Pareto Securities' Healthcare Conference 2020

September 3, 2020

Per Walday, CEO
Ronny Skuggedal, CFO

PCI BIOTECH

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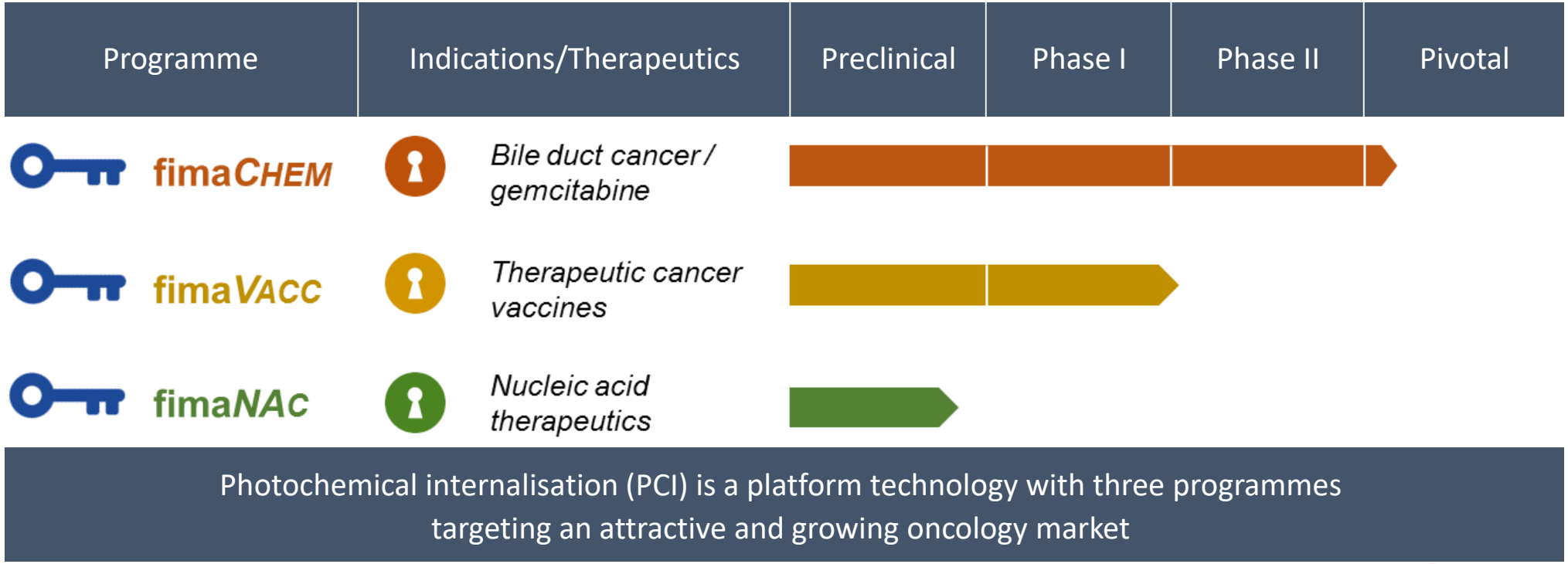
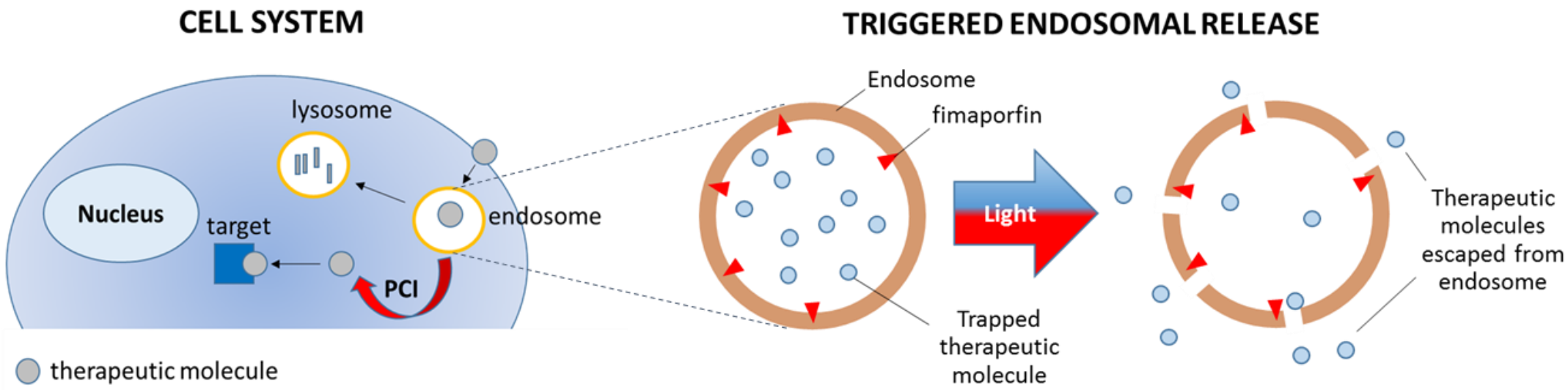
PCI Biotech – enabling intracellular delivery

