BIOEquity 2016

Copenhagen, May 11, 2016

Per Walday, CEO

PCI Biotech

PCI BIOTECH

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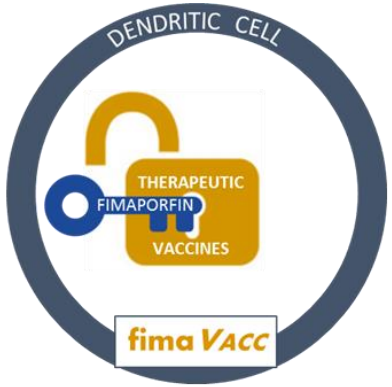
PCI BIOTECH AT A GLANCE

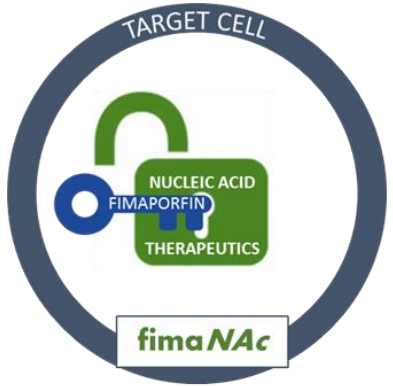
► Unlocking the potential of innovative medicines

- A listed (PCIB:NO) cancer-focused biotech company
- Photochemical internalisation (“PCI”) technology, originating from the Norwegian Radium Hospital
- Clinical program
  - **fima*CHEM*** – Phase I/II with fimaporfin (Amphinex®) for the orphan indication inoperable bile duct cancer
- Pre-clinical programs
  - **fima*VACC*** – Vaccination technology that provides strongly enhanced T-cell responses, moving towards clinical validation
  - **fima*NAc*** – Efficient intracellular delivery of nucleic acid therapeutics, with two active research collaborations

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

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PHOTOCHEMICAL INTERNALISATION

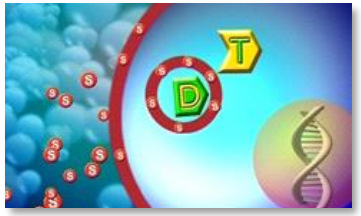
► Triggered endosomal release through illumination

STEP 1:

- Fimaporfin (S) and the active molecule (D) are injected into the body and reaches the target cells

STEP 2:

- Fimaporfin (S) and the active molecule (D) are taken up by the cell, but D is unable to reach the target (T), as it is encapsulated in an endosome
- S is washed away from the cell membrane, but trapped in endosomes



STEP 3:

- Light activates fimaporfin (S) in the membrane of the endosome
- The membrane integrity is affected and the active molecule released

STEP 4:

- The active molecule (D) can now bind to its target (T) and initiate the therapeutic response

D

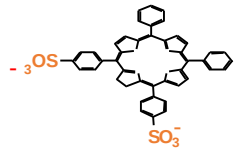
The active molecule

- Anticancer agent, e.g. bleomycin, gemcitabine
- Oligonucleotide, e.g. siRNA
- Protein, e.g. antibody-drug conjugate
- Peptide: e.g. antigen

S

The PCI component

- Light sensitive component
- Fimaporfin - Amphinex®



T

The target

- Target for the active molecule
- E.g. DNA, mRNA, enzyme, microtubuli

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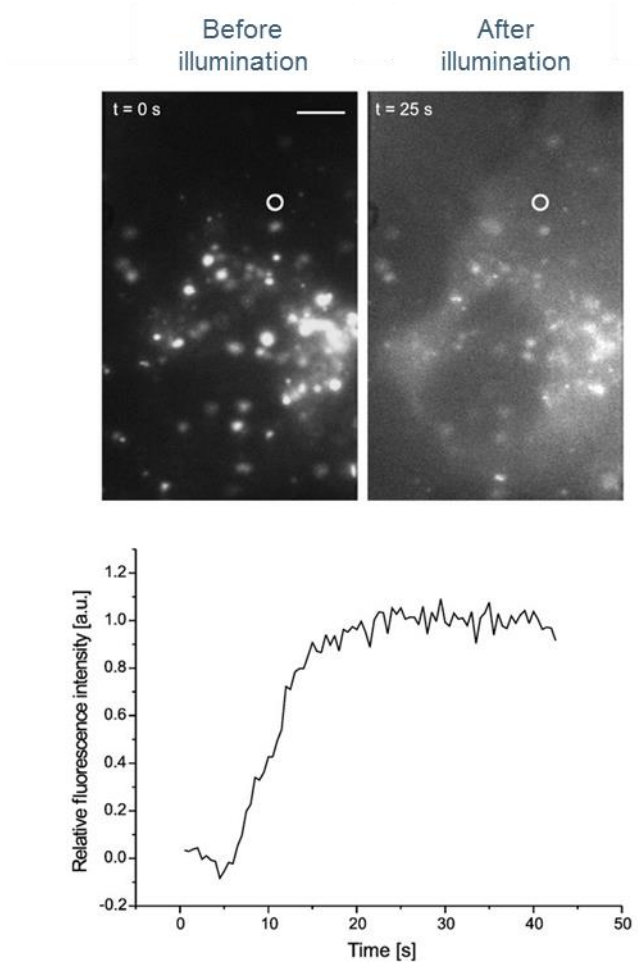
PHOTOCHEMICAL INTERNALISATION

