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PCI BIOTECH

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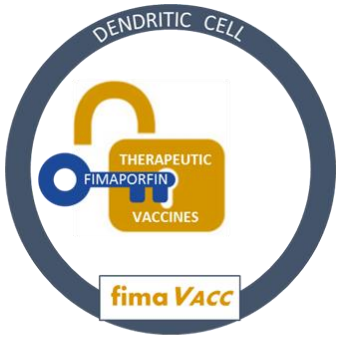
PCI BIOTECH AT A GLANCE

► Unlocking the potential of innovative medicines

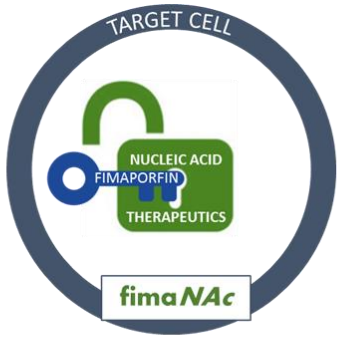
- A listed (PCIB:NO) cancer-focused biotech company
- Photochemical internalisation ("PCI") technology, originating from the Norwegian Radium Hospital
- Clinical programmes
  - **fimaCHEM** – Phase I/II with fimaporfin (Amphinex®) for the orphan indication inoperable cholangiocarcinoma
  - **fimaVACC** – Vaccination technology that provides strongly enhanced T-cell responses, phase I initiated
- Pre-clinical programme
  - **fimaNAc** – Efficient intracellular delivery of nucleic acid therapeutics, with three active research collaborations

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

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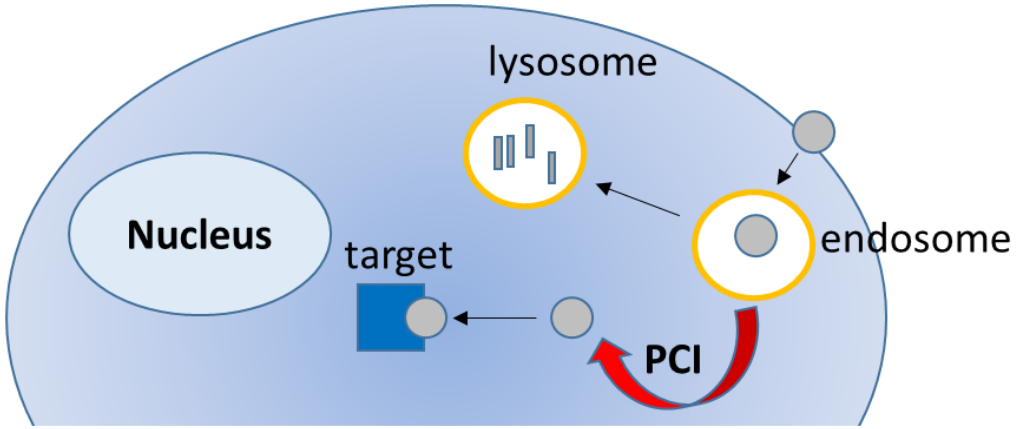
PCI TECHNOLOGY