- A biotech company with an oncology focused pipeline
  - A listed (PCIB:NO) cancer-focused biotech company
  - Solid cash position (approx. 230mill NOK), partly placed in Euro
  - Photochemical internalisation ("PCI") technology
  - One platform technology with three well differentiated assets



PCI TECHNOLOGY – MODE OF ACTION

- Enabling drugs to reach intracellular therapeutic targets



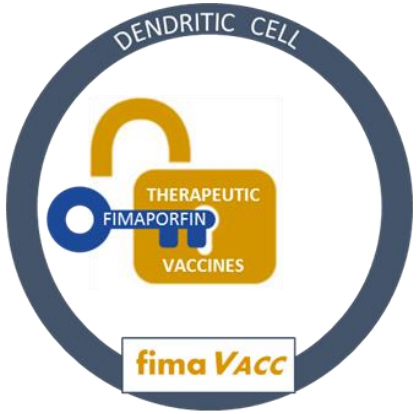
- Small molecules (chemotherapeutics – **fima CHEM**)
- Antigens (peptides/proteins – **fima VACC**)
- Nucleic acids (mRNA, RNAi – **fima NAC**)

PCI TECHNOLOGY

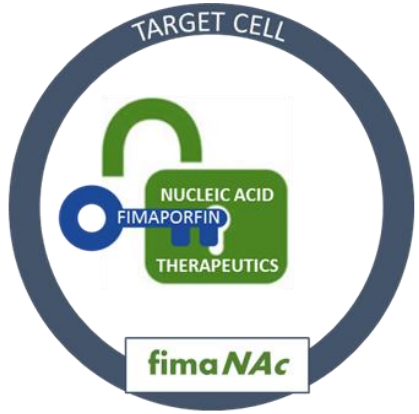
- Enabling drugs to reach intracellular therapeutic targets

PCI – the solution to a key challenge for several modalities

Enabling approved drugs to fulfil unmet local treatment need



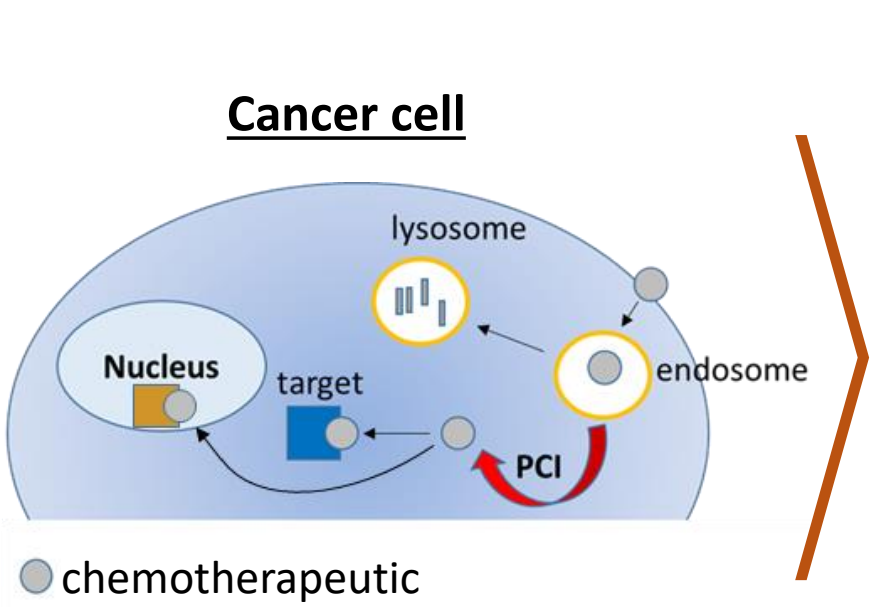
Enhancing cellular immune responses important for therapeutic effect



