BIO Europe

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Dr. Per Walday, CEO

PCI Biotech

PCI BIOTECH

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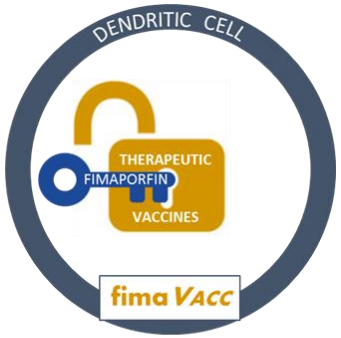
PCI BIOTECH AT A GLANCE

► Unlocking the potential of innovative medicines

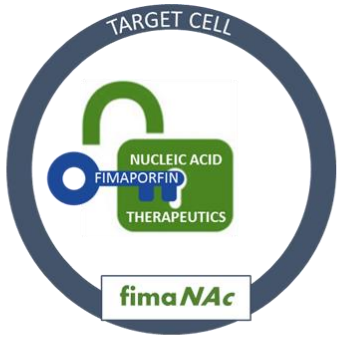
- A listed (PCIB:NO) cancer-focused biotech company
- Photochemical internalisation (“PCI”) technology, originating from the Norwegian Radium Hospital
- Clinical programmes
  - **fima*CHEM*** – Phase I/II with fimaporfin (Amphinex®) for the orphan indication inoperable bile duct cancer
  - **fima*VACC*** – Vaccination technology that provides strongly enhanced cellular immune responses, phase I initiated
- Pre-clinical programme
  - **fima*NAc*** – 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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PHOTOCHEMICAL INTERNALISATION

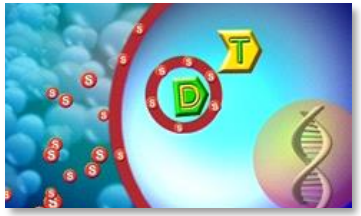
► Triggered endosomal release through illumination

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

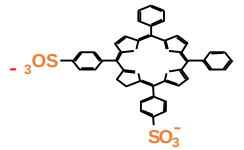
The active molecule

- 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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CHEMOTHERAPEUTICS

- A cornerstone in current cancer therapy

Chemotherapeutics will remain a **CORNERSTONE** in cancer treatment for the foreseeable future

PCI may enhance approximately **20%** of relevant approved chemotherapies

Niche indications may allow for **ORPHAN DRUG** applications

- **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 bile duct cancer with promising early signs of efficacy
- Opportunity for development in further niche indications

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

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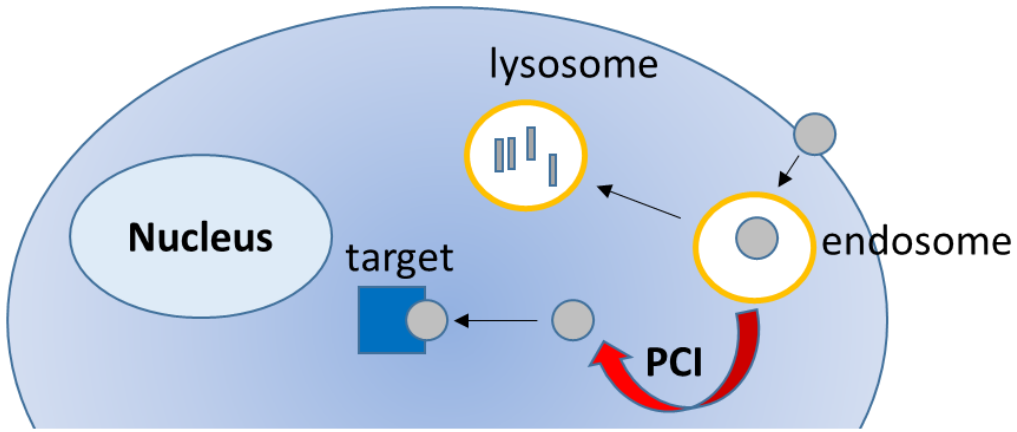
PCI TECHNOLOGY

▶ fimaCHEM – mode of action

Cancer cell



chemotherapeutic

Chemotherapeutics

Endocytosis

fimaCHEM

Release into cytosol

Lysosomal Breakdown

E.g.

