Q4 & interim Full Year 2019 PRESENTATION

February 26, 2020

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PCI Biotech

PCI BIOTECH

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PCI Biotech – unlocking the potential of innovative medicines

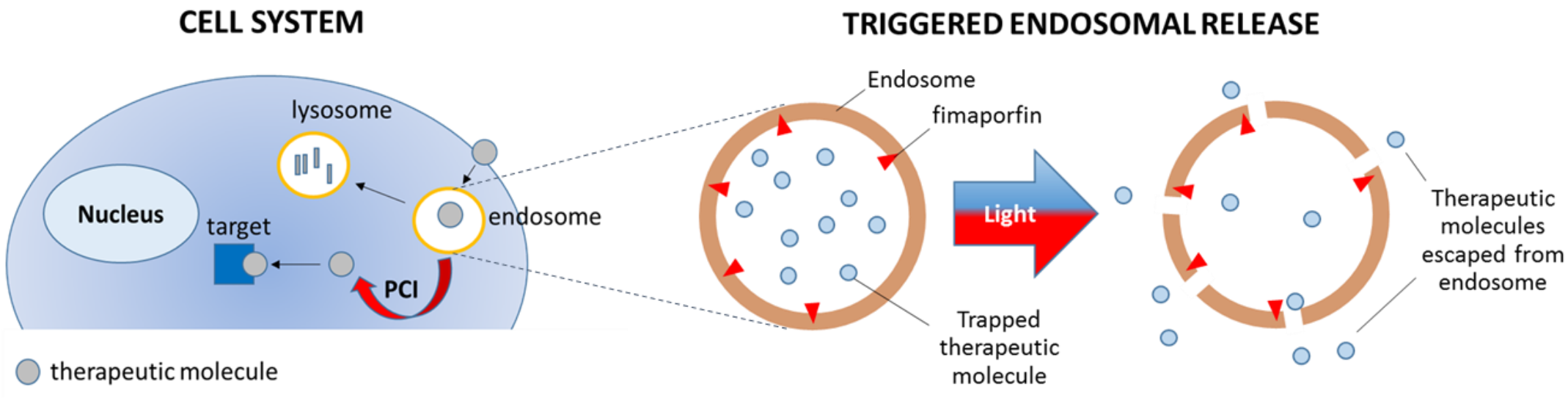
An oncology company with three well differentiated assets

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

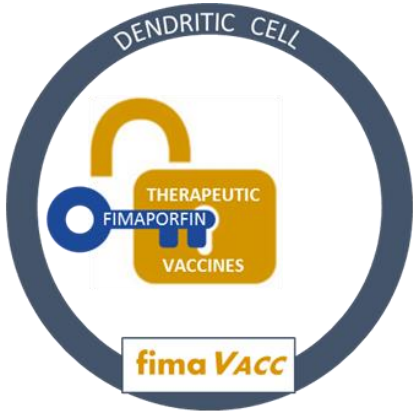


PCI TECHNOLOGY

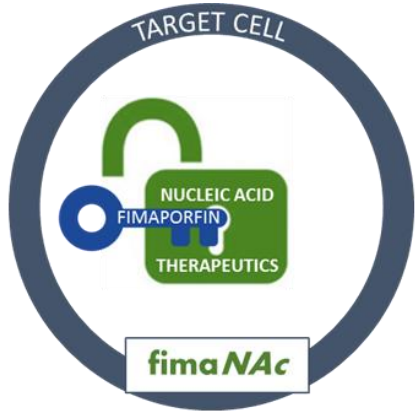
- Enabling drugs to reach intracellular therapeutic targets

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

Q4 HIGHLIGHTS

► fimaCHEM

Phase I results quality checked and finally confirmed

- Encouraging median overall survival (mOS)
- Phase I results:
  - Full study: mOS = 16.1 months
  - Cohort IV: mOS = 22.8 months
  - Extension: mOS = 16.6 months
- Early clinical data in a limited heterogeneous patient population, but consistently encouraging compared to best comparable published data, which has a mOS of less than 12 months