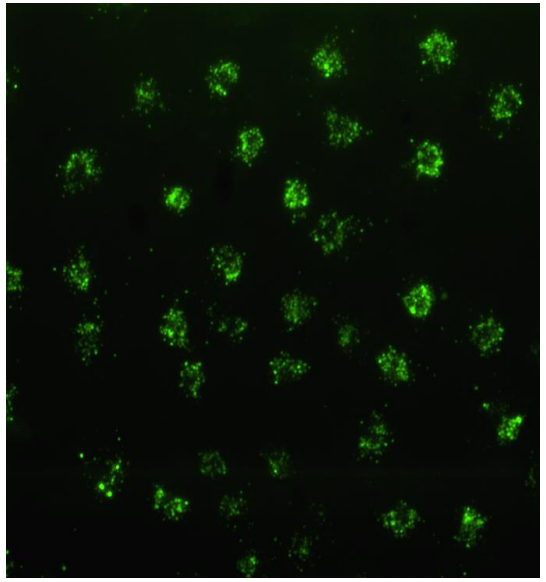
- PCI induced endosomal release

PCI releases Alexa488-dextran from endosomes

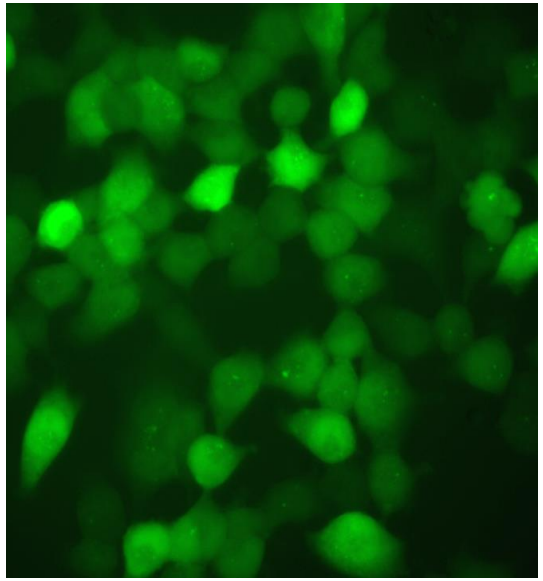


PCI releases fluorescent siRNA from endosomes

Before illumination

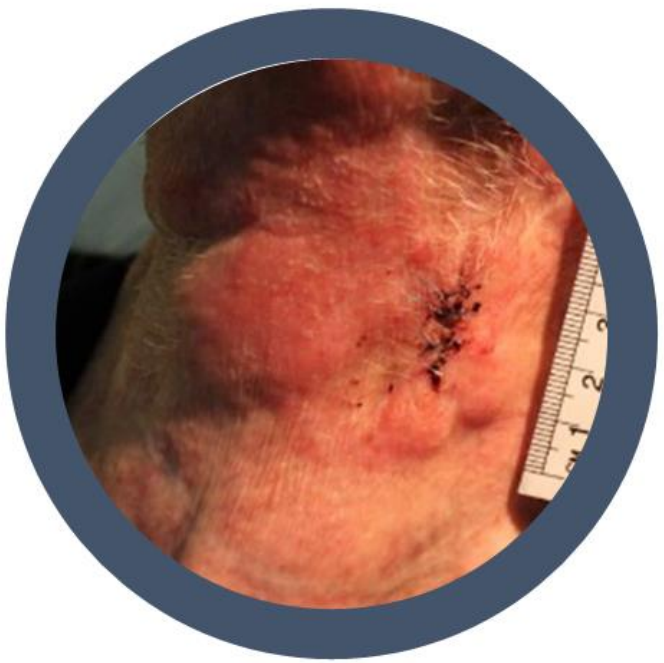


After illumination

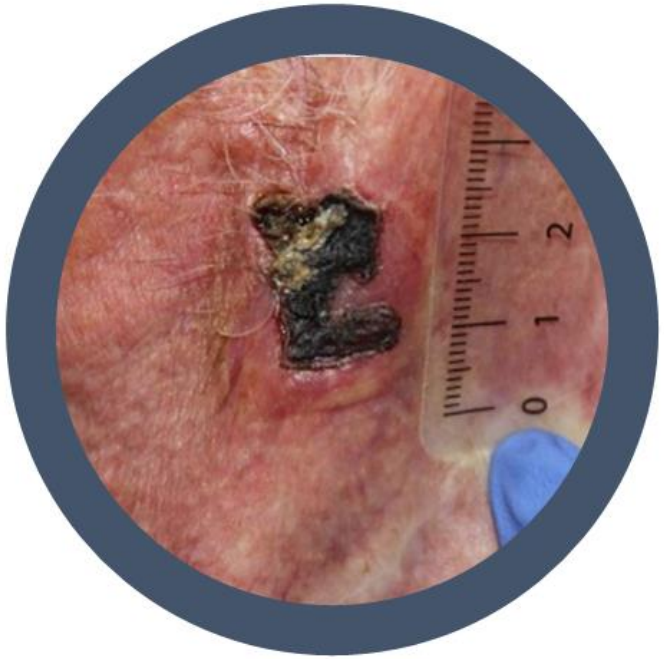


Clinical Technology Validation

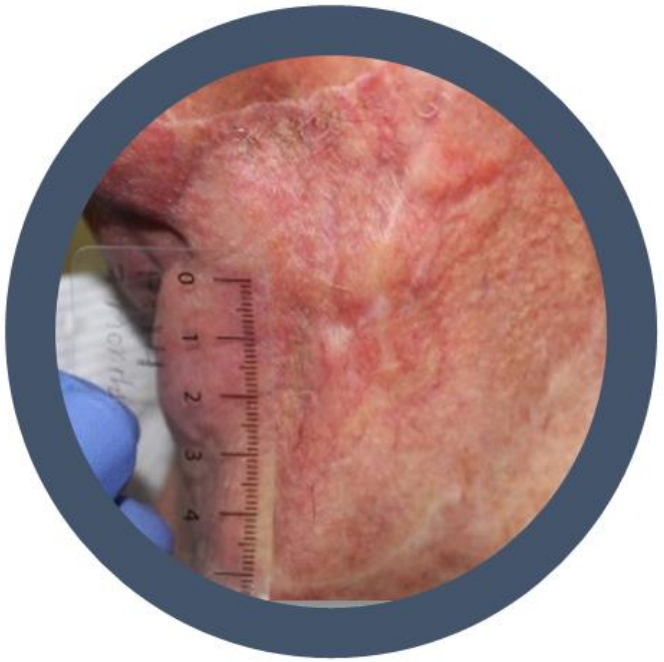
- Phase I of fimaporfin – combined with bleomycin in recurrent/metastatic cancer



