
# General Meeting 2018

OCCI, May 29, 2018

Per Walday, CEO

# IMPOTANT NOTICE AND DISCLAIMER

This presentation may contain certain forward-looking statements and forecasts based on uncertainty, since they relate to events and depend on circumstances that will occur in the future and which, by their nature, will have an impact on PCI Biotech's business, financial condition and results of operations. The terms "anticipates", "assumes", "believes", "can", "could", "estimates", "expects", "forecasts", "intends", "may", "might", "plans", "should", "projects", "programmes", "will", "would" or, in each case, their negative, or other variations or comparable terminology are used to identify forward-looking statement. There are a number of factors that could cause actual results and developments to differ materially from those expressed or implied in a forward-looking statement or affect the extent to which a particular projection is realised. Factors that could cause these differences include, but are not limited to, implementation of PCI Biotech's strategy and its ability to further grow, risks associated with the development and/or approval of PCI Biotech's products candidates, ongoing clinical trials and expected trial results, the ability to commercialise fimaporfin (Amphinex®), technology changes and new products in PCI Biotech's potential market and industry, the ability to develop new products and enhance existing products, the impact of competition, changes in general economy and industry conditions and legislative, regulatory and political factors. No assurance can be given that such expectations will prove to have been correct. PCI Biotech disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

The reservation is also made that inaccuracies or mistakes may occur in this information given about current status of the Company or its business. Any reliance on the information is at the risk of the reader, and PCI Biotech disclaims any and all liability in this respect.

# PCI BIOTECH AT A GLANCE

## ► Unlocking the potential of innovative medicines

- Biopharmaceutical company focusing on development and commercialisation of novel therapies for the treatment of cancer
- Leverages Photochemical Internalisation ('PCI') technology, originating from the Oslo University Hospital – the Radium Hospital
- Platform technology with three programmes targeting an attractive and growing oncology market
- Lead programme, **fimaCHEM**, is a pivotal phase ready orphan designated (EU & US) first-in-class photochemical internalisation product for treatment of bile duct caner – a disease without approved drugs
- Listed on Oslo Børs (PCIB)

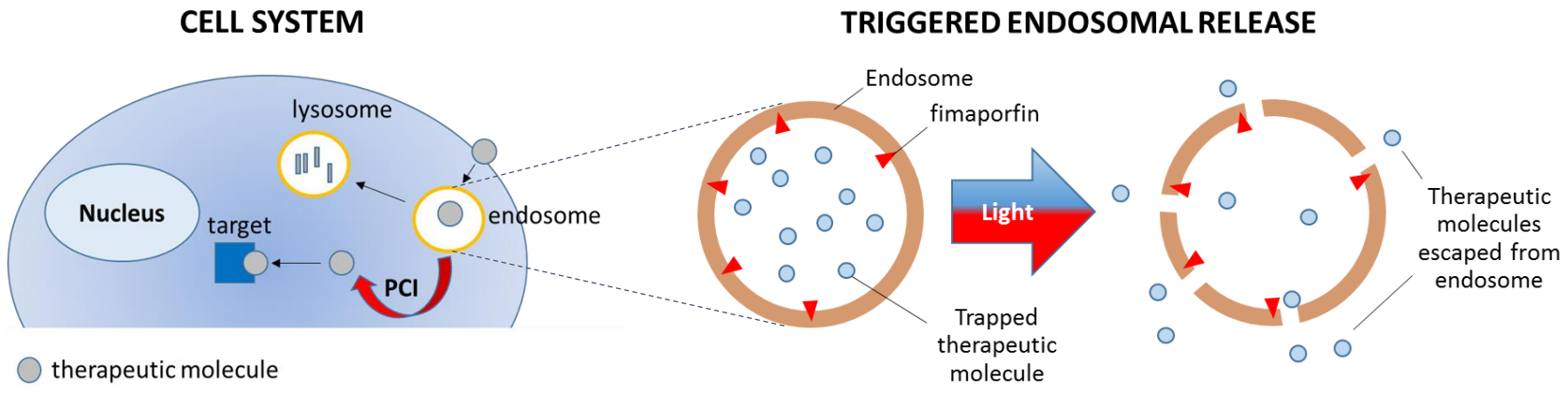
| Programme | Indications / Therapeutics | Preclinical | Phase I | Phase II | Pivotal | Status |
|---|---|---|---|---|---|---|
| fimaCHEM | *Bile duct cancer / gemcitabine* | | | | | - Promising Phase I results for treatment in the orphan indication bile duct cancer<br>- Plan to initiate pivotal study 2H 2018 |
| fimaVACC | *Therapeutic cancer vaccines* | | | | | - Ongoing Phase I study in healthy volunteers<br>- Promising initial immune results<br>- One active R&D collaboration |
| fimaNAC | *Nucleic acid therapeutics* | | | | | - Five active R&D collaborations |