Q4 HIGHLIGHTS

► fimaCHEM

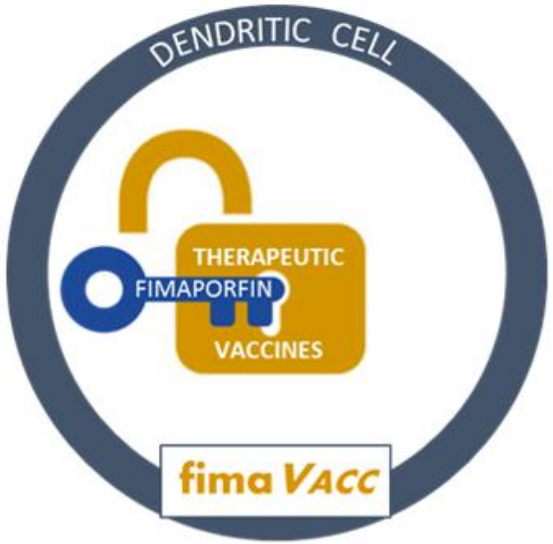
RELEASE – site & enrolment status

- Regulatory and ethics approval in 10 of 11 EU countries + USA
- Opened 7 sites since Q3 report, with 30 of the initially planned 40 sites open by mid-February – 8 sites behind schedule
- Two US sites opened – awaiting enrolment of first US patient
- Patient recruitment and projections are behind schedule – new recruitment initiatives are being implemented to recoup long-term recruitment projections
- Regulatory submissions and contract negotiations ongoing in Asia
- The interim analysis primary endpoint will be modified to objective response rate (ORR) following a post-IND recommendation by the FDA

Q4 HIGHLIGHTS

▶ fima*VACC*

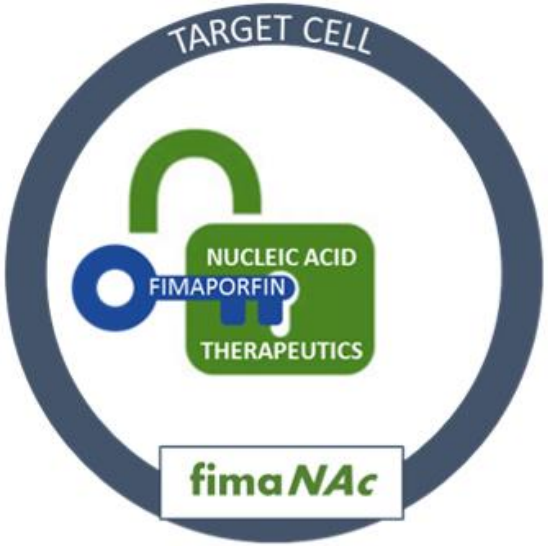
- Clinical proof-of-concept results of enhanced immune responses in healthy volunteers presented at the ESMO Immuno-Oncology Congress in December 2019
- US patent granted in January 2020 with broad coverage for the combination of fima*VACC* with various cytokines
- Two-pronged development strategy with direct partnering efforts and planning for clinical PoC in disease setting



Q4 HIGHLIGHTS

▶ fimaNAc

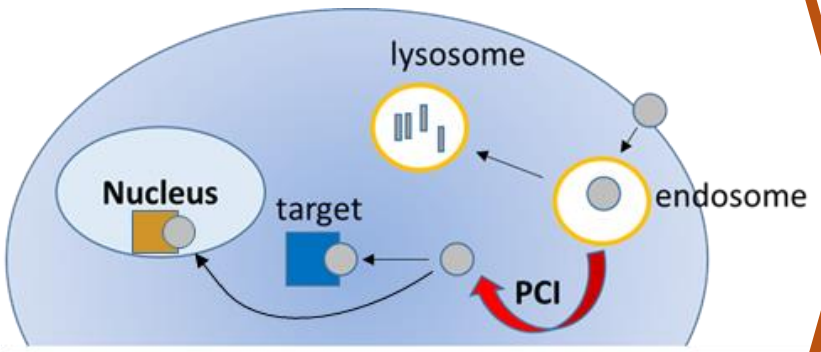
- Expanded the scope of the AstraZeneca research collaboration to evaluate if synergies in oncology are transferrable to other disease areas
- Further potential partnership to be evaluated during 1H 2020



PCI TECHNOLOGY

▶ fimaCHEM – mode of action

Cancer cell



chemotherapeutic

Chemotherapeutics

Endocytosis

fima CHEM

Release into cytosol

E.g.:

Cytotoxic antibiotics	Anti-metabolites	Anti-microtubule agents
DNA intercalation, free radical formation, etc.	DNA/RNA synthesis inhibition; DNA damage	Cell cycle arrest

Lysosomal breakdown

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 **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
[2] Median overall survival