Providing a delivery solution for nucleic acid therapeutics

PCI TECHNOLOGY

- **fima CHEM** – mode of action



Chemotherapeutics

fima CHEM

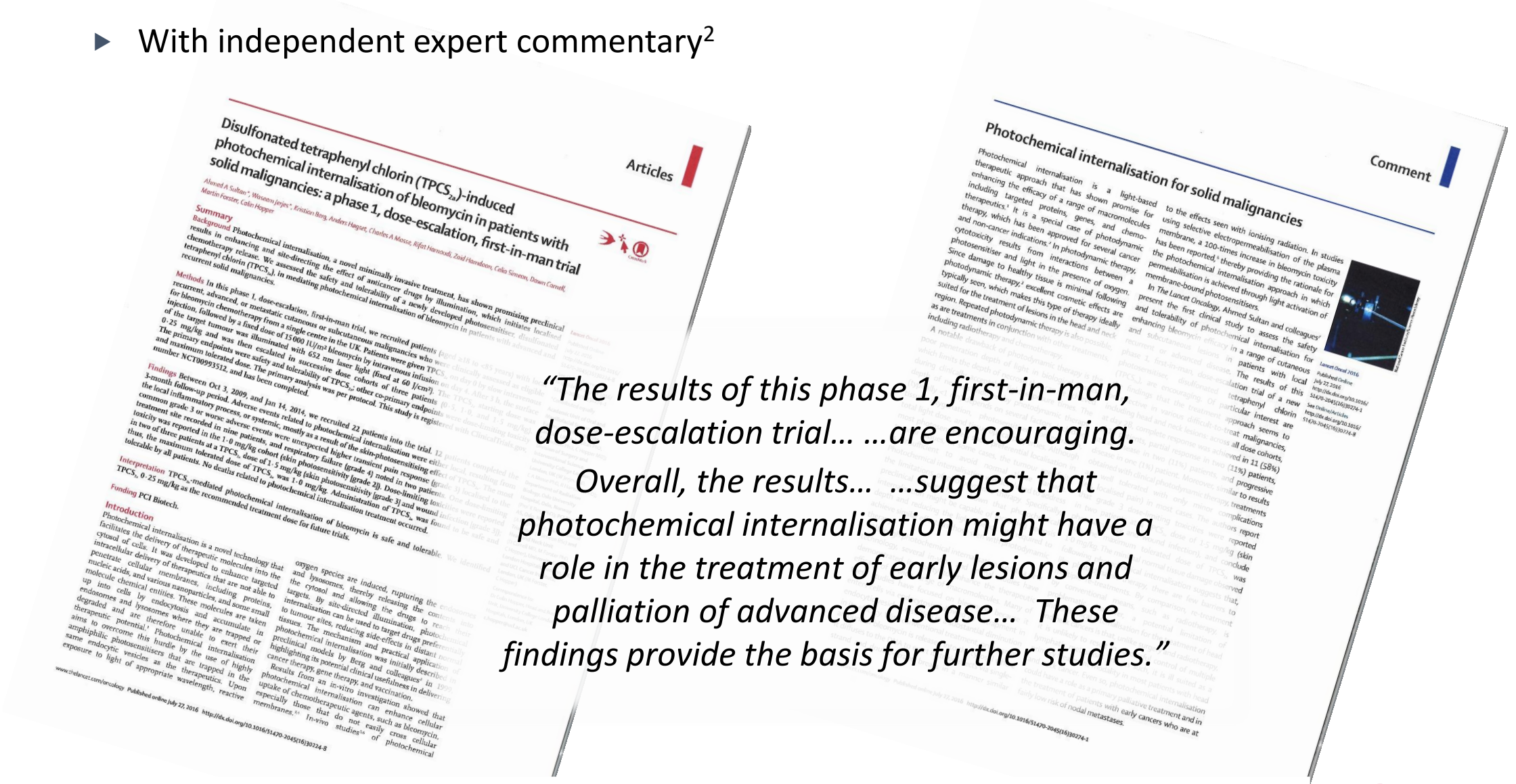
Endocytosis

Release of the trapped chemotherapeutic into the cytosol, thereby enabling it to reach its target and induce the intended therapeutic effect

Lysosomal breakdown

First-In-Man Study Published in Lancet Oncology[1]

- With independent expert commentary[2]



Articles

Disulfonated tetraphenyl chlorin ($TPCS_{2a}$)-induced photochemical internalisation of bleomycin in patients with solid malignancies: a phase 1, dose-escalation, first-in-man trial

Ahmed A Sultan*, Wassesen Jerjes*, Kristian Berg, Anders Hagget, Charles A Mosse, Rifat Hamoudi, Zaid Hamdoon, Celia Simeon, Dawn Carnell, Martin Forster, Colin Hopper

