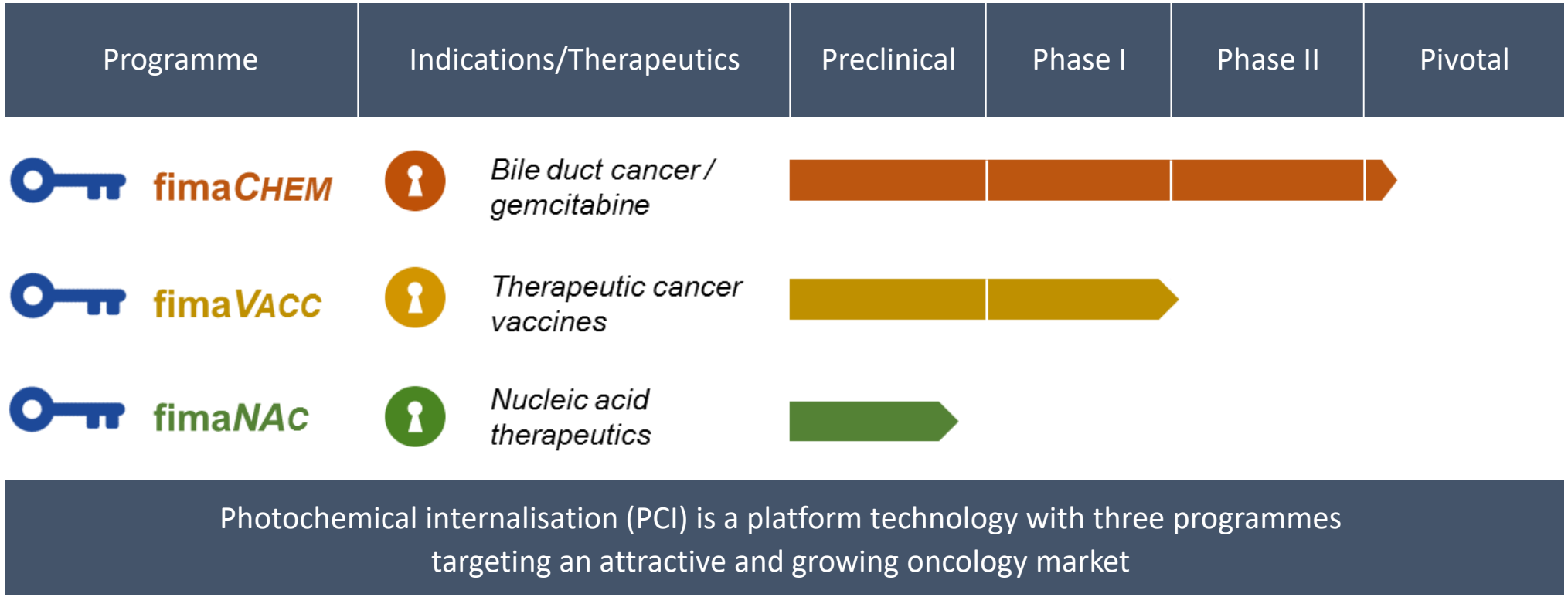
PCI BIOTECH – UNLOCKING THE POTENTIAL OF INNOVATIVE MEDICINES