- Enabling drugs to reach intracellular therapeutic targets

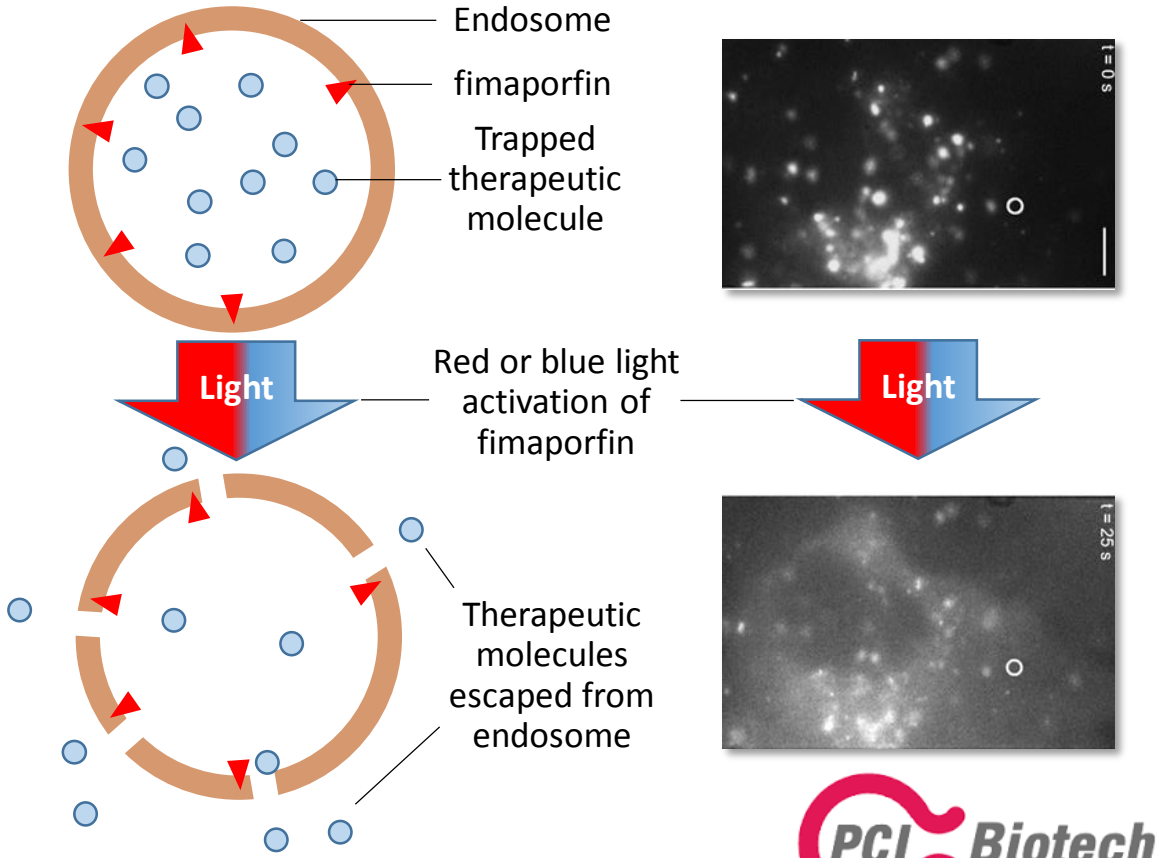
CELL SYSTEM



therapeutic molecule

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

TRIGGERED ENDOSOMAL RELEASE



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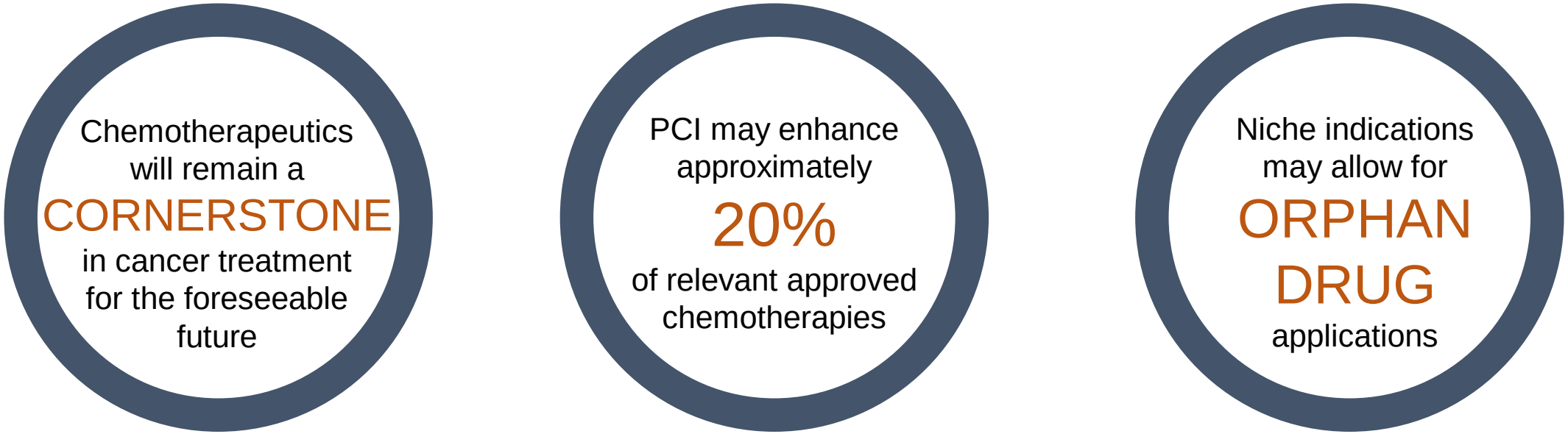
CHEMOTHERAPEUTICS