Summary

Photochemical internalisation for solid malignancies

Comment

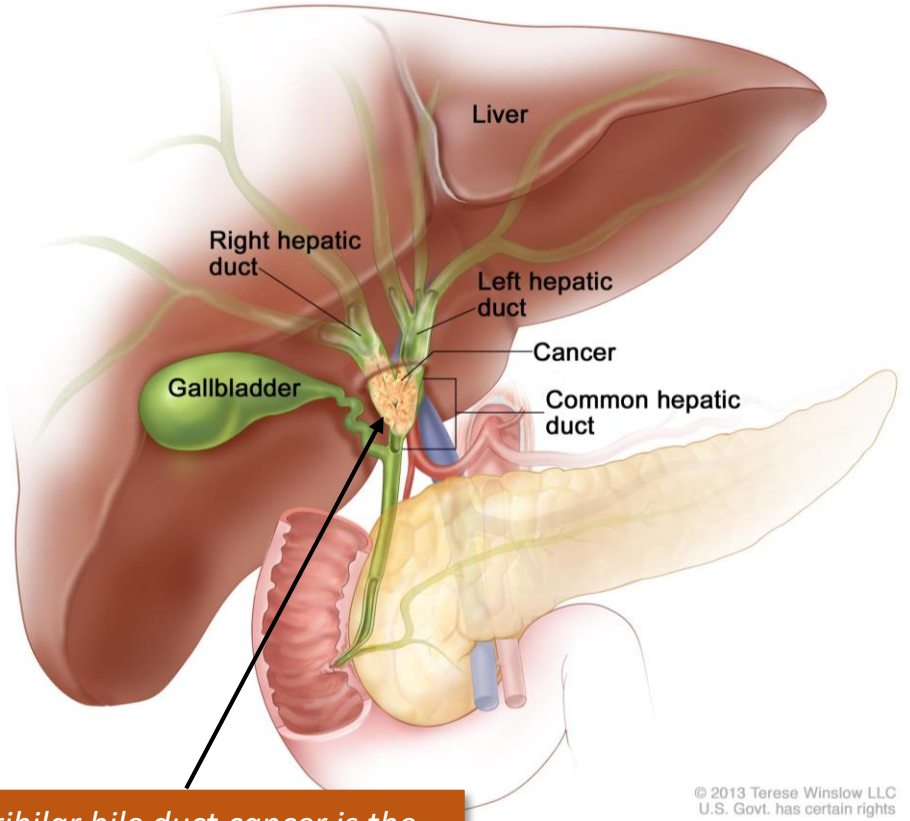
"The results of this phase 1, first-in-man, dose-escalation trial… …are encouraging. Overall, the results… …suggest that photochemical internalisation might have a role in the treatment of early lesions and palliation of advanced disease… These findings provide the basis for further studies."

[1] Sultan et al (2016) Lancet Oncology 17(9):1217-1229
[2] Madsen (2016) Lancet Oncology 17(9):1173-1174

BILE DUCT CANCER

- Incidence, location and classification

- Rare disease: 1-2/100,000 in Western world
- Often referred to as cholangiocarcinoma
- The cancer cells originates from the cells inside the bile duct (called cholangiocytes)
- Cholangiocarcinoma includes:
  - Intrahepatic tumours (10%[1])
  - Perihilar tumours (60-70%[1])
  - Distal tumours (20-30%[1])
  - Different incidence, pathobiology and management



Perihilar bile duct cancer is the main target for PCI treatment

1) Bile duct cancer, American Cancer Society, 30 October 2013

fimaCHEM

- Excellent fit with medical need and existing treatments

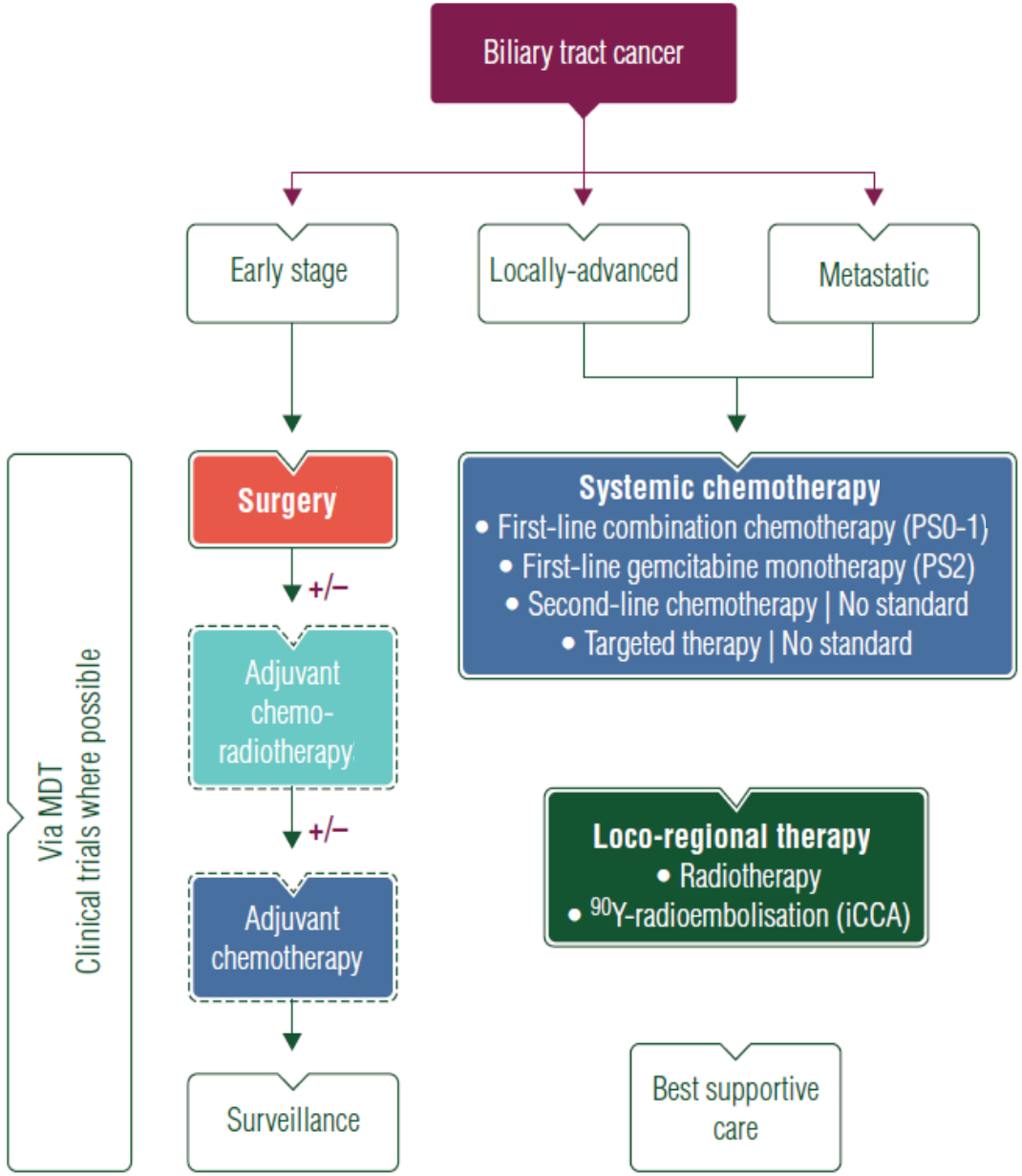
  - **Efficacy:** mOS[1] of **22.8 months** at selected dose (cohort IV) in Phase I dose-escalation (vs. **11-12 months**[2] with SoC for inoperable CCA treatments)
  - **Easy to use:** Illumination through standard endoscopic methods compatible with endoscopic stenting for palliative biliary drainage
  - **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