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

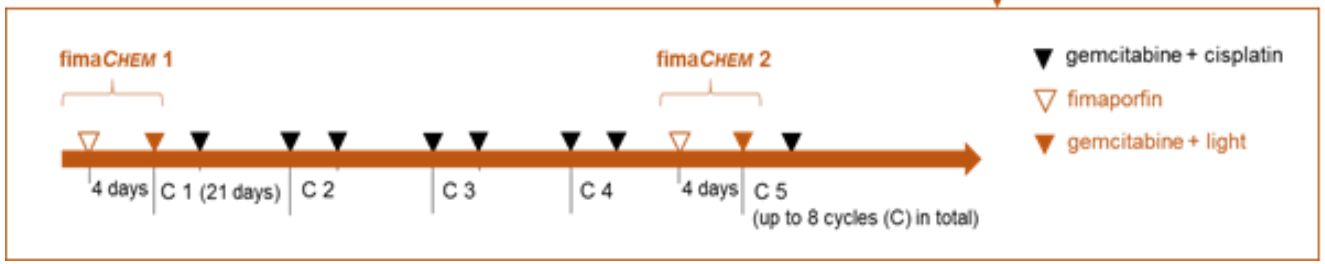
(N=186)
1:1 randomisation

Control (N=93)

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

Experimental (N=93)

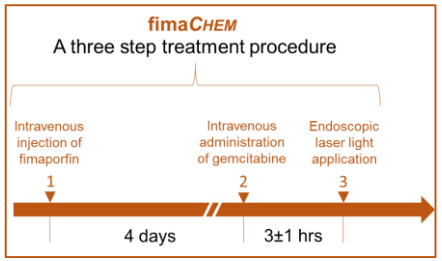
Up to 2 doses of fimaCHEM +
Standard of Care (SoC)
up to 8 cycles



- 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)

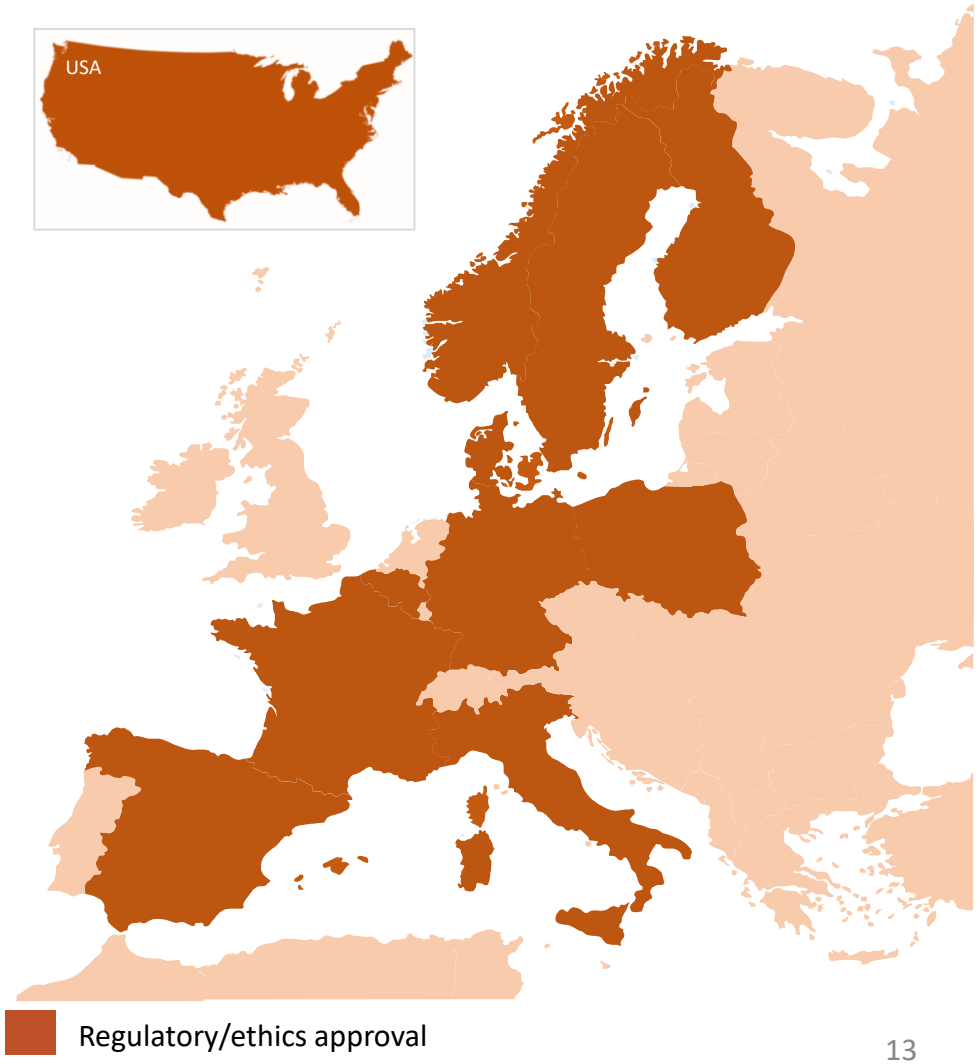
- **fimaCHEM** in addition to current Standard of Care