- A cornerstone in current cancer therapy



- fima CHEM may enable approved drugs to fulfil unmet local treatment needs
- First-in-man study published in Lancet Oncology*, with independent expert commentary
- Ready for Phase II in cholangiocarcinoma with promising early signs of efficacy
- Opportunity for development in further niche indications

* **Lancet Oncology** (2016) **17**(9): p1217–1229

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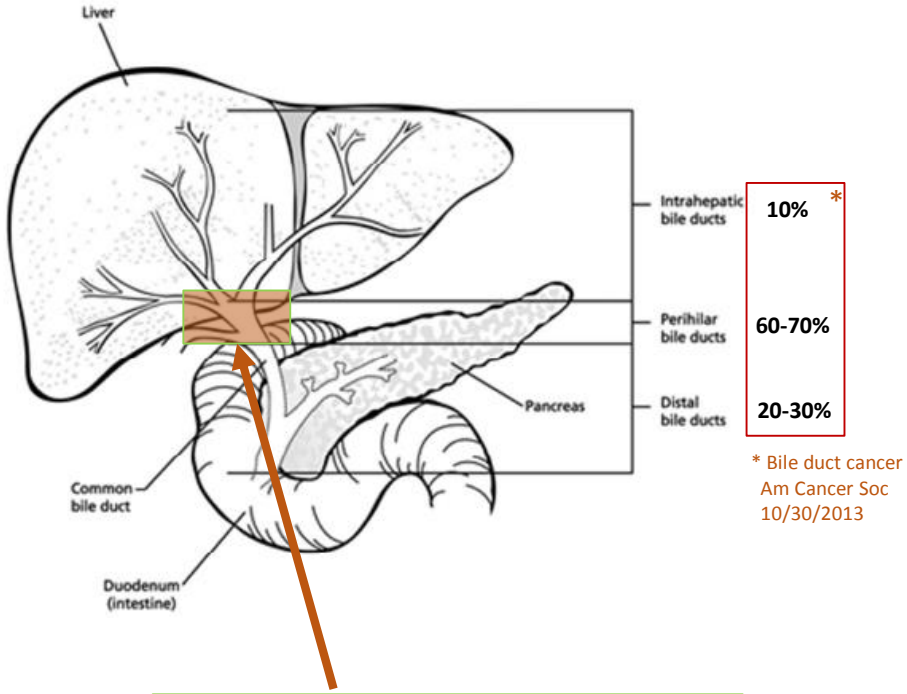
CHOLANGIOCARCINOMA (CCA)

► Location and classification

- Cholangiocarcinoma arises from the malignant proliferation of cholangiocytes – the epithelial cells lining the biliary tree
- The term ‘cholangiocarcinoma’ includes all bile duct cancers:
  - Intrahepatic
  - Extrahepatic (perihilar & distal)
  - The three locations are in many ways different diseases, with different incidence, pathobiology and management
- Over 90% of CCA’s are adenocarcinomas



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CHOLANGIOCARCINOMA

▶ The unmet need

- Rare disease, with an incidence rate of 1-2 per 100,000 in the western world; higher incidences in Asia
- Five-year survival rate of less than 5%, and 0% when inoperable (avg. approx. 12 months survival)
- Current management
  - Surgery
    - Surgery is the only potentially curative treatment for CCA. However, less than ⅓ are resectable at presentation
  - Stenting
    - Endoscopic stenting is the procedure of choice for palliative biliary drainage in patients with unresectable disease
  - Chemotherapy
    - There is no approved chemotherapy for CCA treatment
    - Recommended chemotherapy treatment includes a combination of gemcitabine and cisplatin (documented in the ABC02 trial)

Excellent technology fit with PCI

Targeted illumination is done using standard endoscopic procedure

The active chemotherapy gemcitabine is significantly enhanced by fimaCHEM

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CHOLANGIOCARCINOMA – CLINICAL PHASE I/II STUDY

- Early promising signs of durable response in Phase I

- **6 months radiology data from all dose cohorts – local read**

RECIST*	PD	SD	PR	CR	NA**
Cohort I	1	1			1
Cohort II		1			2
Cohort III		1	1	1	
Cohort IV***	1		2	1	2