- A population well segmented

- **fimaCHEM : A clear Medical positioning** [1]
  - First line treatment for inoperable extrahepatic CCA
- **Incidence rate** [2]**:**
  - US CCA: 1.6/100,000 /year; extrahepatic CCA: 0.86/100,000/year
  - EU5 CCA: 2.4/100,000/year; extrahepatic CCA: 1.4/100,000/year
- **Resectable CCA**[3]**:**
  - Less than one-third of the patients are classified as having a resectable tumour at the time of diagnosis
- **fimaCHEM estimated eligible population**[4]**:**
  - US & Europe: approx. 3,000 patients/year
  - Asia: >4,000 patients/year



1) ISMO clinical practices guidelines, 2016 2) Rarecare project 3) Banales & coll, experts consensus document,(ENS-CCA), 2016 4) PCIB internal analysis

BILE DUCT CANCER – PHASE I DOSE-ESCALATION STUDY

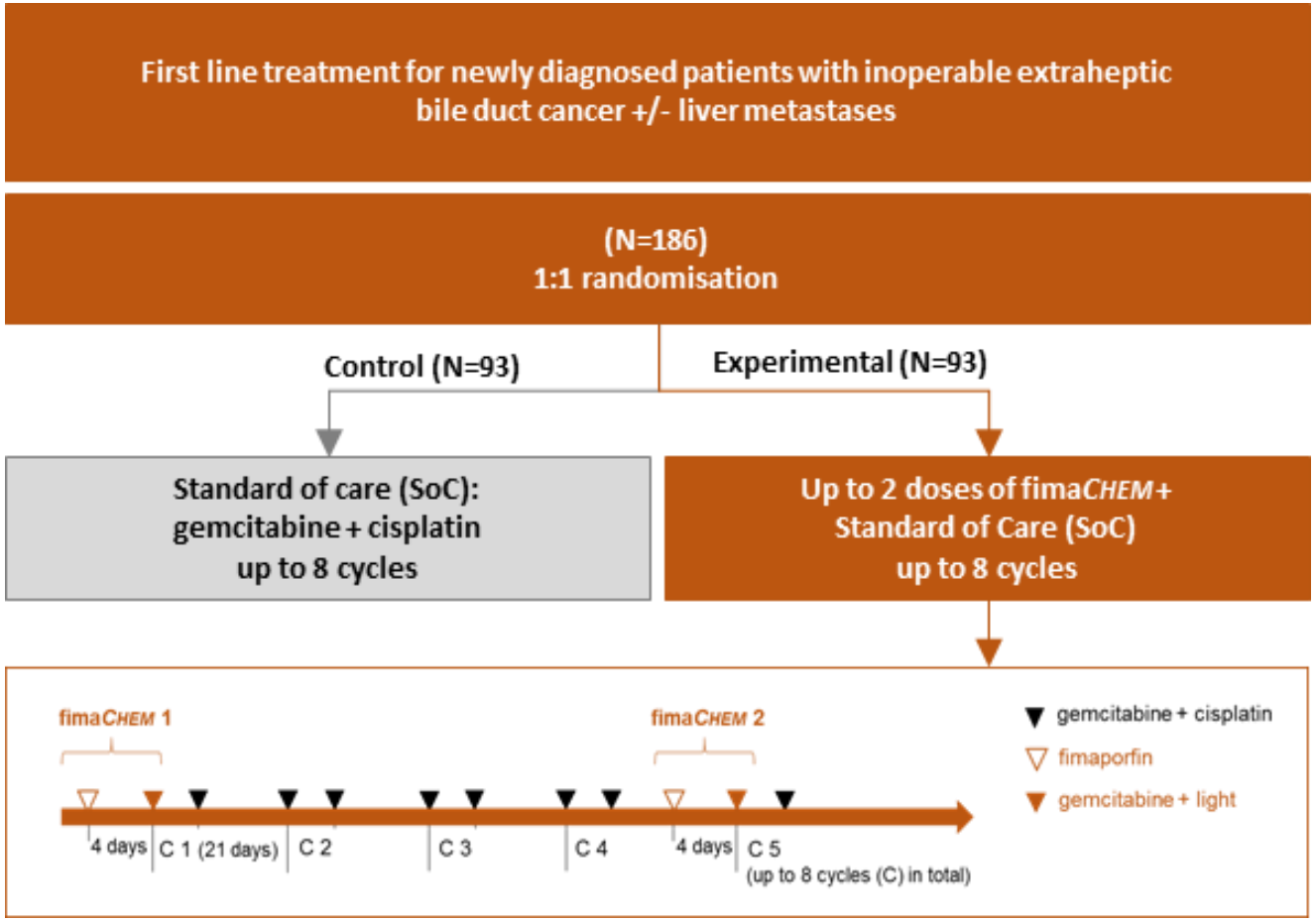
- Positive early signs of efficacy – median Overall Survival of 22.8 months at selected dose