PCI Biotech

# PCI TECHNOLOGY

- Enabling drugs to reach intracellular therapeutic targets

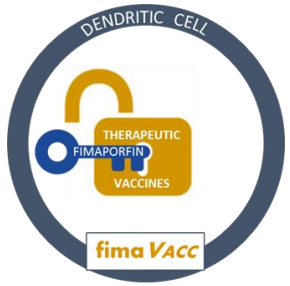
## Mode of action



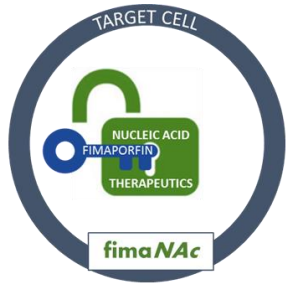

## Broad application

***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 Biotech

# THREE WELL-DEFINED DEVELOPMENT PROGRAMMES

## 1 fimaCHEM

PCI may enhance approximately

**20%**

of relevant approved chemotherapies

- First-in-man study published in Lancet Oncology[1]
- Promising tumour responses in Phase I in inoperable extrahepatic bile duct cancer
- Pivotal phase ready, with potential for approval based on interim read
- Orphan disease with high price potential

## 2 fimaVACC

Total sales of cancer vaccines estimated to reach

**$7.5bn**

in 2022[2]

- Expected market growth largely driven by therapeutic vaccine combinations with checkpoint inhibitors
- Strong preclinical data – ongoing clinical study with promising initial results
- Aim is to out-license the technology on non-/semi-exclusive basis – opportunity to develop own vaccination products

## 3 fimaNAc

Main

**HURDLE IS DELIVERY**

into cells

- Estimated sales of $18bn in 2030[3] (RNAi alone)
- Strong preclinical data with several RNAi's
- Opportunistic collaborative approach
- Aim is to out-license the technology on non-/semi-exclusive basis

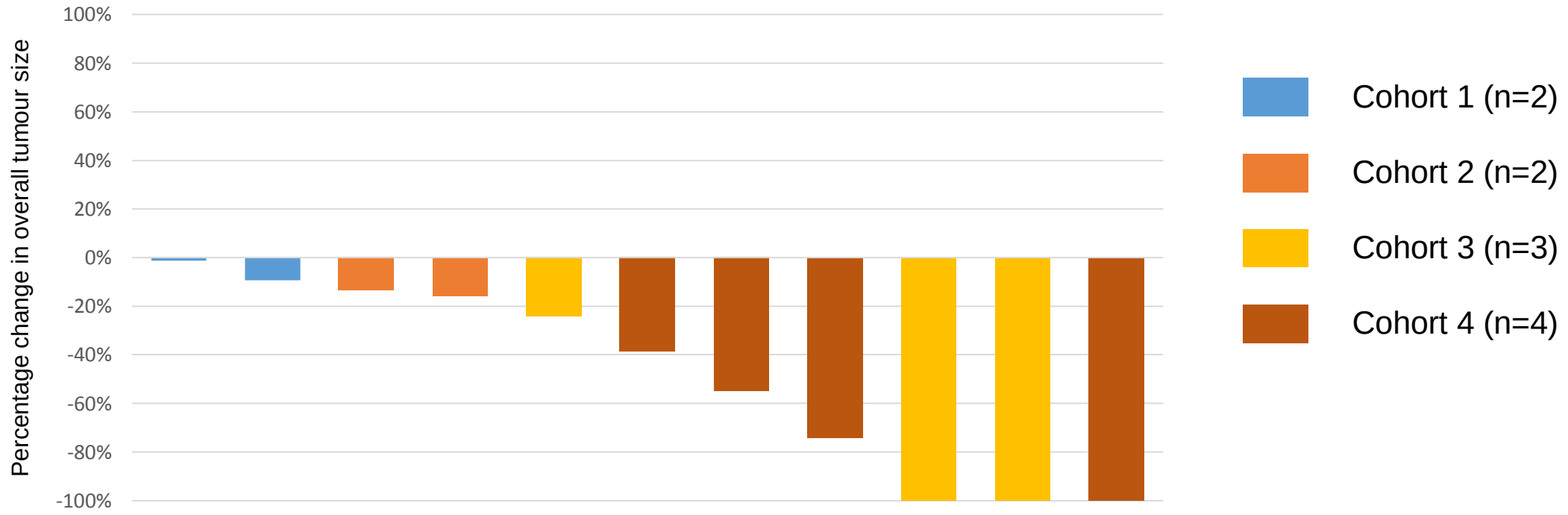
1) Lancet Oncology (2016) **17**(9): p1217–1229
2) GBI Research (2016) Global Cancer Vaccines Market to 2022
3) Research and Markets (2015) RNAi therapeutics market