PD: Progressive disease (>20% growth)

SD: Stable Disease

PR: Partial Response (>30% shrinkage)

CR: Complete Response (no visible tumour)

* Response Evaluation Criteria In Solid Tumours (rules defining when cancer patients improve, stay the same or worsen during treatments)
** Not measurable / Not radiologically evaluable
*** Cohort IV expanded; Four radiologically evaluable patients at 6 months

- Subjects are in the study for 6 months after fimaCHEM treatment
- Dose levels given in Cohort I and II are below what is expected to be effective from previous clinical experience
- Commissioned central independent radiological expert evaluation of Cohort III & IV, as this is an expected requirement from regulatory authorities

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CHOLANGIOCARCINOMA – CLINICAL PHASE I/II STUDY

- Early promising signs of durable response verified by independent expert evaluation

- **6 months radiology data: Cohort III & IV – local vs. independent**

RECIST	PD	SD	PR	CR	NA
Local	1	1	3	2	2
Independent	2	1	2	2	2

- Independent radiological RECIST evaluation of all patient images from Cohort III and IV
- All images evaluated separately by two experts in RECIST and bile duct cancer
- Tumour response reported by local radiologists were in all instances verified at independent evaluation
  - Progressive disease due to appearance of new lesions (one missed at local read)
- **More than 50% response rate** – far above expected with standard treatment

* ***"Maintenance of biliary drainage is critical in patients with advanced biliary cancer… …response in tumor bulk may therefore have a greater effect on survival than would be the case for other cancers."***

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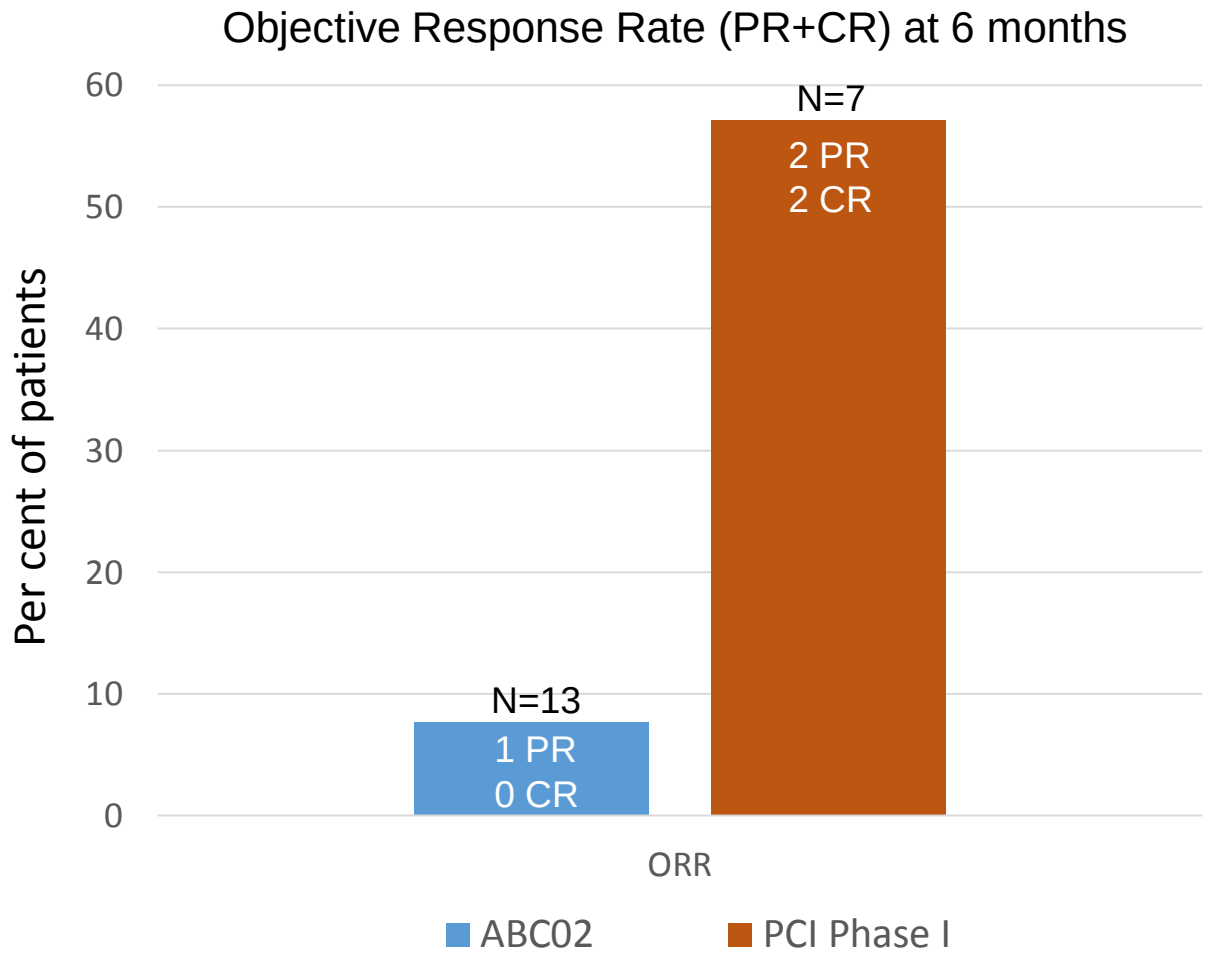
* Valle et al 2010 – landmark publication for cis-gem treatment (NEJM 362;14):