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

- Encouraging tumour response and survival in Cohort IV
- Half of the patients in Cohort IV survived >30 months
- Cohort IV dose has been selected for the pivotal RELEASE study
- Results paved the way for a study with interim analysis for potential accelerated approval
- Safety of two treatments provided in a Phase I Extension

BILE DUCT CANCER – RELEASE STUDY

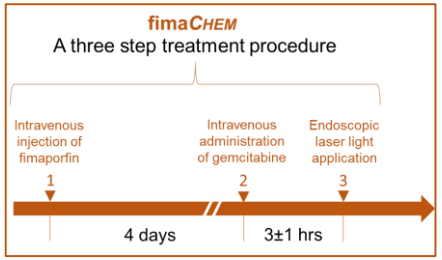
- Pivotal study with potential accelerated/conditional approval on interim analysis



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

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

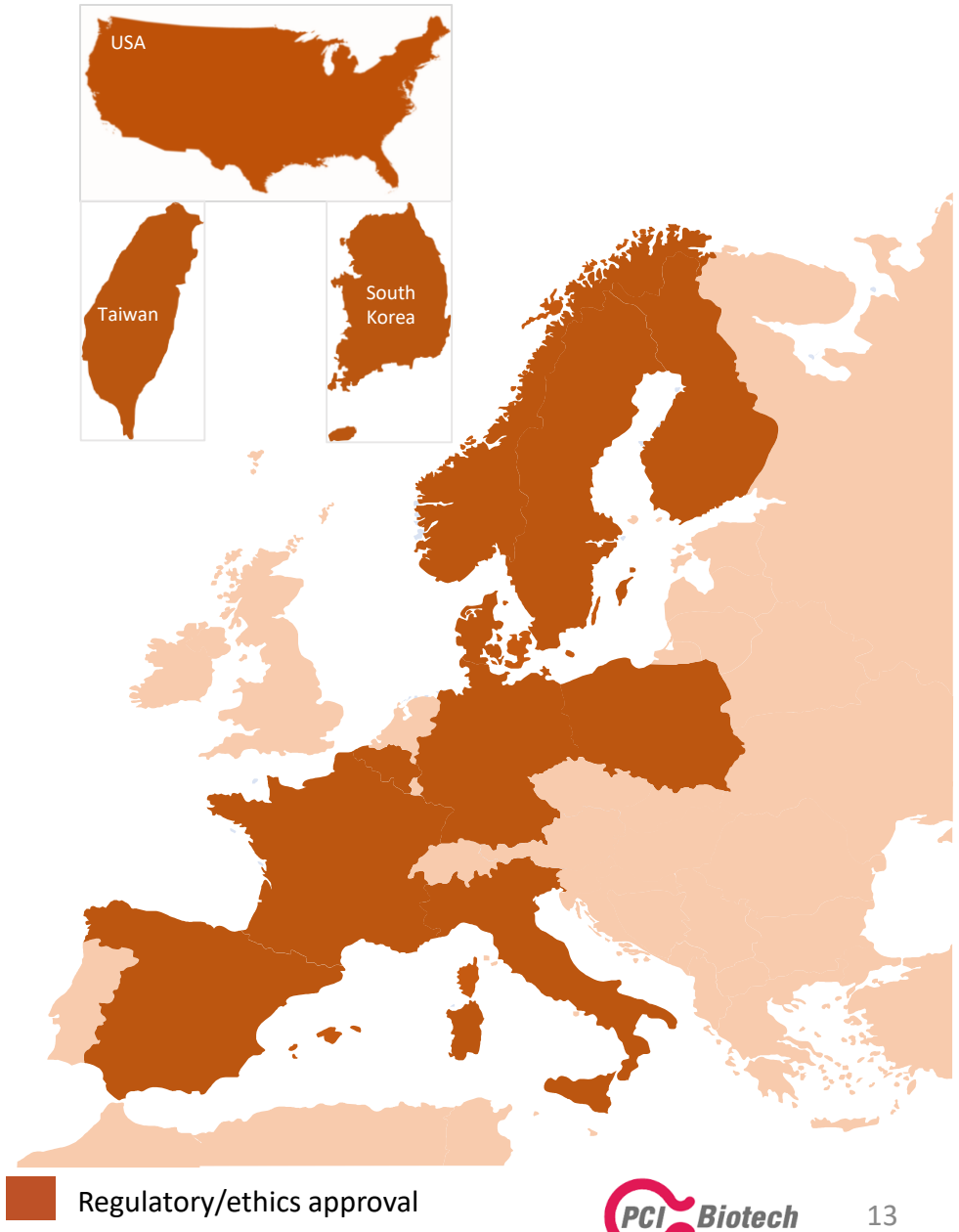
- **fimaCHEM** in addition to current Standard of Care