Bile Duct Cancer – Release Study

- Pivotal study progress

- Regulatory and ethics received for USA and 10 of 11 planned European countries
- 7 new sites opened since Q3 report: 30 sites open for patient enrolment (8 behind original plan)
- Two sites opened in the US – awaiting first US patient
- Several initiatives to recoup current lag in opening of sites and enrolment projections
  - Increase number of sites
  - Deployment of field-based personnel
  - Eligibility criteria review
- 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: Progression free survival (PFS) Secondary endpoint: Objective Response Rate (ORR)	• Orphan drug designation in EU & USA – potential accelerated approval • Primary EP will be changed to ORR
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:

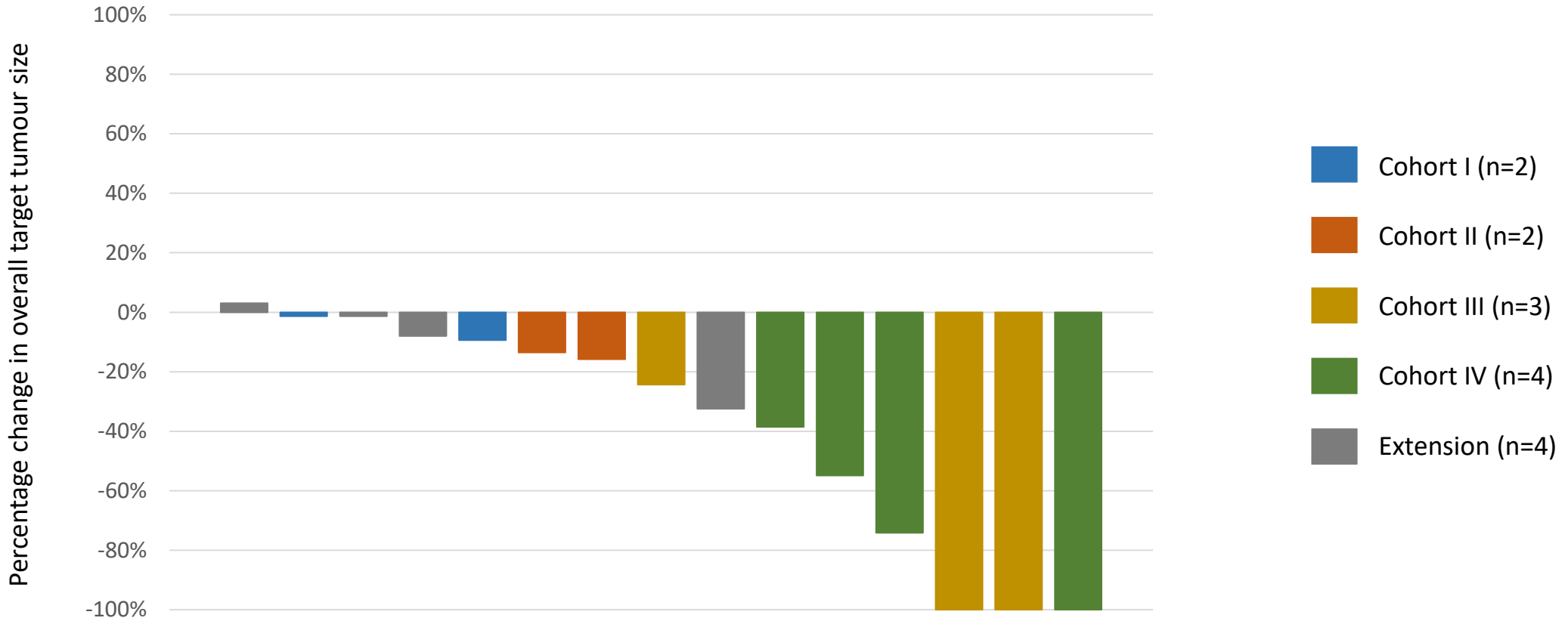
First patient enrolled in Europe in May 2019	• First patient in the US expected in 1H 2020 and Asia 2H 2020
Seamless safety review by IDMC when 8 patients have undergone two fimaCHEM treatments	• IDMC = Independent Data Monitoring Committee
Event driven interim analysis after 60 progression free survival (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)

