Q2 & 1H 2020 PRESENTATION

August 26, 2020

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PCI BIOTECH

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PCI Biotech – enabling intracellular delivery

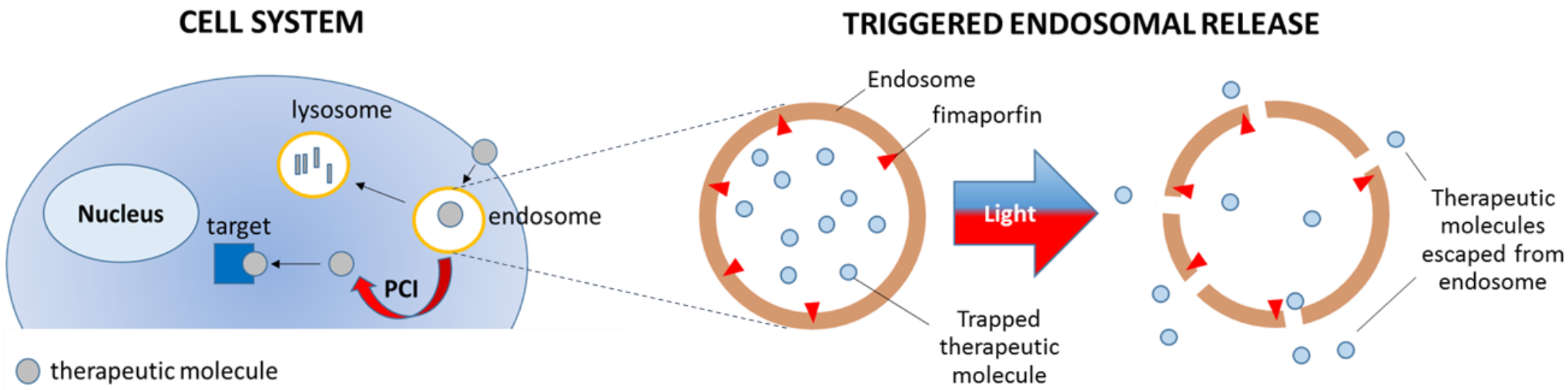
- A biotech company with an oncology focused pipeline

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

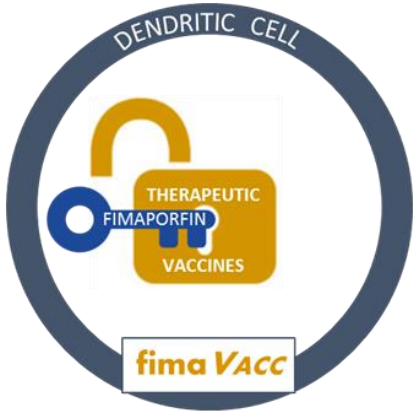


PCI TECHNOLOGY

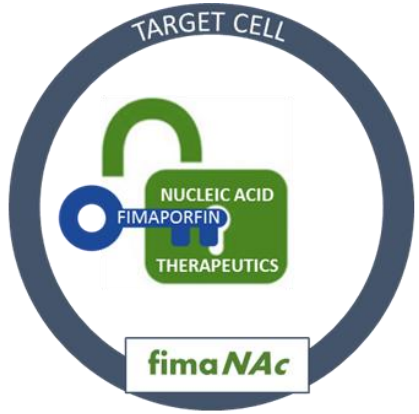
- Enabling drugs to reach intracellular therapeutic targets

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

1H 2020 HIGHLIGHTS

- fimaCHEM

RELEASE – effect of the COVID-19 pandemic

- The main priorities during the COVID-19 pandemic has been identification and implementation of potential mitigating actions for the RELEASE study progress
- Screening into the RELEASE study has been severely affected in the first half of 2020 with only one patient recruited during the pandemic and the study has yet to enrol the first US patient
- The situation is still unclear, and the long-term consequences of the pandemic are uncertain