Bile Duct Cancer – Release Study

- Pivotal study progress

- Regulatory and ethics received for South Korea, Taiwan, USA and 10 of 12 planned European countries
- 44 sites open for patient enrolment – plan to include >50
- 8 sites recently opened in Asia – awaiting first Asian patient
- 6 sites open in the US – awaiting first US patient
- Screening severely affected by the COVID-19 outbreak, with only one patient recruited during the pandemic
- The situation is still unclear, and the long-term consequences of the pandemic are uncertain
- 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

- 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)

BILE DUCT CANCER – RELEASE STUDY DESIGN

- Randomised study with interim analysis for potential accelerated/conditional approval

- **Orphan designation granted in both the US and EU**
- **Fastest way to market determined through regulatory interactions with authorities**

- 1st line treatment of patients with inoperable extrahepatic bile duct cancer
- >50 key hospitals (Europe, Asia & USA)
- Formal interim analysis of ORR when 120 patients are enrolled
- Interim read for potential accelerated approval expected 2H 2022 / 1H 2023

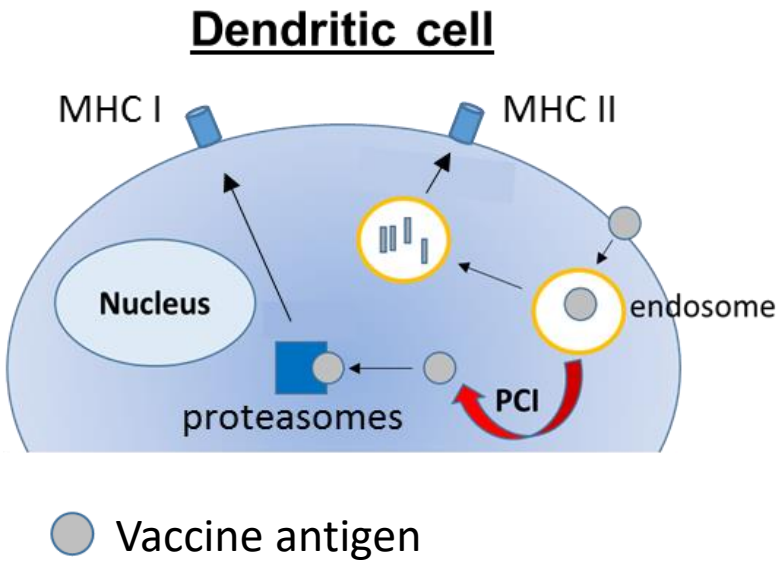
- Randomisation (1:1) of 186 patients
- Primary endpoint: PFS[a], with OS[b] as key secondary
- Interim analysis primary endpoint: ORR[c]
- Regular IDMC[d] review, but no formal futility stop

- **First patient included in Europe May 2019**
- **Prevalence of bile duct cancer is higher in Asia – study expanded to include Asian sites**

[a]PFS: Progression Free Survival; [b]OS: Overall Survival; [c]ORR: Objective Response Rate; [d]IDMC: Independent Data Monitoring Committee