Baseline



Day 28



Day 90

- Very promising early signs of tumour response across a range of fimaporfin dose levels
- Apparent strong selectivity for cancer in several patients
- Well tolerated with appropriate pain control and anaesthesia

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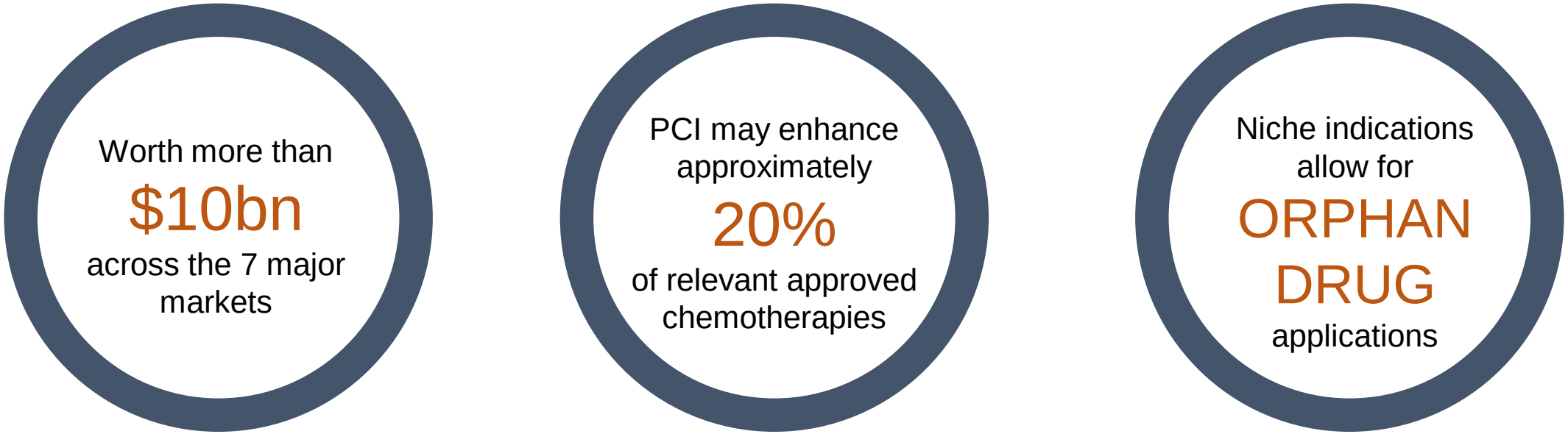
CHEMOTHERAPEUTICS

- A cornerstone in current cancer therapy



- fima CHEM may enable approved drugs to fulfil unmet local treatment needs
- Aim is to complete Phase II in cholangiocarcinoma before out-licensing
- Opportunity for development in further niche indications

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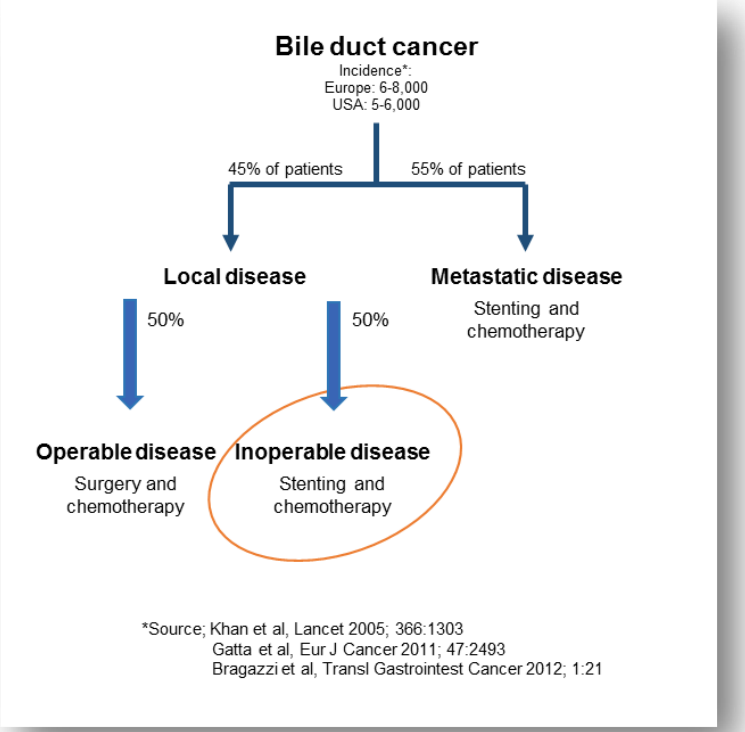
BILE DUCT CANCER

A rare but fatal disease

- Rare disease, with an incidence rate of 1-2 per 100,000 in the western world
- Five-year survival rate of less than 5%, and 0% when inoperable



Why target bile duct cancer?