CHOLANGIOCARCINOMA – CLINICAL PHASE I/II STUDY

- Comparing response rate to cis/gem landmark publication (ABC02) in NEJM



ABC02 subpopulation*
- Treatment naïve
- Hilar carcinoma
- Cis/gem treatment
- Local read
- N=13

PCI Phase I
- Treatment naïve
- Hilar carcinoma
- fima CHEM + cis/gem treatment
- Cohort III & IV
- Independent evaluation
- N=7

* Courtesy of Dr Juan Valle, first author of landmark publication for cis-gem treatment (NEJM 2010 362;14)

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CHOLANGIOCARCINOMA

- Phase I – Good safety and tolerability

- **No apparent increase in adverse reactions with increasing doses**
- **No Dose Limiting Toxicity (DLT) observed, including Cohort IV**
- **The most common Adverse Events seen during the DLT window**
  (from fima CHEM treatment and including Cycle 1 of chemotherapy)
  - Mild photosensitivity reactions
  - Abdominal pain
  - Cholangitis

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IMMUNOTHERAPY

- A new hope for millions of patients

Total estimated immunotherapy sales of **$35bn** in 2023*

More than **100** projects in development**

Combinations with **THERAPEUTIC VACCINES** may enhance CPI[1] response rates

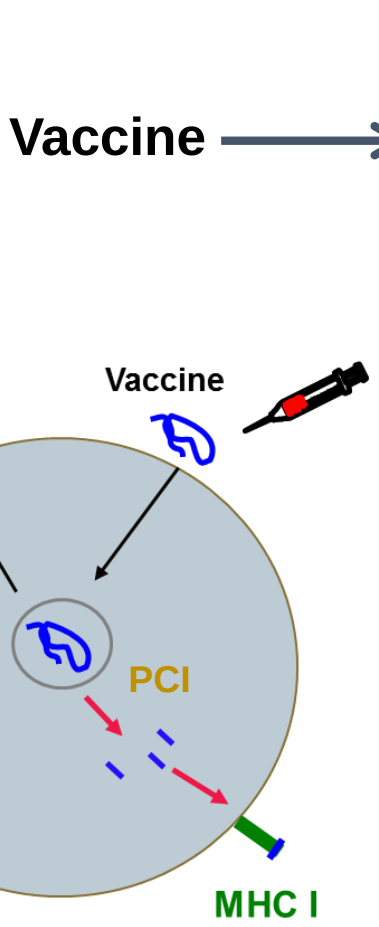
- **fima VACC** enhances cellular immune responses important for therapeutic effects
- Initiated Phase I study in healthy volunteers for clinical validation
- Aim is to out-license the technology on non-/semi-exclusive basis
- Opportunity to develop own therapeutic vaccination products