1H 2020 HIGHLIGHTS

- fimaCHEM

RELEASE – opening of sites in Asia

- Good progress in Asia, with the first 8 RELEASE study sites recently opened
- 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
- A total of 44 sites are open by mid-August 2020 across EU, US and Asia and >50 sites are planned to be included into the study

1H 2020 HIGHLIGHTS

- fimaCHEM

RELEASE – initiatives to recoup delays

- Several new initiatives to recoup long-term recruitment projections are being implemented, with the aim to accelerate patient inclusion when the current constraints on clinical trials inflicted by the COVID-19 pandemic are resolved
- A complete picture of the consequences for the RELEASE study and the effect of the new initiatives are not yet available
- The expected timeline for the planned interim analysis by 1H 2022 is therefore extended to 2H 2022/1H 2023 and the current cash-position may therefore not be sufficient to reach interim read of the RELEASE study

1H 2020 HIGHLIGHTS

- fimaCHEM

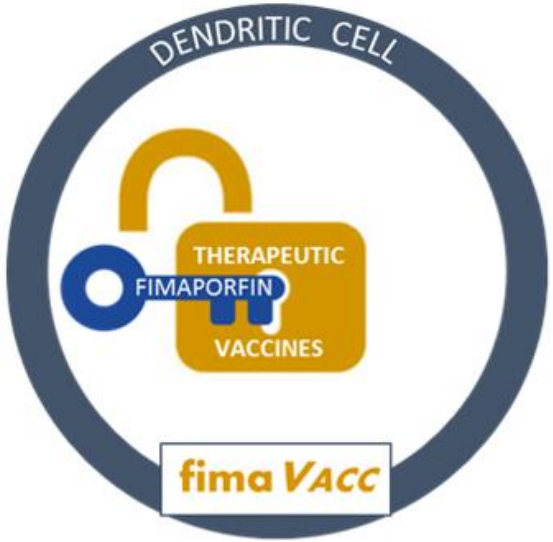
Phase I case report series article accepted for publication

- An article with a case report series from the Phase I study has been accepted for publication in *Endoscopy International Open*, and is soon expected to be available online
- The article provides a detailed description of treatment effects in three select patients at the dose chosen for RELEASE

1H 2020 HIGHLIGHTS

- **fimaVACC**

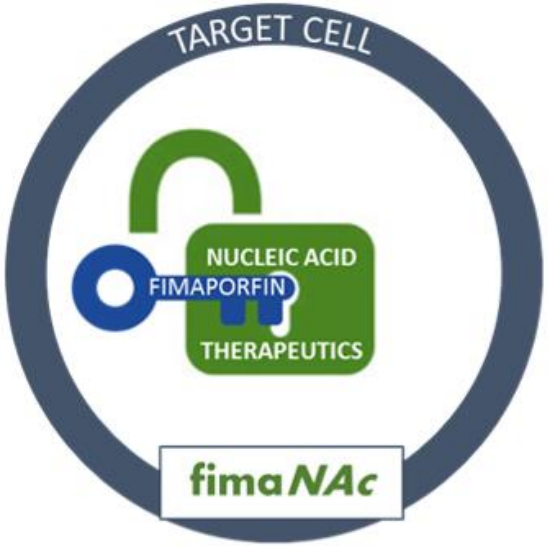
  - Two US patents granted in 1H 2020, providing broad coverage for the combination of **fimaVACC** with
    - Various cytokines – immune signaling substances
    - Toll-like receptors – a new important class of adjuvants



1H 2020 HIGHLIGHTS

- **fimaNAc**

  - The evaluation period under the preclinical research collaboration with AstraZeneca has been extended by 6 months and the evaluation of the potential for a further collaboration now runs to the end of 2020
  - The research collaborations have recently been reviewed for progress and value to PCI Biotech, and prioritised accordingly, resulting in closure of three collaborations