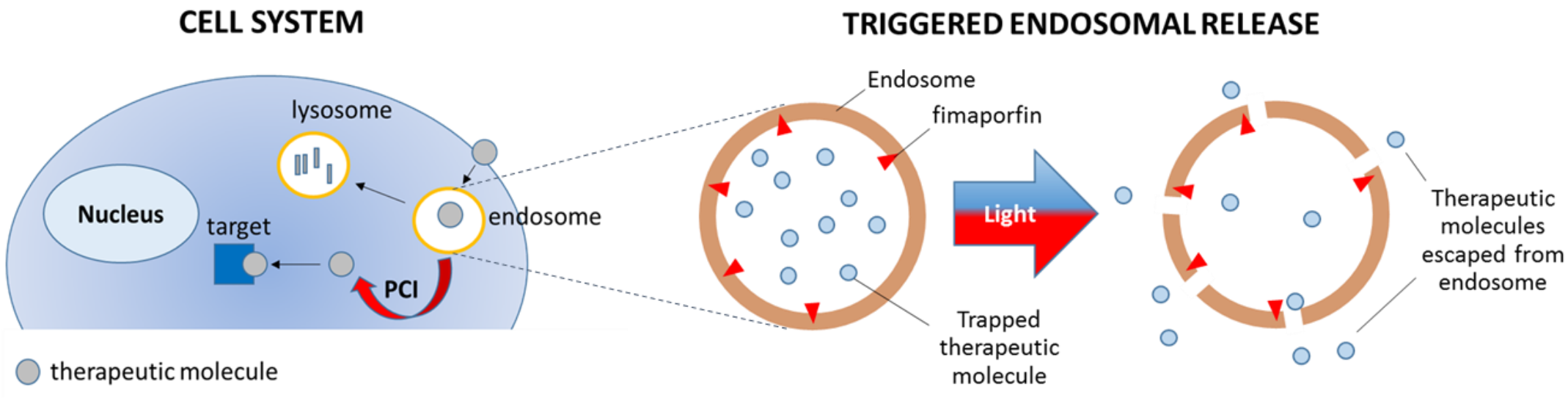
An oncology company with three well differentiated assets



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

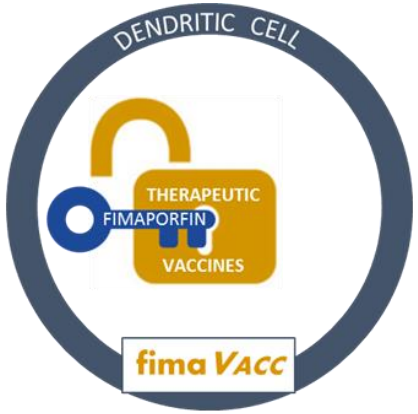


PCI TECHNOLOGY

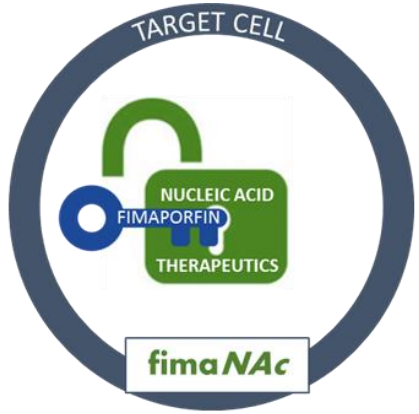
- Enabling drugs to reach intracellular therapeutic targets

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 HIGHLIGHTS

► fimaCHEM

RELEASE – regulatory & site status

- Regulatory and ethics approval in 10 of 11 EU countries + USA and Taiwan
- Opened 4 sites since Q4 2019 report, with 34 of the initially planned 40 sites open by end-April
- Five US sites open – awaiting enrolment of first US patient
- Regulatory and ethics submissions ongoing in South Korea

Q1 HIGHLIGHTS

► fima CHEM

RELEASE – effect of the COVID-19 pandemic

- RELEASE study site activations are impacted
  - Five sites behind original plan
- The majority of open sites have halted or reduced patient screening
  - Patient enrolment delays
  - First US patient may slide over to 2H 2020
- A complete picture of the long-term consequences is not yet available, but delays in patient recruitment and increased costs are expected
- Currently not clear that the cash-position will suffice to reach interim read of the RELEASE trial, given the uncertainty surrounding long-term consequences

Q1 HIGHLIGHTS

► fima CHEM

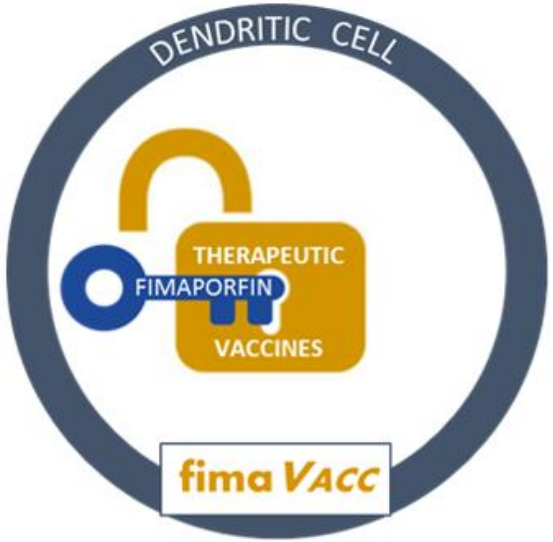
RELEASE – main priorities and new initiatives