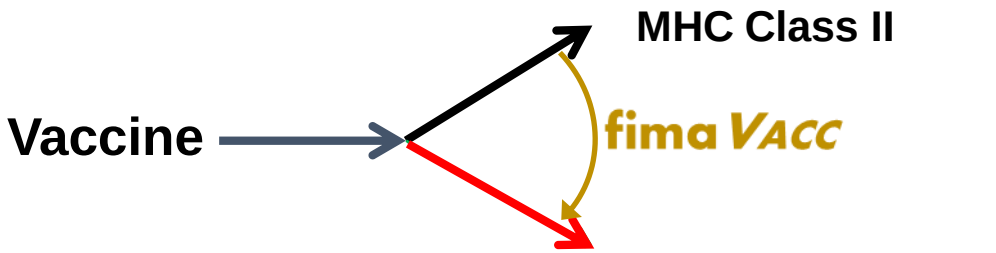
* Citi Research "Immunotherapy – the beginning of the end for cancer". Baum, May 2013
** Clinicaltrials.gov. PCIB analysis, August 2016

[1]CPI: Checkpoint inhibitors

PCI FOR VACCINATION

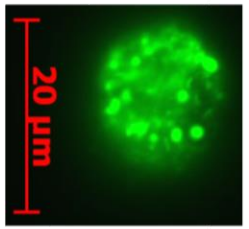
► **fima VACC** enhances cytotoxic T-cell response by light-induced cross presentation



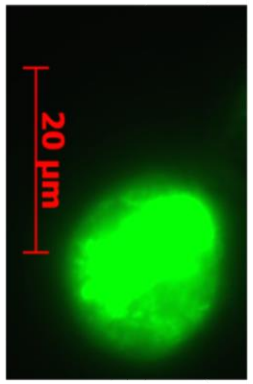


Generate more disease specific cytotoxic T-cells

Attack cancer and virus-infected cells more efficiently



Antigen in endosomes



After fima VACC treatment

Ovalbumin antigen in JAWSII dendritic cells

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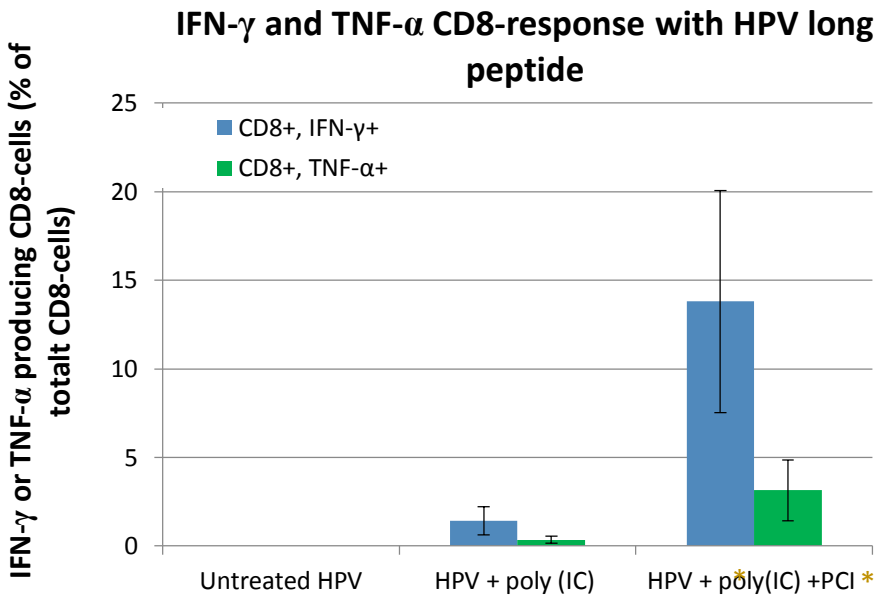
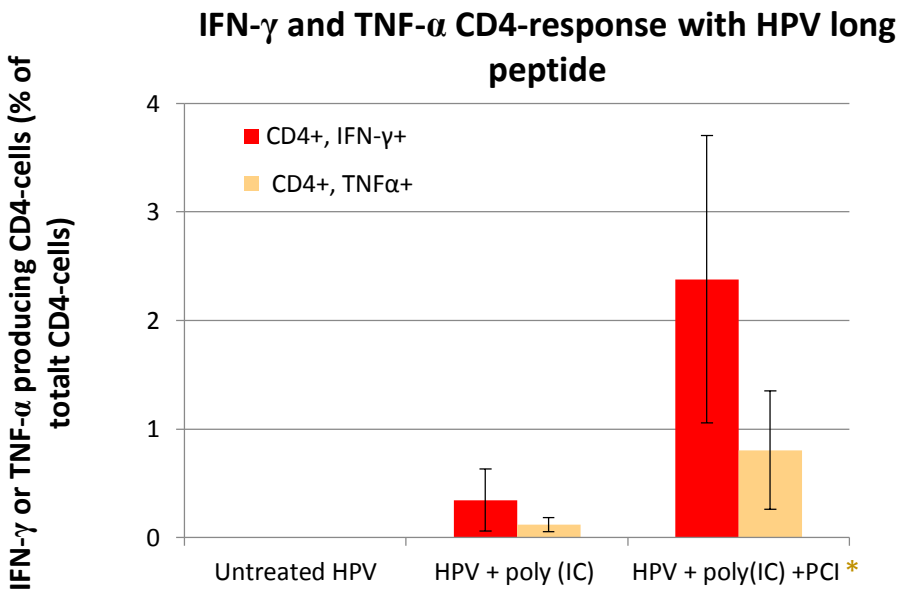
HPV ANTIGEN-SPECIFIC INDUCTION OF CYTOKINES