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

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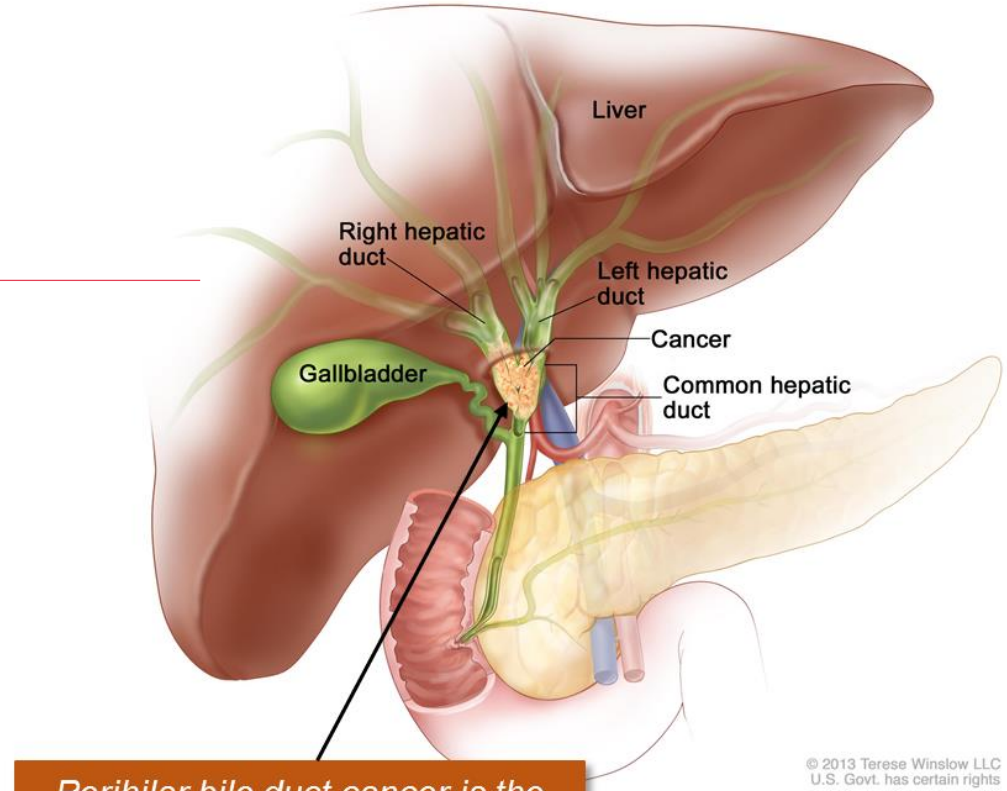
BILE DUCT CANCER

▶ The unmet need

- Rare disease (1-2 per 100,000)
  - Intrahepatic tumours (10%*)
  - Perihilar tumours (60-70%*)
  - Distal tumours (20-30%*)
- Five-year survival <5%; 0% when inoperable (avg. 12mo survival)
- Current management
  - Surgery is the only potentially curative treatment
    - Less than ⅓ are resectable
  - Stenting
    - **Endoscopic** stenting for palliative biliary drainage
  - No approved chemotherapy
    - **Gemcitabine** and cisplatin recommended



Perihilar bile duct cancer is the initial target for PCI treatment

Excellent technology fit with PCI

Targeted illumination is done using standard endoscopic procedure

Active chemotherapy gemcitabine is significantly enhanced by **fima CHEM**

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* Bile duct cancer, Am Cancer Soc, 10/30/2013