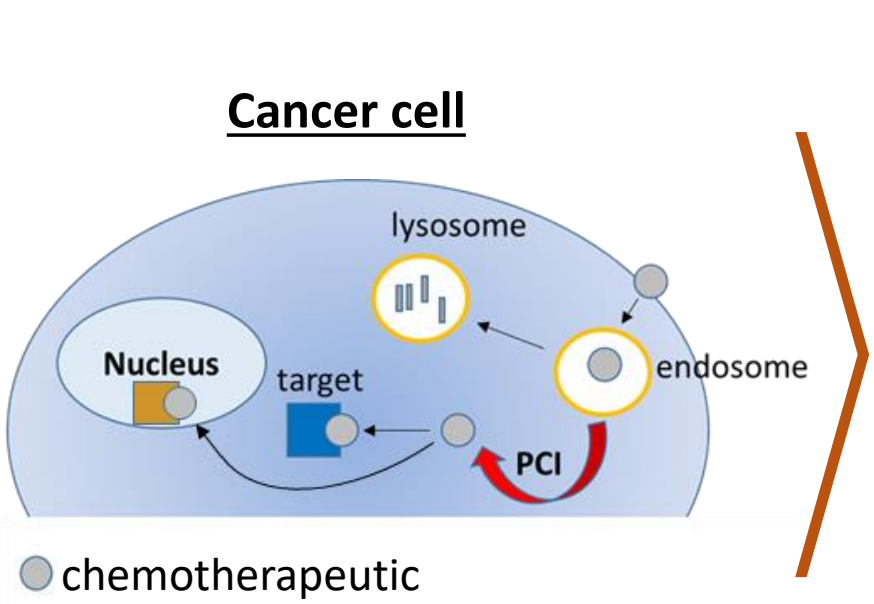


- **Corporate**

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