- Immunisation with **fima VACC** enhances level of cytokine producing CD8 and CD4 T-cells





*PCI = fima VACC

- Per cent IFN-γ- and TNF-α- producing cells after *in vivo* immunisation with **fima VACC** increased 10 and 7 times for CD8- and CD4-cells, respectively
- Phase I study with HPV antigen in healthy volunteers initiated – read-out 1H 2017

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NUCLEIC ACID THERAPEUTICS

- A treatment modality with huge potential

- 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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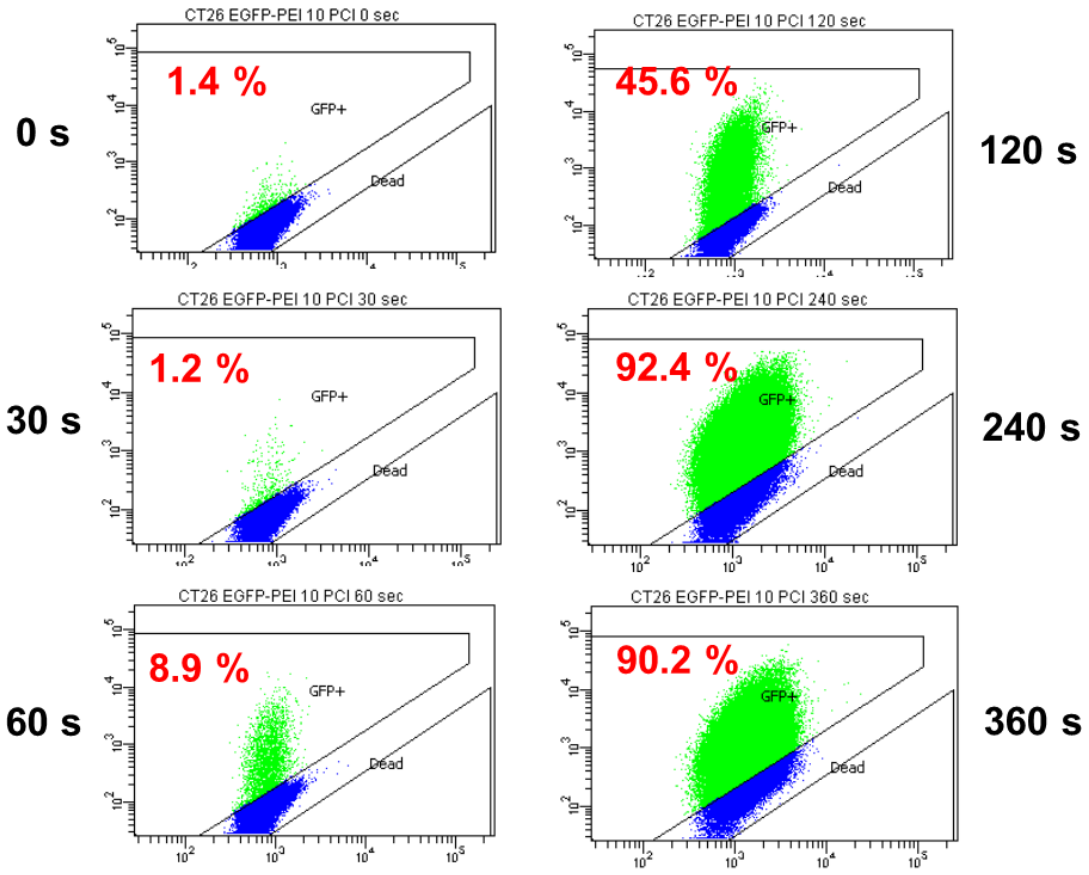
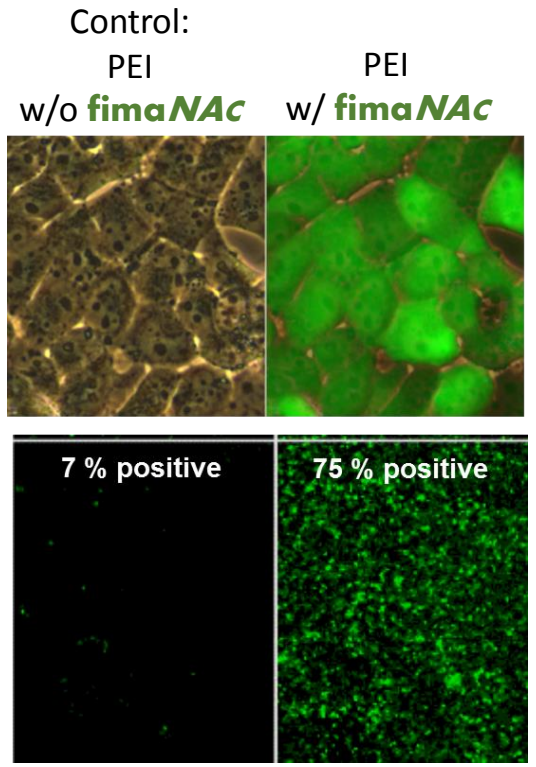
* Research and Markets “RNAi therapeutics market”. Dec 2015