BILE DUCT CANCER – 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 IV***	1		2	1	2
Cohort III		1	1	1	
Cohort II		1			2
Cohort I	1	1			1

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 in the study for 6 months after PCI treatment
- After 6 months patients are followed for survival only
- Commissioned central independent radiological expert evaluation of Cohort III & IV - expected requirement from regulatory authorities

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BILE DUCT CANCER – CLINICAL PHASE I/II STUDY

- Convincing response at target tumour level

- **6 months central read radiology data: Cohort III & IV – response at single lesion level**

Measurable lesions	Lesion shrinkage		Stable lesion	Lesion growth
19 (total number of targets selected across two central readers)	**17**	**12** (lesion not detectable)	**1** (<20% reduction & <10% increase)	**1** (>10% mass increase)
		5 (>20% mass reduction)		

- All images evaluated separately by two radiology experts
- **Shrinkage of almost 90% of selected target lesions, with more than 60% being undetectable at 6 months**
- "*Change in tumor size by RECIST correlates linearly with overall survival in Phase I oncology studies*" [1]

[2] ***"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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[1] Jain et al 2012 – JCO 30:2684-90 (analysis of 24 phase I studies)
[2] Valle et al 2010 – NEJM 362:1273-81 (landmark publication for cis-gem treatment in bile duct cancer)

IMMUNOTHERAPY

- A new hope for millions of patients

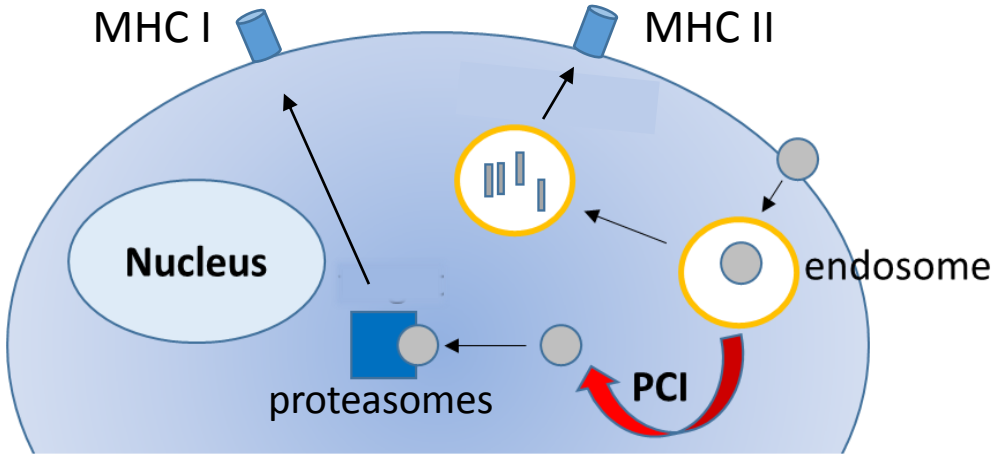
- fima VACC enhances cellular immune responses important for therapeutic effects
- Initiated Phase I study in healthy volunteers for clinical validation
- Aim is to out-license the technology on non-/semi-exclusive basis
- Opportunity to develop own therapeutic vaccination products

* Citi Research "Immunotherapy – the beginning of the end for cancer". Baum, May 2013
** Clinicaltrials.gov. Therapeutic cancer vaccines, PCIB analysis, August 2016
*** CPI: Checkpoint inhibitors