- Significant inoperable patient population with high unmet local treatment need
- Orphan indication without approved medical treatments
- Limited development pipeline
- Active chemotherapy enhanced by PCI
- Easy access with light through routine endoscopic methods

Attractive due to orphan benefits and absence of satisfying treatments

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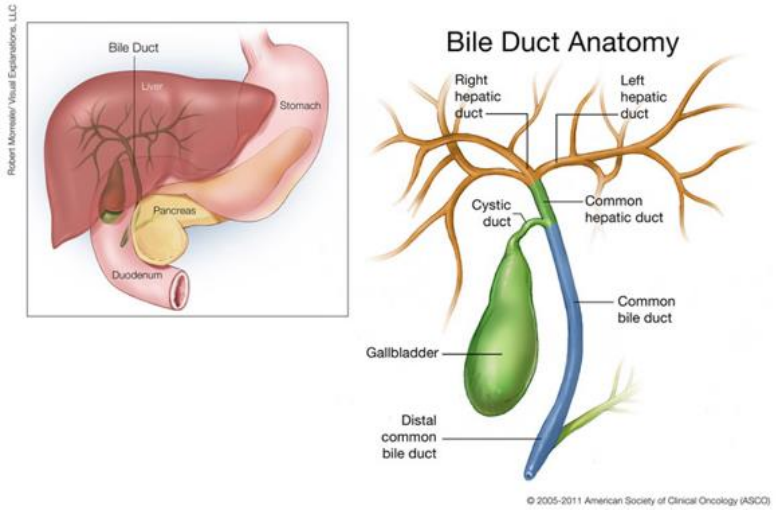
BILE DUCT CANCER

- Progressing into Phase II with promising early signs of efficacy

Current status and plans:

- Phase I/II trial ongoing with fimaporfin
  - combination with gemcitabine
  - open-label, multi-center trial in up to 45 patients
  - activation of fimaporfin by intraluminal illumination



- Safety driven European Phase Ib completed
- Fourth dose cohort concluded Jan 2016 – no safety concerns
- Promising early signs of efficacy in third dose cohort – awaiting fourth dose cohort results

- Progressing into Phase II
- Increasing number of sites
- Opening of IND and including US sites
- Obtain orphan designation

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BILE DUCT CANCER – CLINICAL PHASE I/II STUDY

► Early signs of response – preliminary data

► 6 months radiology (CT) data from 3 dose cohorts

	PD	SD	PR	CR	NA*
Cohort 1	1	1			1
Cohort 2		1			2**
Cohort 3		1	1	1	
Cohort 4	Not yet available – subjects on-going				

* Not measurable / Not evaluable by CT
** Considered SD at 6 months by the investigator

- Subjects are in the study for 6 months after PCI treatment
- Dose levels given in cohort 1 and 2 are below what is expected to be effective from previous clinical experience

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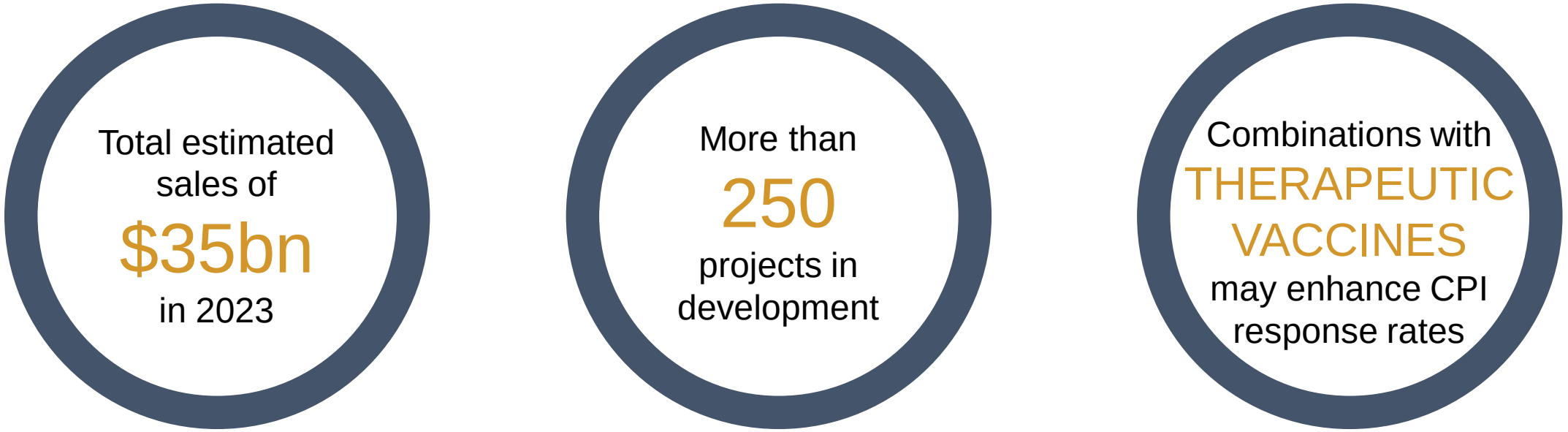
IMMUNOTHERAPY

- A new hope for millions of patients



- fima VACC enhances cellular immune responses important for therapeutic effects
- Moving towards clinical validation, potentially in healthy volunteers
- Aim is to out-license the technology on non-/semi-exclusive basis
- Opportunity to develop own therapeutic vaccination products

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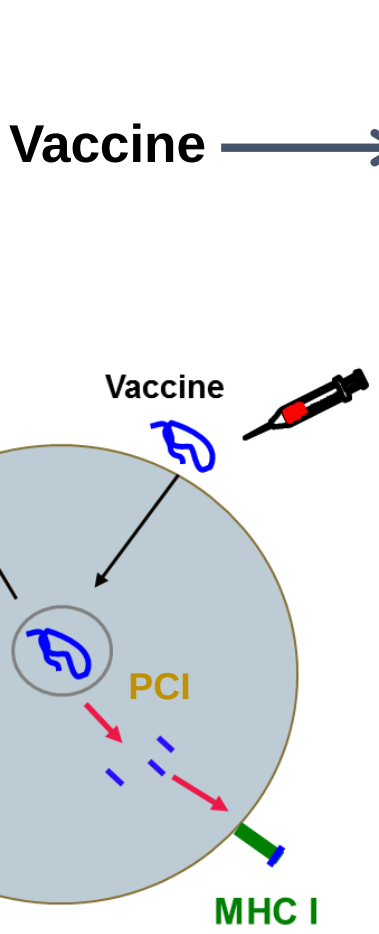
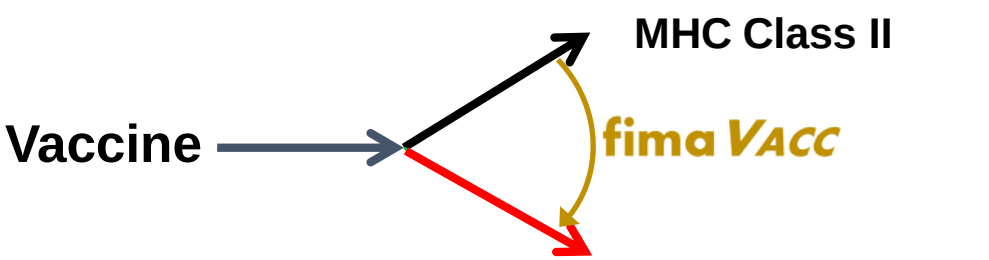
PCI FOR VACCINATION