- The main priorities for the RELEASE study
  - Identification and implementation of mitigating actions for progress
  - Identification and removal of unnecessary recruitment hurdles
- Exploring initiatives to recoup long-term recruitment projections
  - Potential modifications to screening parameters
  - Expansion into new countries
  - Deployment of field based personnel
- Intention to accelerate patient inclusion when the current restrictions of the COVID-19 pandemic are resolved, with the aim to reach interim analysis by Q2 2022

Q1 HIGHLIGHTS

fima*VACC*

- Two US patents granted in 2020, providing broad coverage for the combination of fima*VACC* with
  - Various cytokines – immune signaling substances
  - Toll-like receptors – a new important class of adjuvants
- Two-pronged development strategy with direct partnering efforts and planning for clinical PoC in disease setting

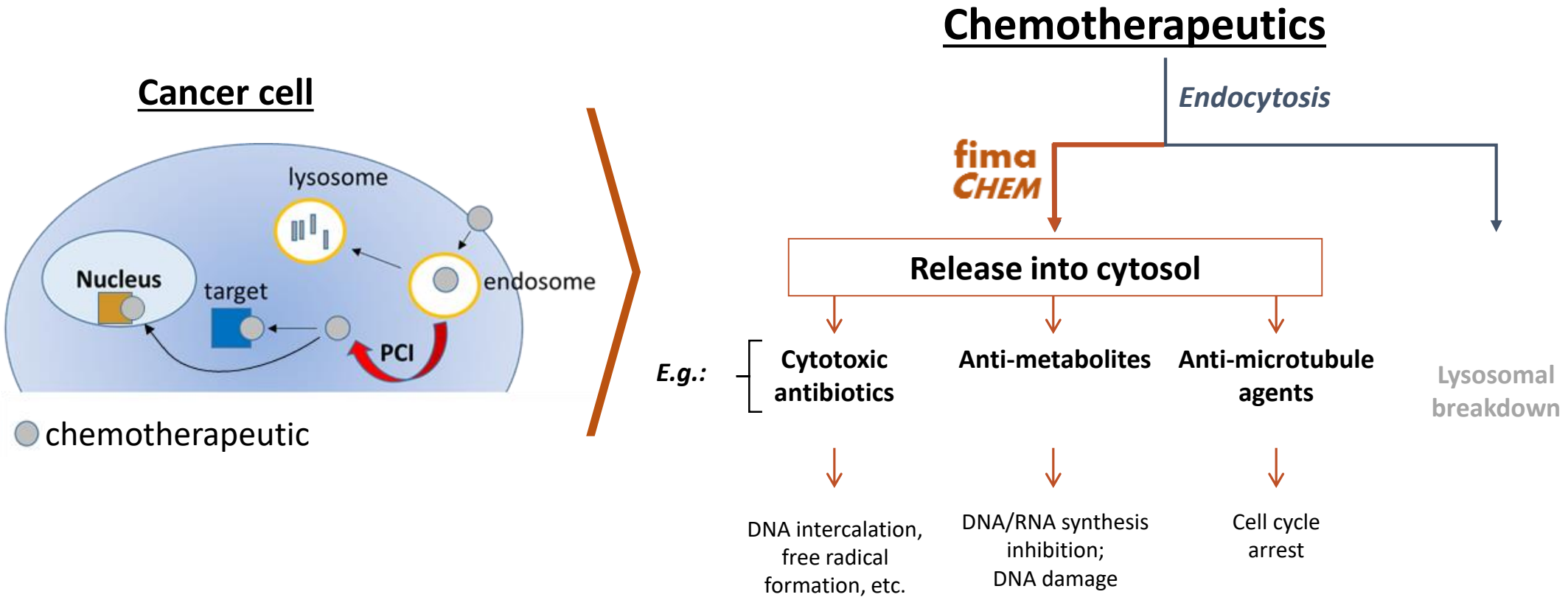


Corporate

- The management team has been strengthened with appointment of CMO Dr Amir Snapir and CBO Mr Ludovic Robin