PCI TECHNOLOGY

▶ fima VACC – mode of action

Dendritic cell



vaccine antigen

Vaccine

fima VACC

MHC Class I

↓

Generate more disease specific cytotoxic T-cells

↓

Attack cancer and virus-infected cells more efficiently

MHC Class II

↓

Antibodies and helper T-cells

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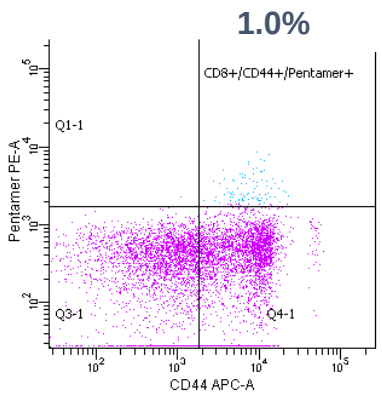
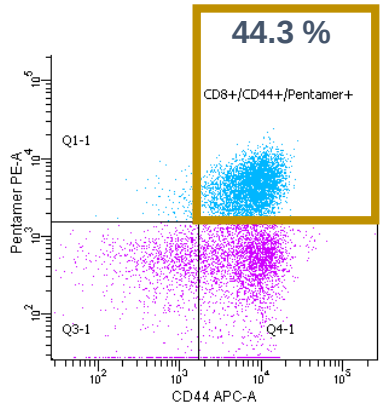
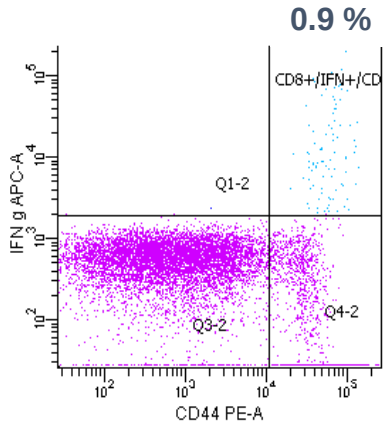
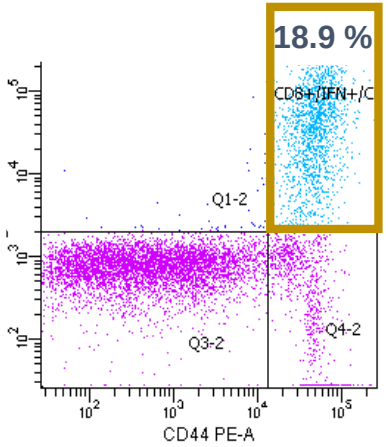
fima VACC STRONGLY ENHANCES VACCINATION EFFECTS

- Impressive effects with clinically relevant HPV therapeutic vaccine in mice

	Vaccination without fima VACC	Vaccination with fima VACC
Amount of activated antigen-specific CD8 T-cells in blood		
Amount of activated antigen-specific CD8 T-cells in spleen		

Cytotoxic (CD8) T-cells

- Most important immune cells to fight tumours
- Difficult to induce with vaccination
- fima VACC strongly enhances the ability of vaccines to induce CD8 T-cells:
  - >20 and >40 times enhancement seen in spleen and blood cells, respectively
  - Generation of immunological memory

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THERAPEUTIC VACCINATION WITH fima VACC

- Opportunity to play a key role in second generation immunotherapy

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

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

Open-label, antigen-adjuvant controlled study in up to 80 healthy volunteers initated

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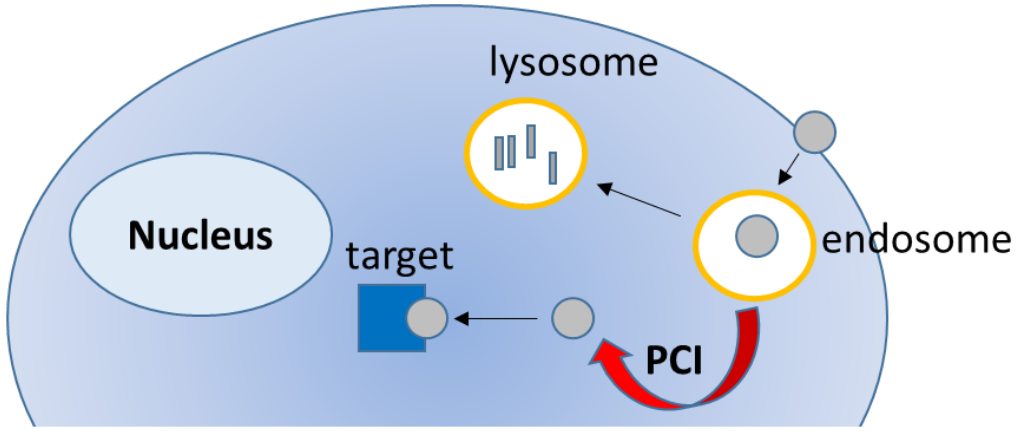
* Research and Markets “RNAi therapeutics market”. Dec 2015