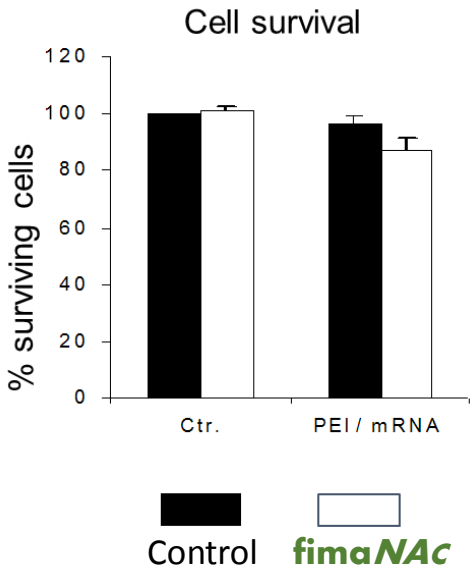
ENHANCING mRNA DELIVERY

- Strongly increased GFP synthesis with increasing light doses

fimaNAc with polyethylenimine (PEI) vehicle







RESEARCH COLLABORATIONS

- Four active collaborations within nucleic acid therapeutics and vaccination

fimaNAc

Top-10 large pharma company

- Agreement signed in 3Q 2015 and further extended in 2Q 2016
- Evaluate synergistic effects between companies' technologies
- One of the global leaders in nucleic acid therapeutics
- Collaborative research funded by partner

RXi Pharmaceuticals

- Agreement signed 2Q 2015
- RXi Pharmaceuticals listed on Nasdaq (NASDAQ: RXII)
- Discovers and develops innovative therapeutics within dermatology and ophthalmology

BioNTech

- Agreement signed Q3 2016
- BioNTech AG is a fully integrated biotechnology company developing individualised cancer immunotherapies
- Pioneering disruptive technologies ranging from individualised mRNA medicines through innovative Chimeric Antigen Receptors and T-cell Receptor products and novel antibody checkpoint immunomodulators.

fimaVACC

Ultimovacs

- Agreement signed 1Q 2016
- Ultimovacs AS, Norwegian immunotherapy company
- Developing UV1, a therapeutic cancer vaccine directed against human telomerase

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- Enquiries

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