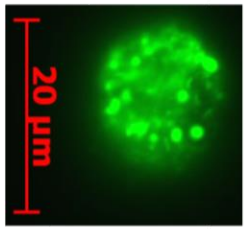
- Enhancing cytotoxic T-cell response by light-induced cross presentation



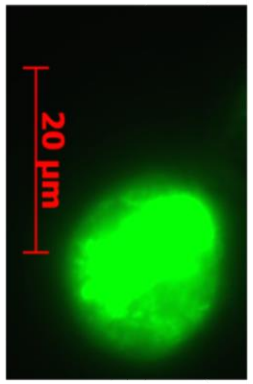


Generate more disease specific cytotoxic T-cells

Attack cancer and virus-infected cells more efficiently



Antigen in endosomes



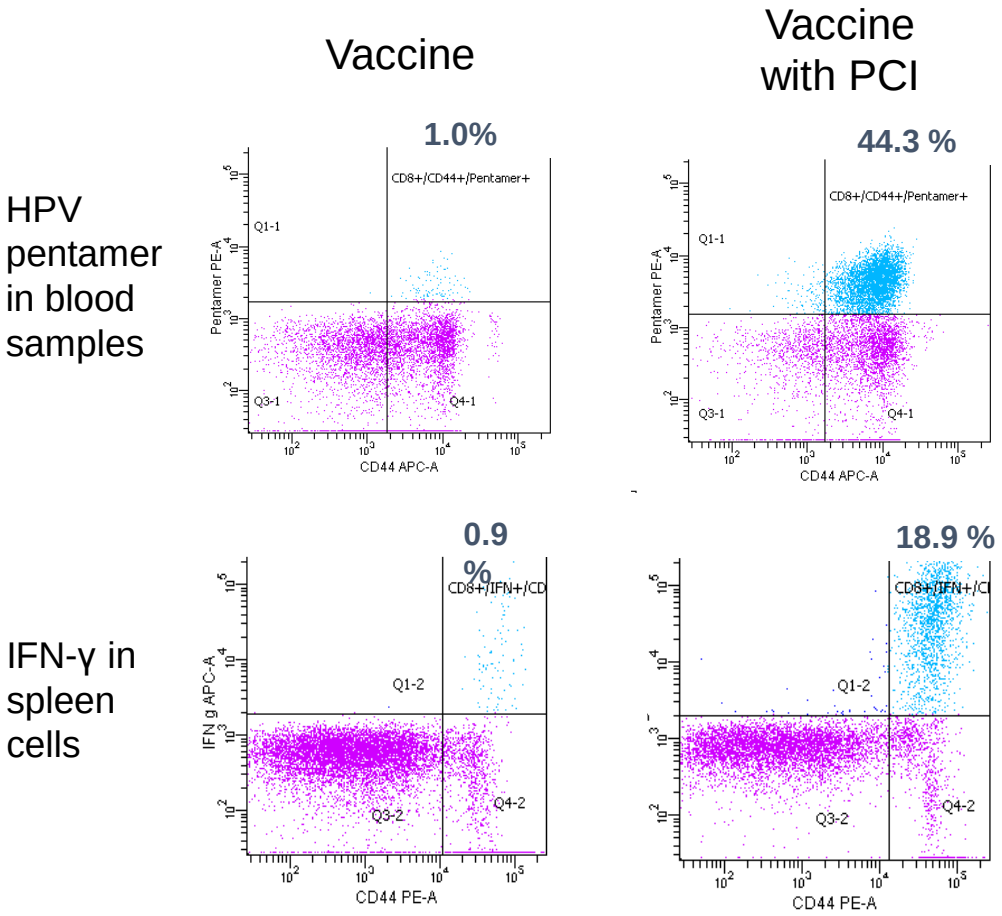
After fima VACC treatment

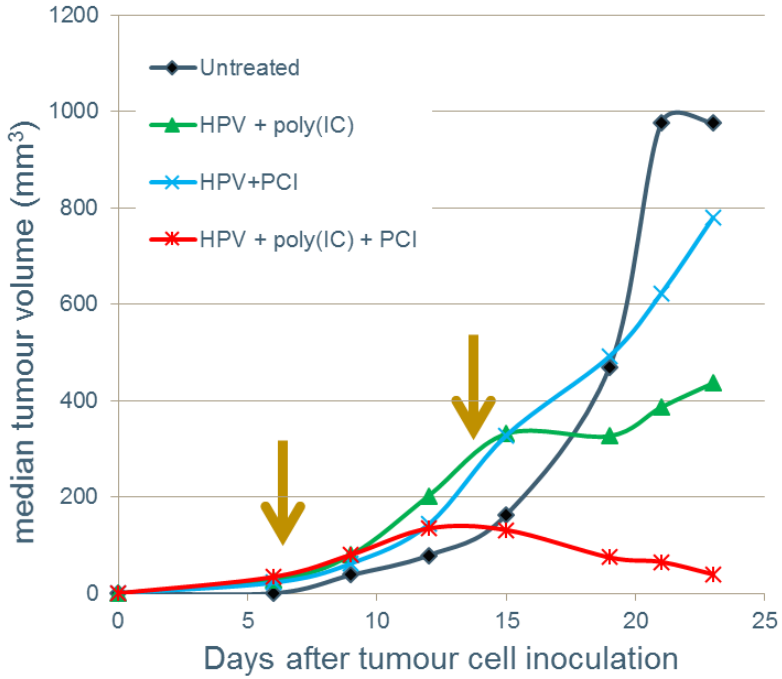
Ovalbumin antigen in JAWSII dendritic cells