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

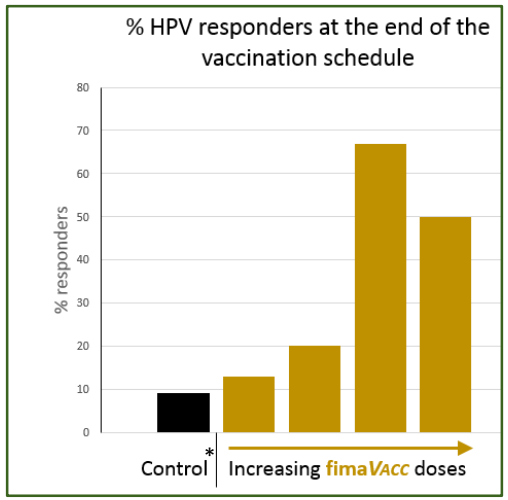
SOLID PROGRESS OF THE fimaVACC PROGRAMME

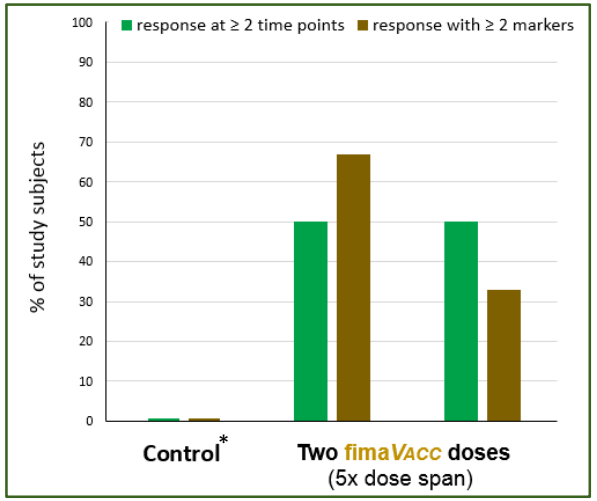
- Successful clinical proof-of-concept and broad IP protection

- Unique mode of action for CD8 T-cell induction
  - CD8 induction by MHC class I antigen presentation in dendritic cells and macrophages
- Solid preclinical data set
  - Strong immune and treatment response data in several different disease models
- Phase I study in healthy volunteers provided successful clinical proof-of-concept for fimaVACC
  - Overall objective to determine the safety, tolerability and immune response
  - Proof of concept and efficacy achieved in terms of intradermal dosing in humans achieved
- Broad use patents granted with coverage until 2035
  - Recent IP for combinations with cytokines and a new important class of adjuvants

SUCCESSFUL CLINICAL PROOF-OF-CONCEPT IN HEALTHY VOLUNTEERS

- Phase I study shows enhanced immune responses compared to a state-of-the-art adjuvant





fimaVACC provides:

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

- Results show that the addition of **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**

*Control group with the Poly-IC adjuvant Hiltonol

SOLID PROGRESS OF THE fimaVACC PROGRAMME

- Growing robust evidence

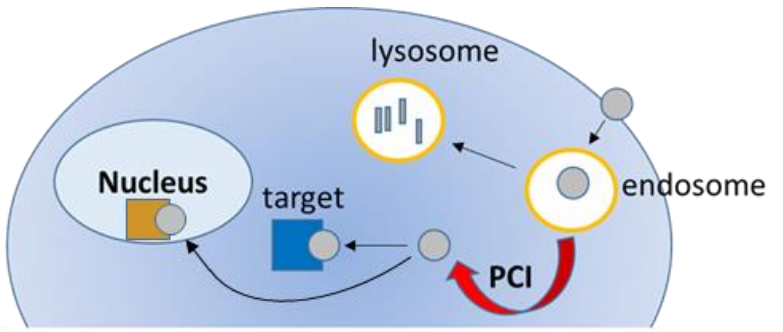
  - Positive clinical study results presented at ESMO Immuno-Oncology Congress in December 2019
  - Publication in process in scientific journal
  - Next step: moving to Phase II with a partner or by ourselves (proof-of-concept in a disease setting)

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 there is now an evaluation period until end of 2020 for determination of potential next steps
- Currently five active collaborations with key players in the field
- PCI Biotech continues to pursue new and value-adding collaborative opportunities

AstraZeneca

eTheRNA

DC PRIME

APOSENSE

IMV IMMUNOVACCINE

GOOD PROGRESS AND EXCITING OUTLOOKS

fimaCHEM

Progressing development in bile duct cancer towards marketing authorisation application

- Encouraging tumour response and survival data from Phase I
- Orphan drug status granted in EU and USA
- Fastest way to market determined through regulatory interactions with authorities
- Global pivotal RELEASE study with interim read for accelerated approval

fimaVACC

Successful clinical PoC with enhanced immune responses

- Vaccination technology available for licensing
- Plan for clinical proof of concept in a disease setting

fimaNAc

Providing an intracellular delivery solution for nucleic acid therapeutics

- A versatile technology with strong preclinical data
- Research collaborations with key players in the field

Q&A

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

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

www.pcibiotech.com