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

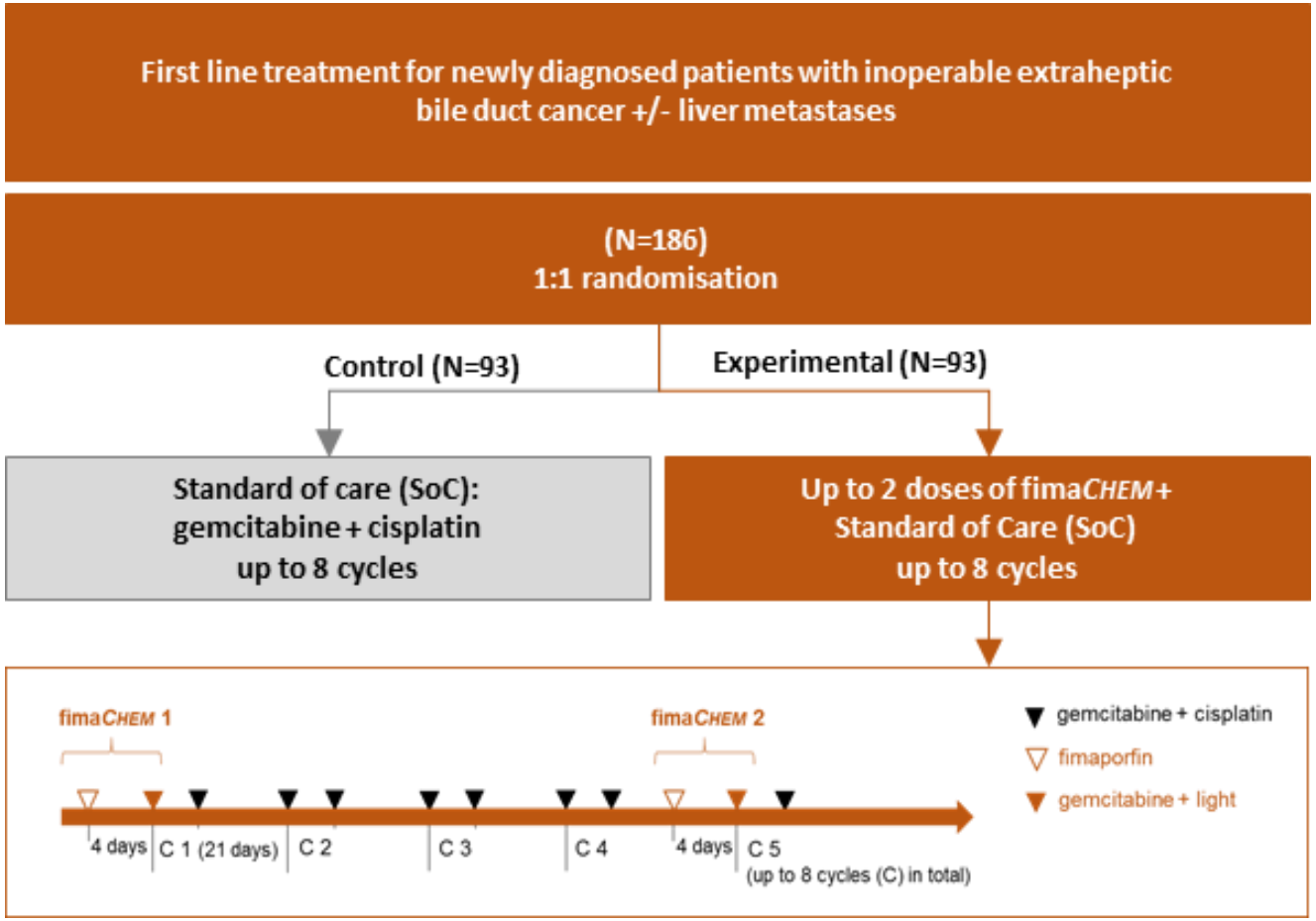
- Excellent fit with medical need and existing treatments