THERAPEUTIC VACCINATION

- *In vivo* immunisation with HPV long peptide

fima VACC strongly enhance CD8 T-cell response and induces strong anti-tumour response





- Intradermal vaccination at days 6 and 13 after tumour cell inoculation
- 5 animals per group

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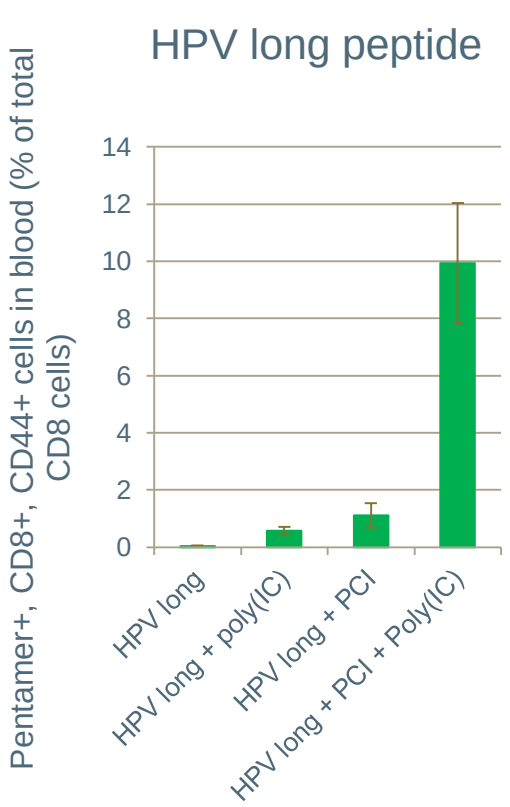
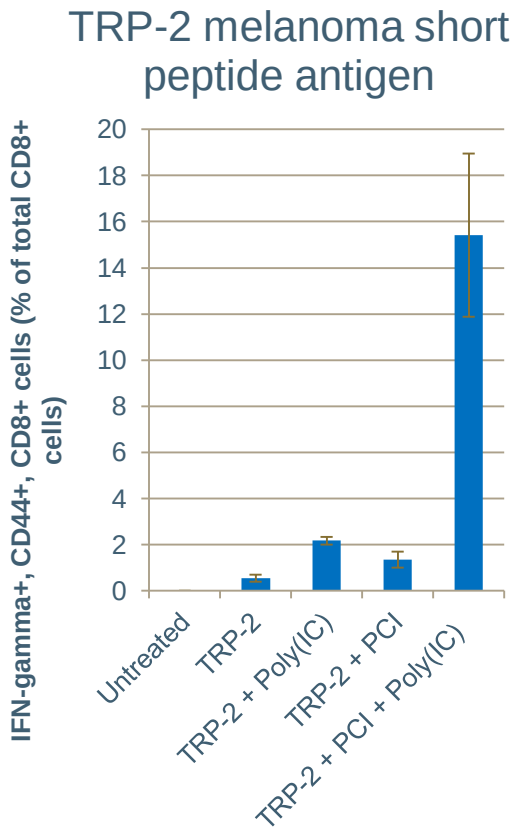
SYNERGY WITH OTHER TECHNOLOGIES

► Acts synergistically with other vaccination enhancement technologies

- Acts synergistically with several commonly used vaccine adjuvants
- Works with many different peptide antigens and stimulates both CTL proliferation and IFN-γ production





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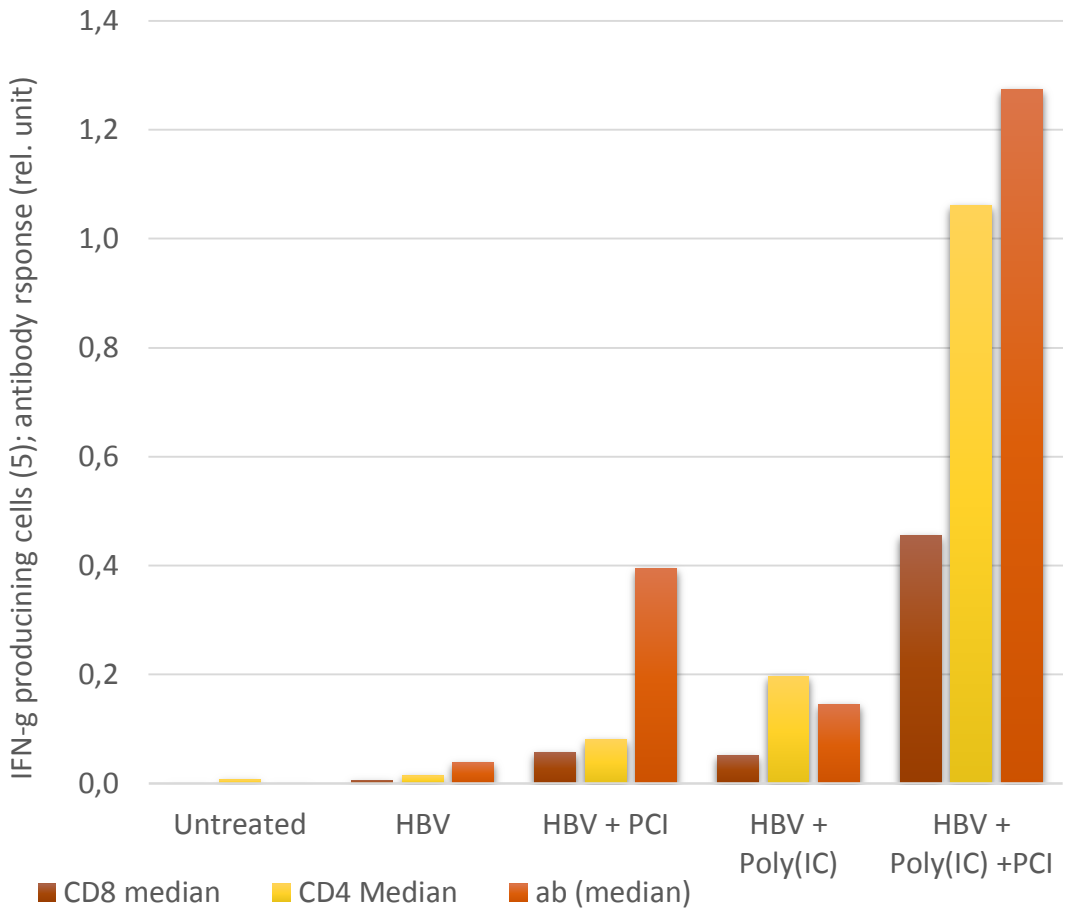
ELICIT STRONG IMMUNE RESPONSES