PCI TECHNOLOGY

▶ fimaCHEM – mode of action



BILE DUCT CANCER – EXTRAHEPATIC INOPERABLE

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

High unmet medical need

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

fimaCHEM advantages

- mOS of **22.8 months** at highest 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

BILE DUCT CANCER – RELEASE STUDY

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

First line treatment for newly diagnosed patients with inoperable extraheptic bile duct cancer +/- liver metastases

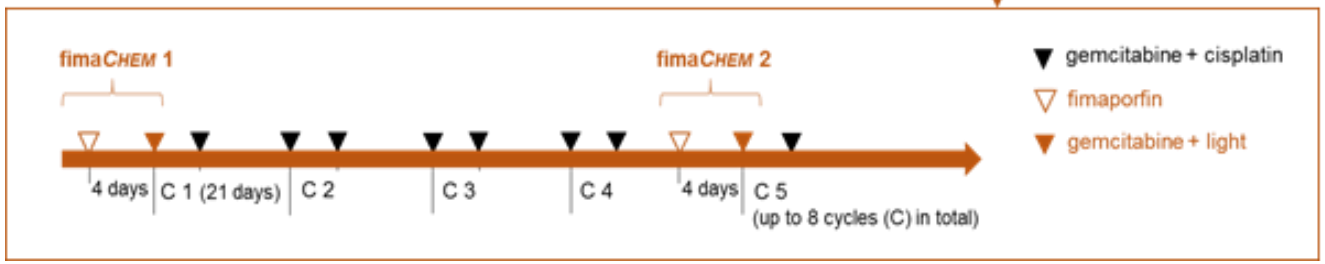
(N=186)
1:1 randomisation

Control (N=93)

Standard of care (SoC):
gemcitabine + cisplatin
up to 8 cycles

Experimental (N=93)

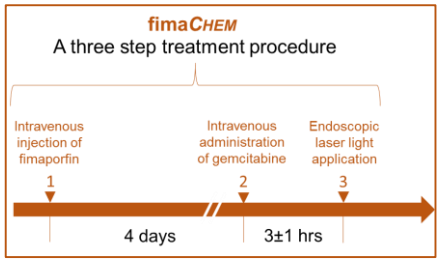
Up to 2 doses of fimaCHEM +
Standard of Care (SoC)
up to 8 cycles



- Rare disease (1-2 cases per 100,000 in EU and US)
- More common disease in Asia
- Limited development pipeline

- Initially planned approx. 40 clinical sites in EU & US
- 11 European countries + USA
- Start-up activities ongoing in Asia (S Korea and Taiwan)

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



Bile Duct Cancer – Release Study

- Pivotal study progress

- Regulatory and ethics received for Taiwan, USA and 10 of 11 planned European countries
- 4 new sites opened since Q4 2019 report: 34 sites open for patient enrolment
- Five sites opened in the US – awaiting first US patient
- Initiatives with the aim to recoup delay when the current restrictions of COVID-19 have resolved
  - Eligibility criteria review
  - Increase number of countries/sites
  - Deployment of field-based personnel
- Site preparations 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: Objective Response Rate (ORR) Secondary endpoint: Progression free survival (PFS)	• 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:

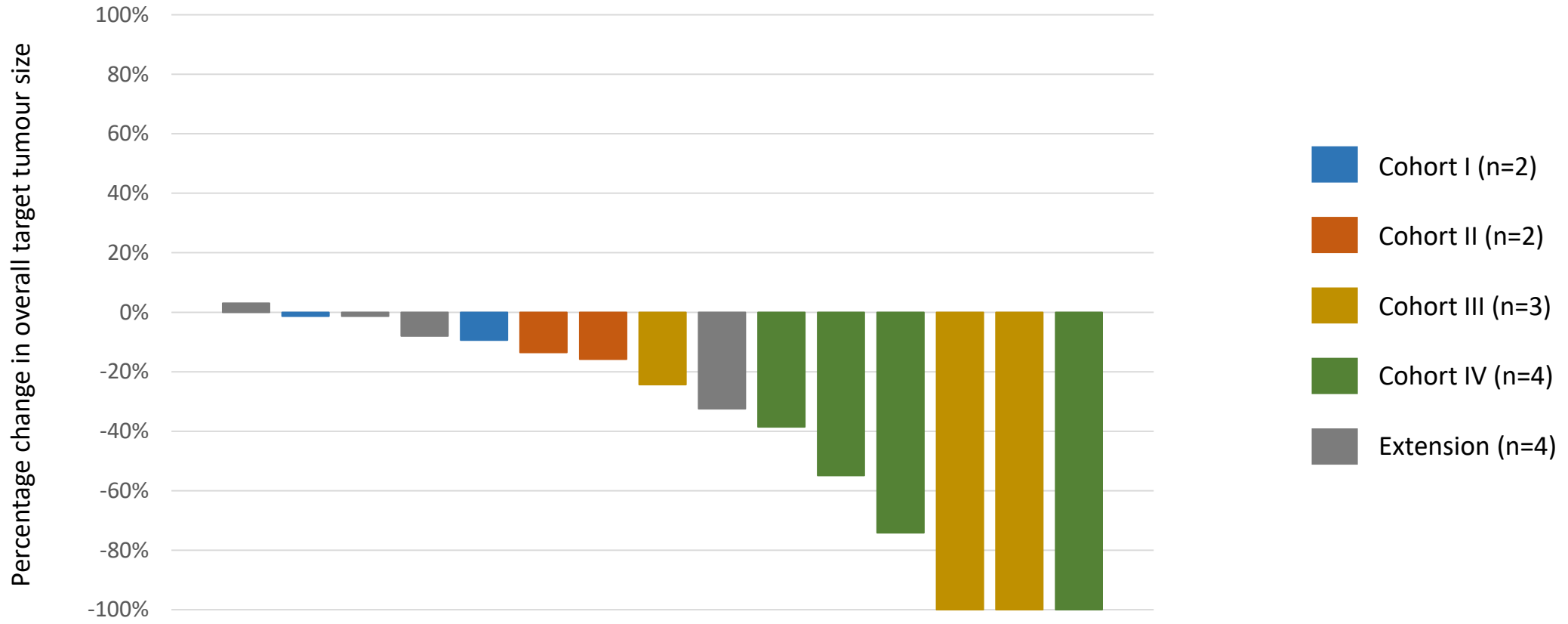
First patient enrolled in Europe in May 2019	• First patients in the US and Asia expected 2H 2020
Seamless safety review by IDMC when 8 patients have undergone two fimaCHEM treatments	• IDMC = Independent Data Monitoring Committee
Objective Response Rate (ORR) when 120 patients have been enrolled	• Interim analysis expected approximately Q2 2022
Timing and format for study conclusion may be impacted by outcome of Interim analysis	• Final analysis expected approximately Q3 2023

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)

(Cohort I, II & Extension: Local read; Cohort III & IV: Central read)



BILE DUCT CANCER – PHASE I DOSE-ESCALATION STUDY

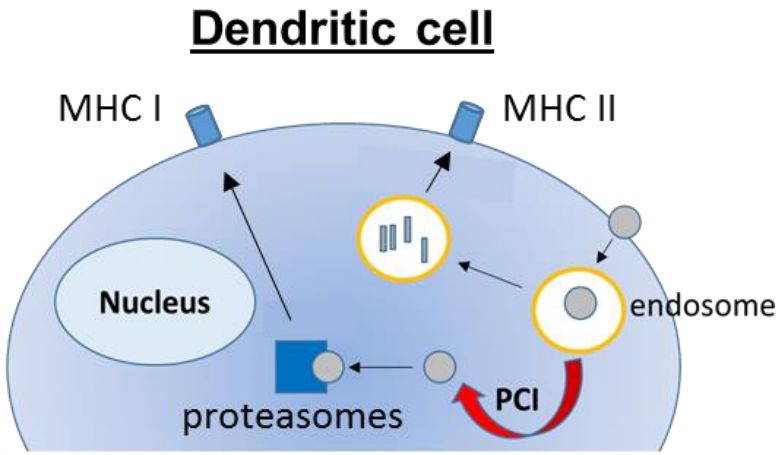
- Positive early signs of efficacy – median Overall Survival of 22.8 months at selected dose