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



BILE DUCT CANCER – PHASE I DOSE-ESCALATION STUDY

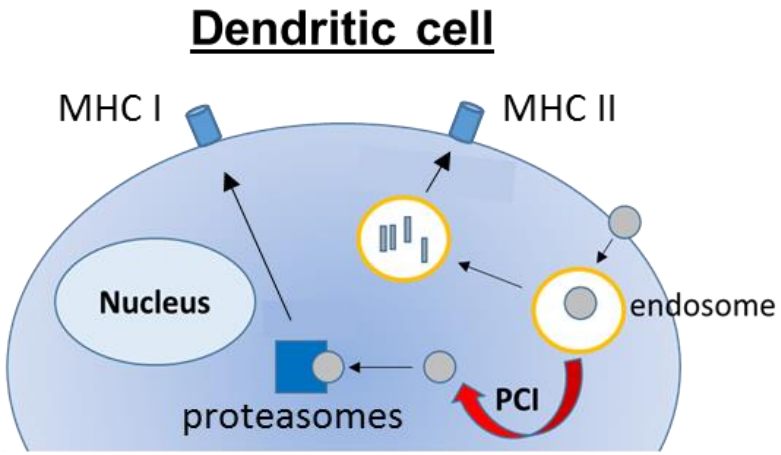
- Positive early signs of efficacy – median Overall Survival of 22.8 months at selected dose

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

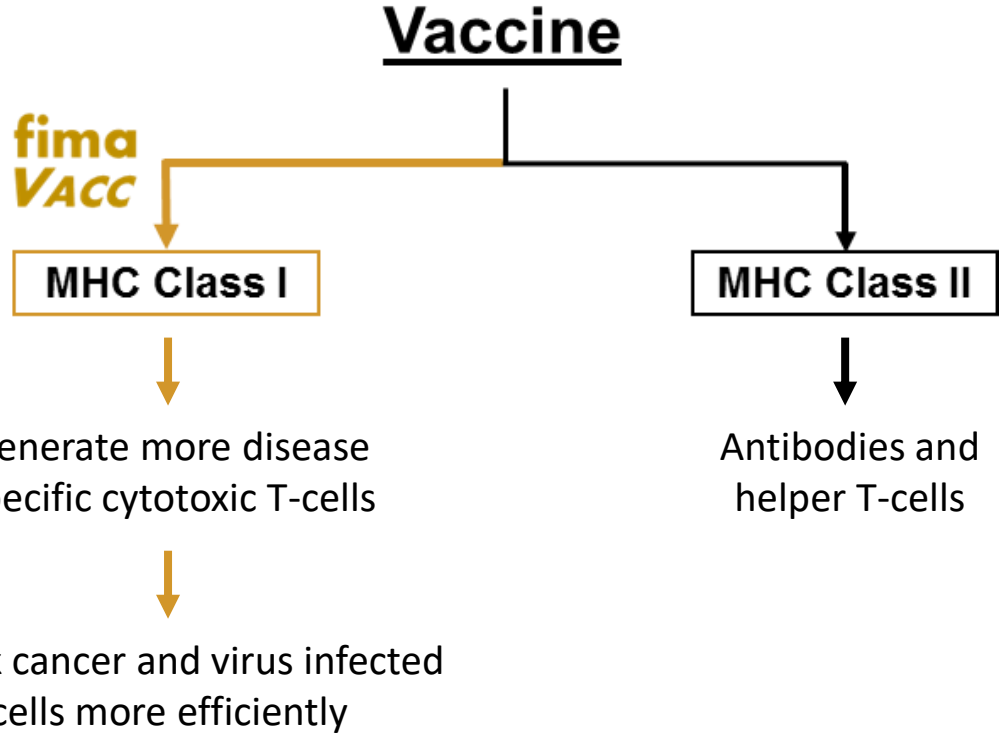
- Cohort IV dose has been selected for the pivotal RELEASE study
- Half of the patients in Cohort IV survived >30 months
- One patient in Cohort IV still alive by mid-November, which is more than 4 years survival
- Final follow-up reached and study closed – no further updates
- Encouraging Phase I results paved the way for a pivotal trial, with interim analysis
- 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