- Improving the efficacy of therapeutic cancer vaccines

PCI induces CD8, CD4 and antibody responses



Promising data from preclinical testing:

- Elicit strong responses in all important aspects of immune responses
- Induce antigen-specific killer T-cells
- Works in synergy with other state-of-the-art vaccine enhancement technologies
- Opportunity for clinical validation

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THERAPEUTIC VACCINATION WITH fima VACC

- Opportunity to play a key role in second generation immunotherapy

- Unique mode of action
  - indication of CTL-induction by MHC class I antigen presentation in dendritic cells and macrophages
- Broad applicability
  - peptide and protein antigens
  - particulate antigen formulations
  - prophylactic & therapeutic vaccination
- Safety of fimaporfin confirmed in Phase I studies
- Excellent stability
  - stable at room temperature
  - stable in solution
  - can be autoclaved
- Cost effective synthesis

NUCLEIC ACID THERAPEUTICS

- A treatment modality with huge potential

Estimated sales of
USD 18bn
in 2030
(RNAi alone)

mRNA is a hot
new field with
HIGH DEAL ACTIVITY

Main
HURDLE IS DELIVERY
into cells

- fimaNAc may provide a delivery solution for many nucleic acid therapy applications
- Opportunistic collaborative approach
- Aim is to out-license the technology on non-/semi-exclusive basis

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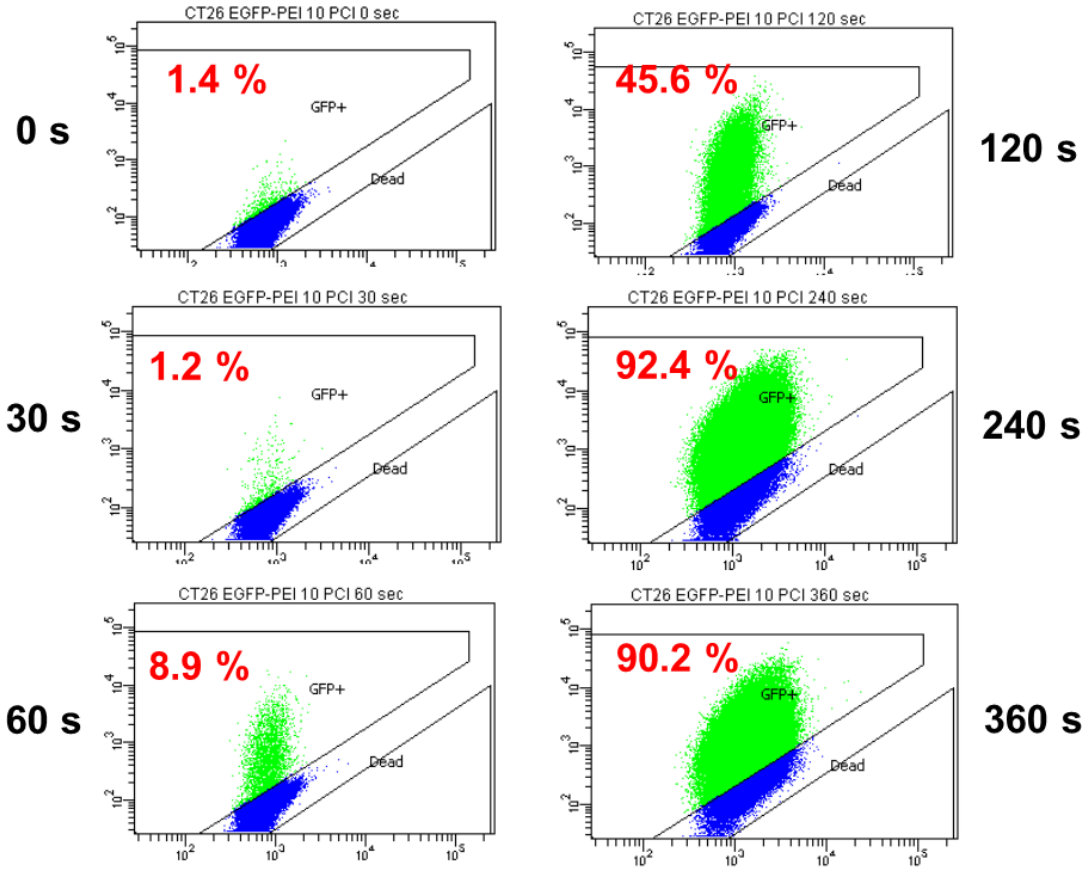
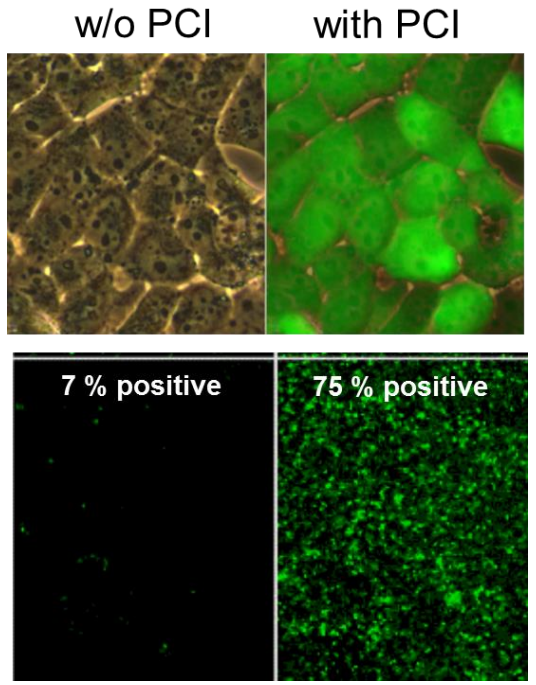
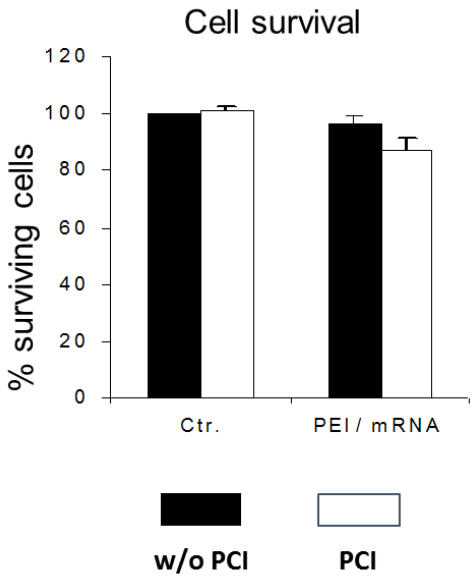
ENHANCING mRNA DELIVERY