  - **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

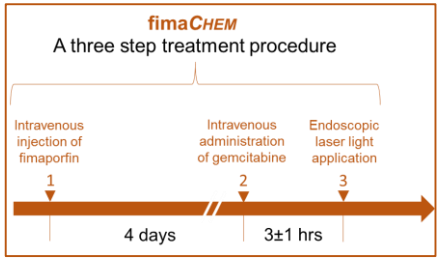
- Pivotal study with potential accelerated/conditional approval on interim analysis



- Rare disease
- More common disease in Asia
- Limited development pipeline

- >50 clinical sites planned
- Across 12 European countries, 2 Asian countries + USA

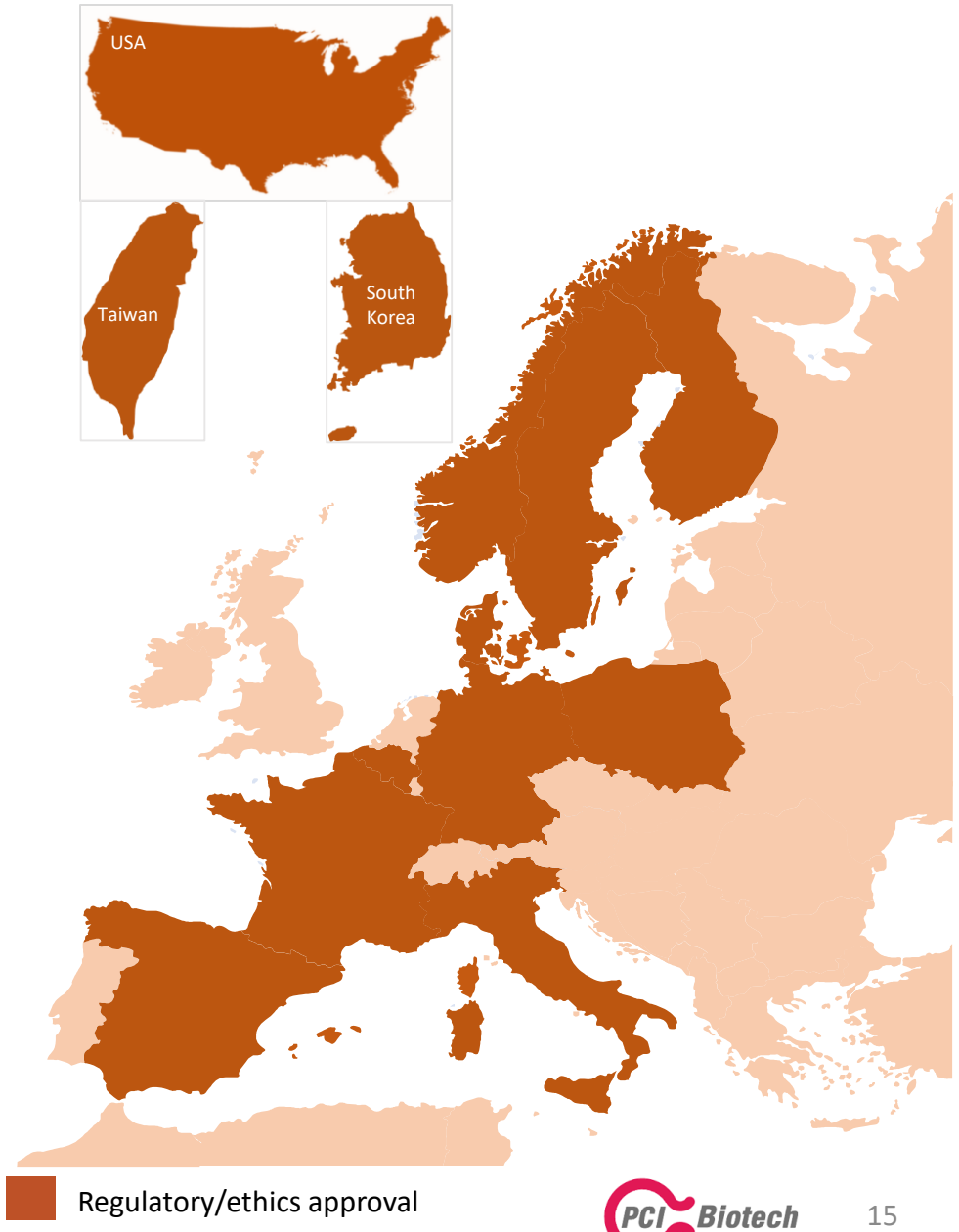
- **fimaCHEM** in addition to current Standard of Care