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)	22.8 months	16.1 months

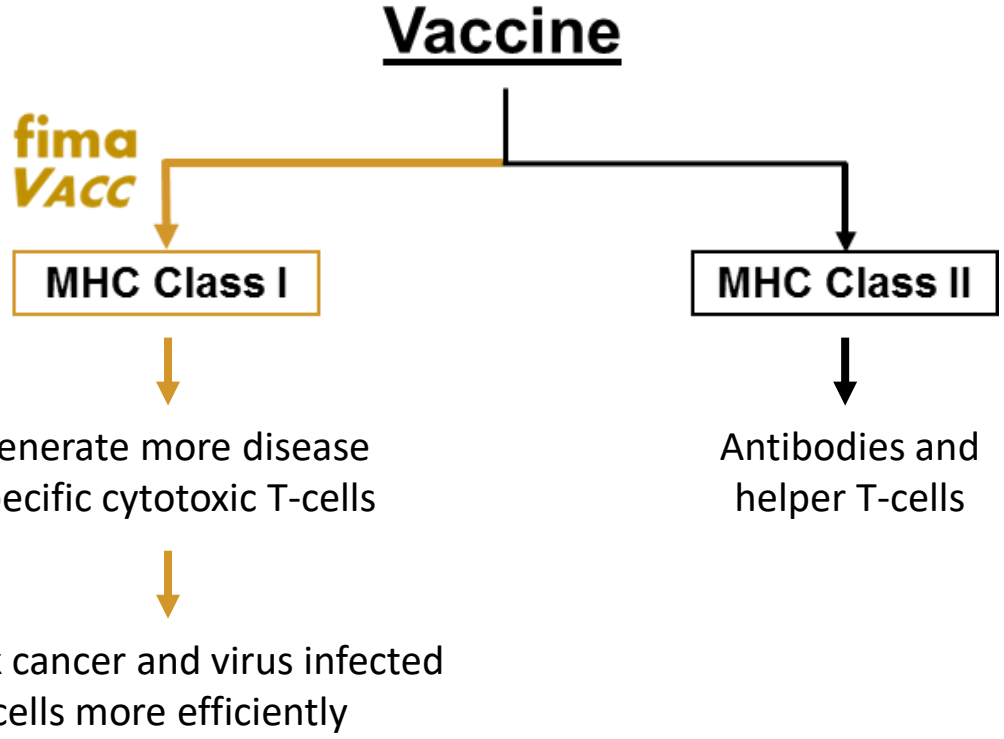
- Study closed and Cohort IV dose selected for the pivotal RELEASE study
- Half of the patients in Cohort IV survived >30 months
- One patient in Cohort IV was still alive at final censoring – more than 4 years survival
- Encouraging Phase I results paved the way for a pivotal trial, with potential for accelerated approval
- Safety of two treatments provided in a Phase I Extension – up to two treatments allowed in RELEASE

PCI TECHNOLOGY

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



Vaccine antigen



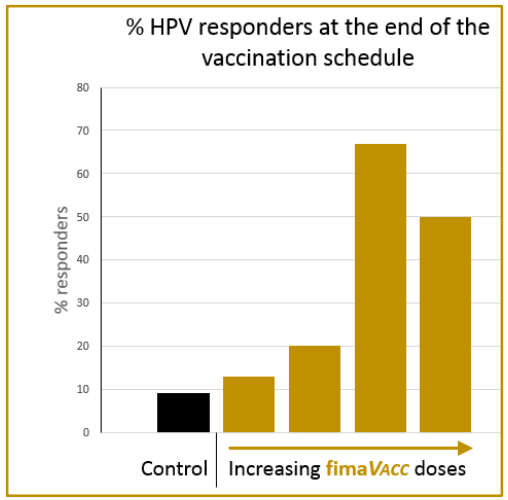
SOLID PROGRESS OF THE fimaVACC PROGRAMME