- Strongly increased GFP synthesis with increasing light doses

fimaNAc with polyethylenimine vehicle







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Research Collaborations

► Three active collaborations within nucleic acid therapeutics and vaccination

Top-10 large pharma company

- Agreement signed in 3Q 2015
- Evaluate synergistic effects between companies' technologies
- One of the global leaders in nucleic acid therapeutics
- Collaborative research funded and initiated
- Data generated in research collaboration to be evaluated- potential for a further partnership

RXi Pharmaceuticals

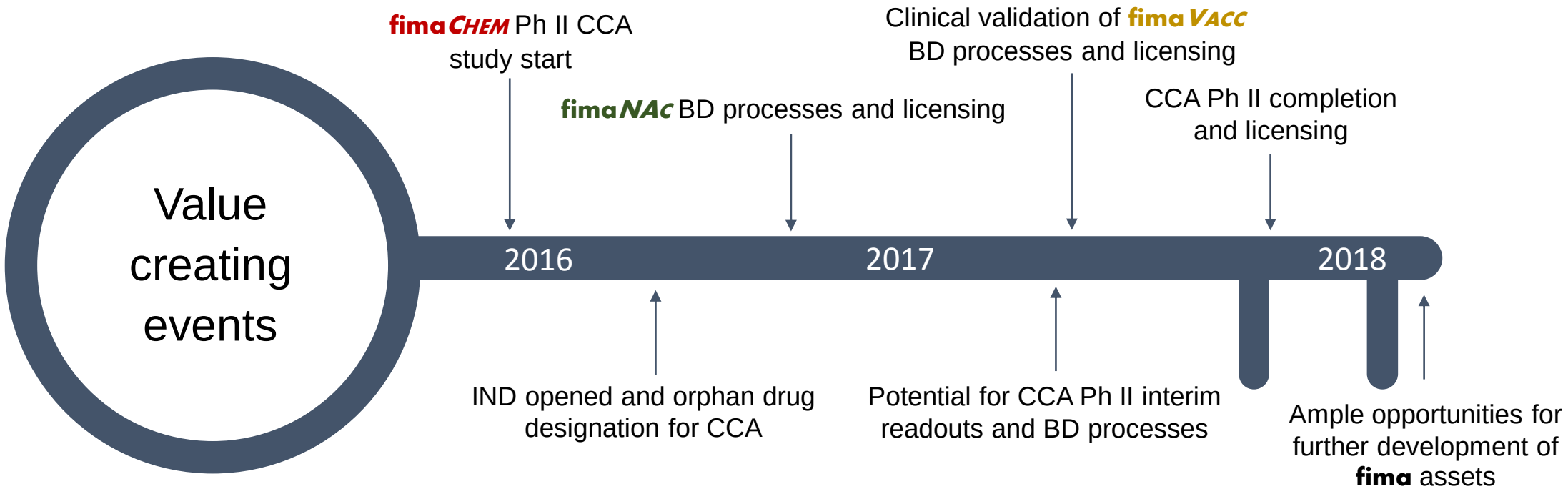
- Agreement signed 2Q 2015
- RXi Pharmaceuticals listed on Nasdaq (NASDAQ: RXII)
- Discovers and develops innovative therapeutics within dermatology and ophthalmology
- Results achieved from this research collaboration to be evaluated- potential for closer collaboration

Ultimovacs

- Agreement signed 1Q 2016
- Ultimovacs AS, Norwegian immunotherapy company
- Developing UV1, a therapeutic cancer vaccine directed against human telomerase
- Results from this research collaboration to be evaluated- potential for closer collaboration

KEY MILESTONES THROUGH 2018

- Unlocking the true potential of innovative medicine



Enquiries

Dr Per Walday
Chief Executive Officer
E: pw@pcibiotech.com
M: +47 917 93 429

Mr Ronny Skuggedal
Chief Financial Officer
E: rs@pcibiotech.com
M: +47 940 05 757