BILE DUCT CANCER – RELEASE STUDY

- Pivotal study progress

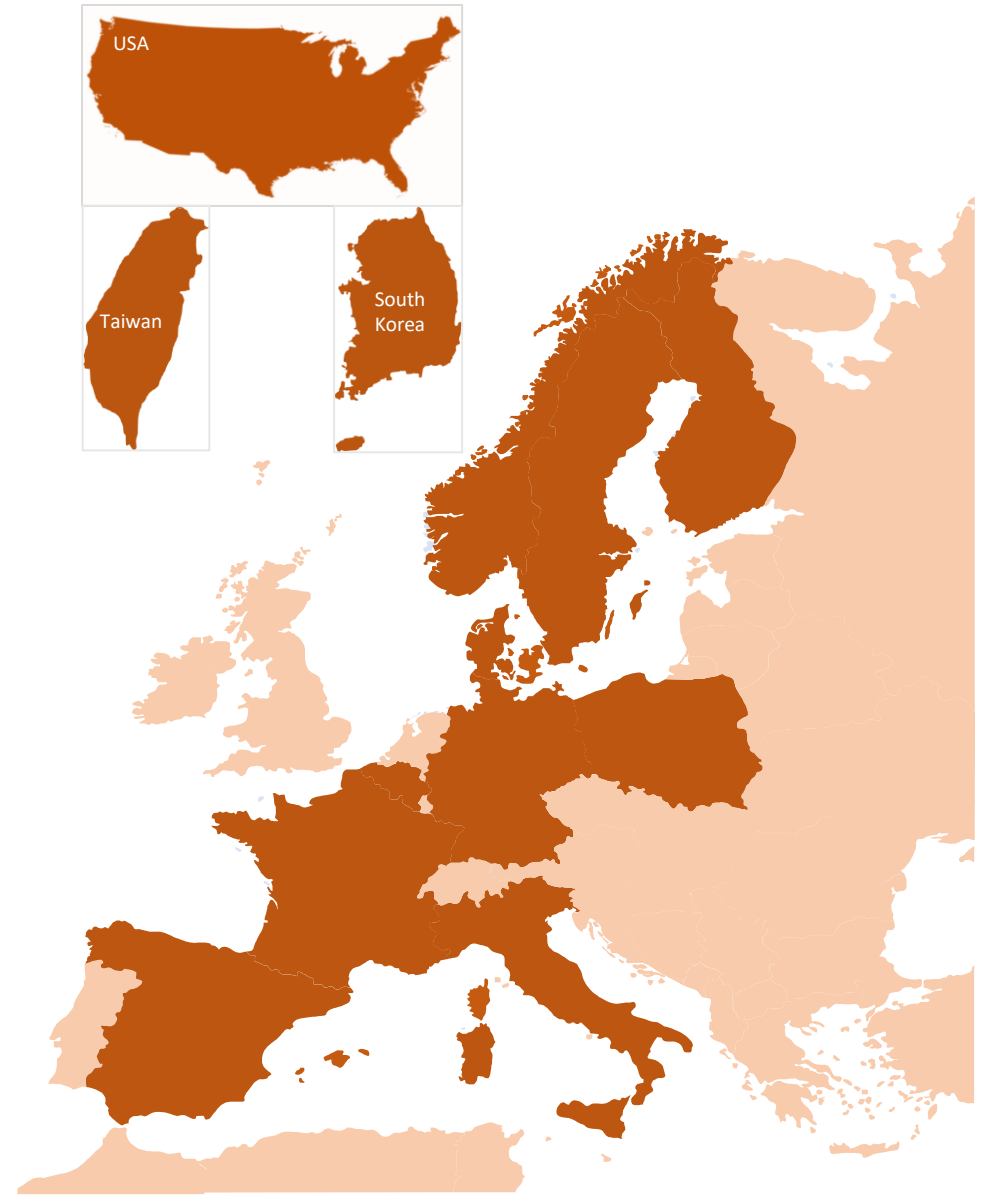
  - Regulatory and ethics received for South Korea, Taiwan, USA and 10 of 12 planned European countries
  - 10 new sites opened since Q1 2020 report: 44 sites open for patient enrolment
  - 8 sites recently opened in Asia – awaiting first Asian patient
  - 6 sites open in the US – awaiting first US patient
  - Initiatives with the aim to recoup delay when the effects of the COVID-19 pandemic have resolved
    - Eligibility criteria modifications
    - Increase number of countries/sites
    - Deployment of field-based personnel
    - Online outreach to attract patients outside hospital networks



Bile Duct Cancer – Release Study

- Pivotal study progress

  - Screening in the RELEASE study has been severely affected by the COVID-19 outbreak, with only one patient recruited during the pandemic
  - The negative effect on enrolment into the RELEASE study is probably due to several factors
    - The **fimaCHEM** treatment procedure involves hospital resources that may be under pressure during the pandemic
    - Bile duct cancer is a rare disease with few patients per site, so patient inclusion into RELEASE is not an 'established routine'
    - The study is primarily performed at tertiary centres, which may be heavily burdened by COVID-19
    - Treatment at tertiary centres often require patient travel, which is challenging during the pandemic
  - The company is working hard to mitigate these effects wherever possible
  - The situation is still unclear, and the long-term consequences of the pandemic are uncertain