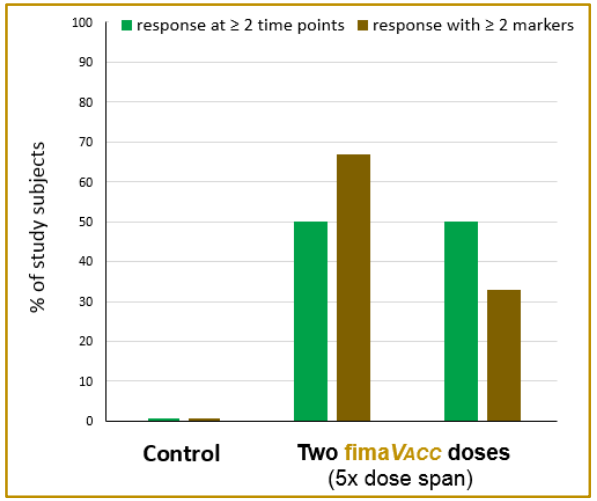
- Successful clinical proof-of-concept and further IP protections

- 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 across a wide dose span
- US patents granted in January 1) and April 2) 2020
  1. Provides broad coverage for the combination of fimaVACC with various cytokines
     - Cytokines are small signalling proteins secreted by immune cells to regulate immunity
     - Used to modulate appropriate and effective vaccine responses
  2. Provides broad coverage for the combination of fimaVACC with toll-like receptor (TLR) agonists
     - TLRs sense pathogen-associated structures as danger signals
     - TLR agonists represent promising vaccine adjuvants

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

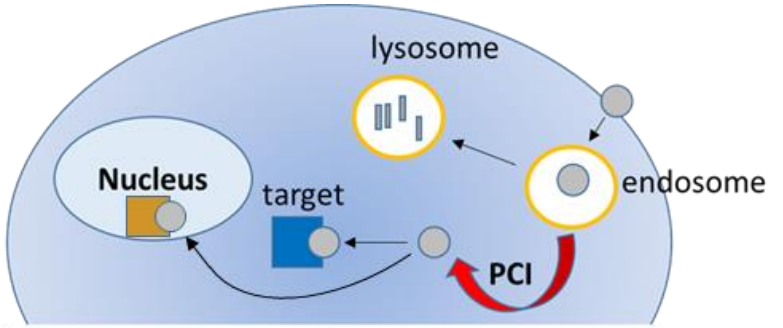
- Study results presented at ESMO Immuno-Oncology Congress in Dec 2019
- Data to be published in scientific journal
- Phase I results being used in direct partnering efforts and plan for clinical proof-of-concept in disease setting

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

- AstraZeneca experimental collaboration to evaluate synergies in several disease areas ended in Dec 2019, with an additional 6 months period for determination of potential next steps

AstraZeneca

IMV IMMUNOVACCINE

BAVARIAN NORDIC

eTheRNA

Phio PHARMACEUTICALS

BIONTECH

CORPORATE

- Strengthened the management team

  - Amir Snapir, MD, PhD, appointed Chief Medical Officer
    - +10 yrs experience in global clinical development of novel therapeutics from early clinical translation to marketing authorization
    - Extensive international regulatory experience
    - Will lead the strategy and execution of all clinical development

  - Ludovic Robin, PharmD, MBA appointed Chief Business Officer
    - +25 yrs business development and marketing & sales experience from pharma and biotech
    - Participated in the launch of >15 original orphan drugs and specialty pharmaceuticals
    - Will lead all business and commercial development activities

FINANCE

- Key financial figures
  - Other income (public grants) slightly impacted by scheme and project modifications
  - Positive exchange rate effects on bank deposits – leads to net positive P&L in the quarter
  - Solid cash position, partly placed in Euro

(figures in NOK 1,000)	Q1 2020	Q1 2019	FY 2019
Other income (public grants)	1 919	2 425	9 392
Operating results	-15 974	-17 929	-88 804
Net financial result	*20 401*	*-4 895*	*58*
Net profit/loss	4 427	-22 824	-88 746

(figures in NOK 1,000)	Q1 2020	Q1 2019	FY 2019
Net change in cash during the period	-22 940	-15 124	-86 574
Exchange rate effect on cash in foreign currency	*19 917*	*-5 445*	*-1 649*
Cash and cash equivalents per 31.12.2019	261 103	349 326	349 326
Cash and cash equivalents per 31.03.2020	**258 080**	**328 757**	**261 103**

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
2H 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	**fimaCHEM** – 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	**fimaVACC** – a clinical stage vaccination technology with encouraging cellular immune responses **fimaNAC** – 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

FOR ENQUIRIES

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