PCI Biotech

# BILE DUCT CANCER – CLINICAL PHASE I/II STUDY

## ► Encouraging early signs of efficacy in Phase I

- Interim average overall survival (OS) of all 16 patients in Phase I was 17.4 months per March 2018, with 25% of the patients still being alive. Median OS ended at 14.4 months
- Best overall response (all radiologically evaluable patients) – almost all showed tumour reduction




Source: PCI Biotech data
Note: 1) Cohort 1 and 2: Local read; Cohort 3 and 4: Central read

# BILE DUCT CANCER

## ▶ Status and strategy going forward

- **Orphan designation**
  - Granted in both the US and EU, recognising the medical need and potential therapeutic benefits
- **Phase I dose-escalation completed with good tolerability and promising early signs of efficacy**
  - Tumour shrinkage in almost all radiologically evaluable patients
  - Encouraging interim overall survival data, with 25% of patients still alive
- **Fastest way to market determined through regulatory interactions with authorities**
  - Single randomised pivotal study with potential for accelerated / conditional approval based on interim analysis
- **Preparations for pivotal phase progressing towards initiation 2H 2018**
  - Full study design to be announced upon completion of clinical advisory interactions

# PROGRESSING CLINICAL TRANSLATION

## ► Phase I study in healthy volunteers

- Overall objective:
  - Determine the safety, tolerability and immune response of **fimaVACC** in healthy subjects
- Study consists of three parts:
  1. Tolerability of intradermal fimaporfin, adjuvant and light (without vaccine)
  2. **fimaVACC** vaccination: dose finding (fimaporfin and light) and cohort expansion
  3. Optimisation of the **fimaVACC** regimen
- Status:
  - More than 90 subjects have so far been treated
  - Part 1 is completed
  - Part 2 is completed
    - Initial data suggest overall T-cell enhancement at tolerable doses, as well as early responses and high response rates
    - Vast number of study samples available – near-term focus on characterisation of the immune response
  - Part 3 TBD
  - Expected study completion: 2H 2018

Vaccination features: fimaVACC

*Enhanced T-cell blood levels* ✓

*High T-cell response rates* ✓

*Early T-cell responses* ✓


*Patented disposable "band-aid-like" device for user-friendly illumination of the vaccination site*

# RESEARCH COLLABORATIONS

- Six active collaborations within nucleic acid therapeutics and vaccination

**fimaNAc**

| | |
|---|---|
| RXi | - Collaboration initiated 2Q 2015<br>- Listed on Nasdaq, developing innovative therapeutic siRNA<br>- Collaboration expanded to immuno-oncology following RXi's MirImmune acquisition |
| **Top-10 large pharma** | - Collaboration initiated 3Q 2015<br>- A global leader in nucleic acid therapeutics<br>- Collaboration expanded to include *in vivo* studies and duration to end 2Q'18 |
| BIONTECH | - Collaboration initiated 3Q 2016<br>- German biotech company developing individualised cancer immunotherapies<br>- Clinical programmes in melanoma, head & neck, breast, ovarian and pancreatic cancer |
| eTheRNA | - Collaboration initiated 4Q 2016<br>- Belgian biotech with proprietary TriMix platform programming dendritic cells<br>- Clinical programmes in melanoma and triple negative breast cancer |
| IMV™ IMMUNOVACCINE | - Collaboration initiated 2Q 2018<br>- A listed Canadian clinical stage immunotherapy biotech<br>- Multiple clinical-stage programs in cancer and infectious diseases |

**fimaVACC**

| | |
|---|---|
| ultimovacs | - Collaboration initiated 1Q 2016<br>- Norwegian immunotherapy company<br>- Therapeutic cancer vaccine against human telomerase |

# GOOD PROGRESS AND EXCITING OUTLOOKS

fima*CHEM*

**Progressing development in bile duct cancer**

- Encouraging tumour response and emerging survival data from Phase I
- Fastest way to market determined through regulatory interactions with authorities
- Preparations for pivotal phase progressing towards initiation in second half of 2018

fima*VACC*

**Clinical validation of the vaccination technology**

- Initial results suggest overall T-cell enhancement at tolerable doses, as well as early responses and high response rates
- Near-term focus on characterisation of the immune response

fima*NAC*

**Progressing the research collaborations**

- Top-10 pharma collaboration extended to end of first half 2018 and entered into *in vivo* studies
- Research collaboration established with IMV – a Canadian clinical stage immunotherapy biotech