fimaCHEM

- Expanding RELEASE to Asia – recruitment enhancement with a market upside

  - The expansion to Asia is done to enhance patient recruitment and provide access to hospitals and key opinion leaders in this region with higher prevalence of bile duct cancer
  - This may also open up the potential Asian business upside – initially the trial has opened in South-Korea and Taiwan, and other commercially interesting countries are considered to be Japan, Hong Kong and China
  - The Asian market is known to be fragmented and PCI Biotech do not foresee to commercialise **fimaCHEM** for bile duct cancer in Asia without a partner
  - A projection of inoperable patients based on the estimated inoperable portion from the Western world (approx. 75%) and an initial estimate of the accessible market in China, suggest a commercially interesting Asian market of more than 4,000 patients (preliminary estimate based on publicly available information[1])

1) Translational Gastrointestinal Cancer, 2012

BILE DUCT CANCER – RELEASE STUDY

- Endpoints, milestones and timelines

Endpoints:

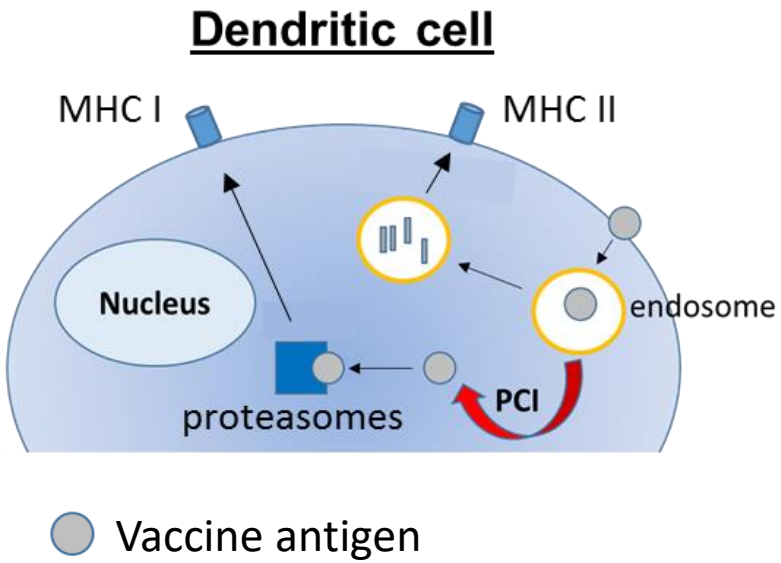
Interim analysis: Primary Endpoint: Objective Response Rate (ORR) Secondary endpoint: Overall Survival (OS)	• Orphan drug designation in EU & USA – potential accelerated approval
Final analysis: Primary endpoint: Progression Free Survival (PFS) Secondary endpoint: Overall Survival (OS)	• Single randomised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

Milestones and timelines:

First 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 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

SOLID PROGRESS OF THE fima*VACC* PROGRAMME

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

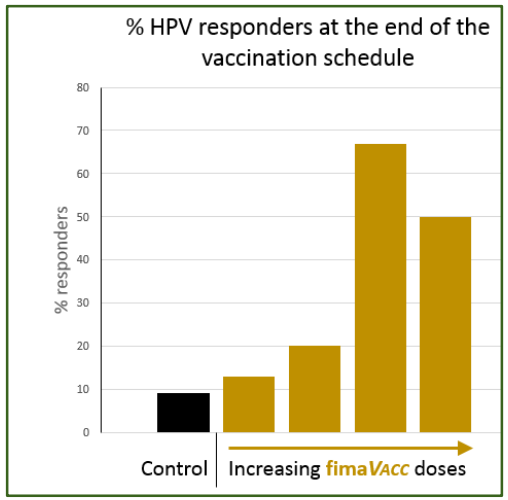
- Phase I study provided successful clinical proof-of-concept for **fima*VACC***
  - Overall objective to determine the safety, tolerability and immune response of fima*VACC*
  - Proof of concept and efficacy in terms of intradermal dosing in humans achieved