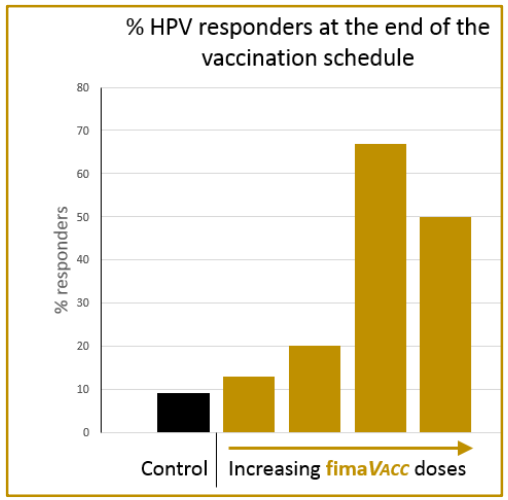
SOLID PROGRESS OF THE fimaVACC PROGRAMME IN 2019

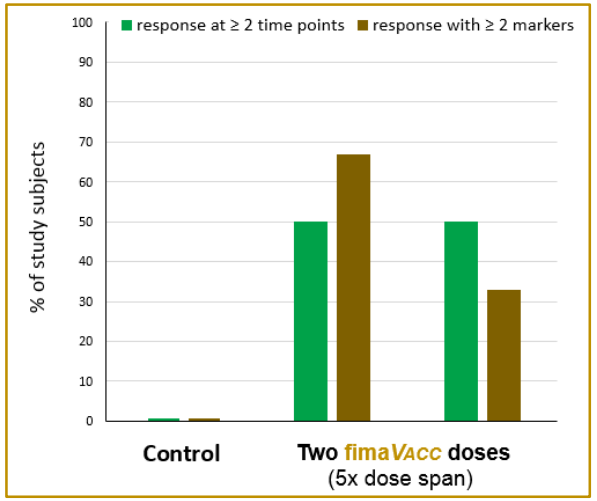
- Successful clinical proof-of-concept and further IP protections

- 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 patent granted in January 2020
  - 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

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

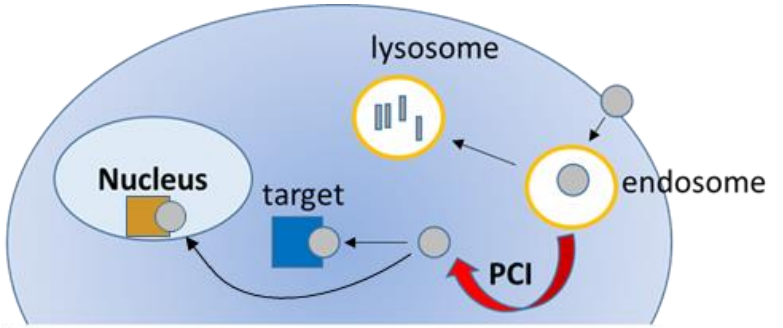
- Study results presented at ESMO Immuno-Oncology Congress in Dec 2019
- Data to be published in scientific journal
- Phase I results being used in direct partnering efforts and plan for clinical proof-of-concept in disease setting

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

fima NAc

Endocytosis

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 collaboration scope was expanded to evaluate whether synergies in oncology could be transferred to other disease areas – with an additional 6 months period for determination of potential next steps

AstraZeneca

IMV IMMUNOVACCINE

BAVARIAN NORDIC

eTheRNA

Phio PHARMACEUTICALS

BIONTECH

FINANCE

- Key financial figures

- Other income (public grants) in line with previous year
- Operating result impacted by start-up activities and initiation of the RELEASE study

(figures in NOK 1,000)	Q4 2019	Q4 2018	FY 2019	FY 2018
Other income (public grants)	2 097	2 972	9 372	9 585
Operating results	-25 350	-14 278	-88 824	-44 519

(figures in NOK 1,000)	Q4 2019	Q4 2018	FY 2019	FY 2018
Net change cash and cash equivalents*	-23 229	328 790	-88 222	298 537
Cash and cash equivalents	261 103	349 326	261 103	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

FOR ENQUIRIES

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