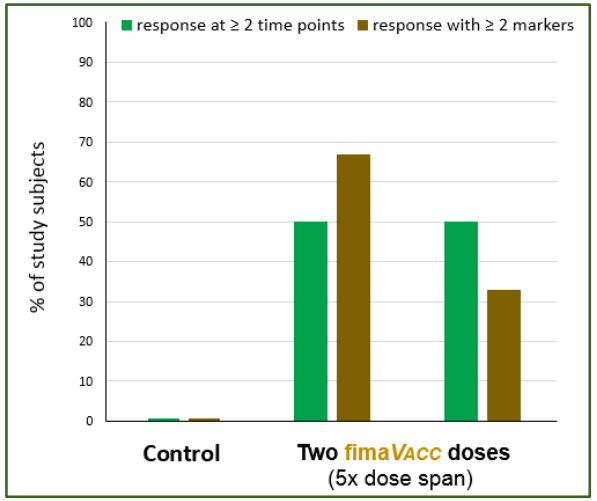
- Two important US patents granted in first half 2020

1. Provides broad coverage for the combination of fima*VACC* 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 fima*VACC* 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

- Growing robust evidence

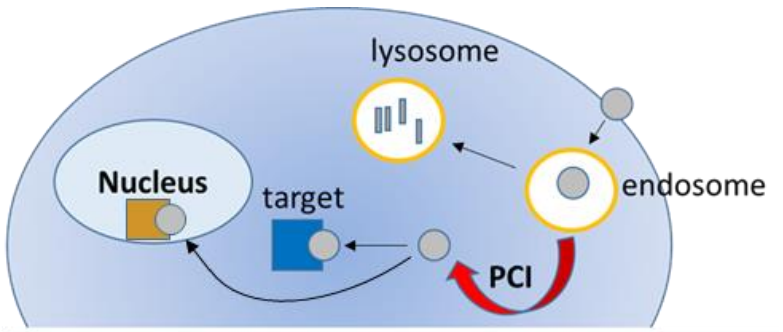
  - Positive clinical study results presented at ESMO Immuno-Oncology Congress in December 2019
  - Publication in process in scientific journal
  - Next step: moving to Phase II with a partner or by ourselves (proof-of-concept in a disease setting)

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

- Collaborations with key players in nucleic acid therapeutics

fimaNAc

- The AstraZeneca experimental collaboration ended in December 2019, and the subsequent 6 months evaluation period has been extended until end of 2020
- The value and progress of all collaborations have been evaluated, and three of these (Phio Pharmaceuticals, Bavarian Nordic and BioNTech) have been closed
- The Israeli company Aposense has been provided with the technology for synergy testing with their molecular nano-motors
- PCI Biotech continues to pursue new and value-adding collaborative opportunities for the **fimaNAc** programme

AstraZeneca

eTheRNA

IMV IMMUNOVACCINE

APOSENSE

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
  - Solid cash position, partly placed in Euro
  - Fluctuations in exchange rate effects on bank deposits

(figures in NOK 1,000)	Q2 2020	Q2 2019	1H 2020	1H 2019	FY 2019
Other income (public grants)	1 919	2 425	3 838	4 850	9 392
Operating results	-22 252	-27 050	-38 226	-44 979	-88 804
Net financial result	*-6 745*	*806*	*13 656*	*-4 089*	*58*
Net profit/loss	-28 997	-26 245	-24 570	-49 068	-88 746

(figures in NOK 1,000)	Q2 2020	Q2 2019	1H 2020	1H 2019	FY 2019
Net change in cash during the period	-19 518	-27 732	-42 458	-42 855	-86 574
Exchange rate effect on cash in foreign currency	*-7 191*	*595*	*12 726*	*-4 850*	*-1 649*
Cash and cash equivalents	231 370	301 621	231 370	301 621	349 326

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 site opened in RELEASE
2H 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	**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

FOR ENQUIRIES

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