PCI TECHNOLOGY

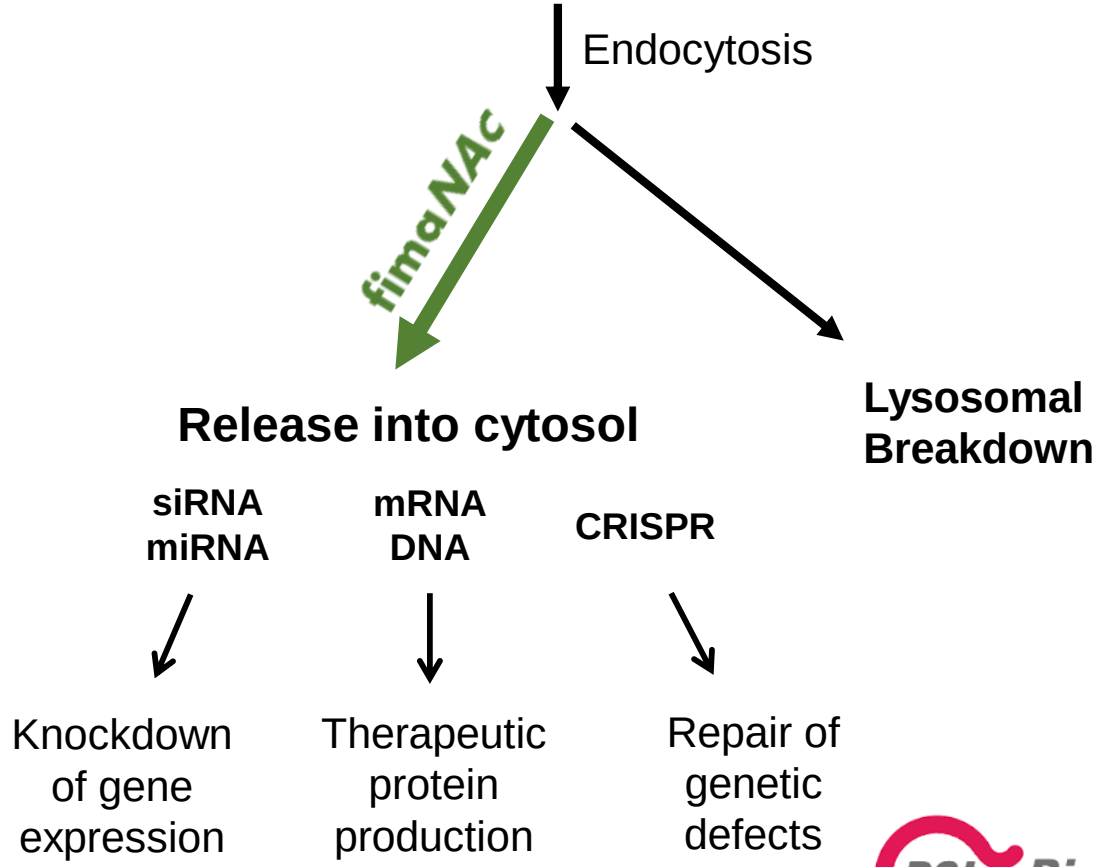
▶ fimaNAc – mode of action

Target cell



nucleic acid therapeutic

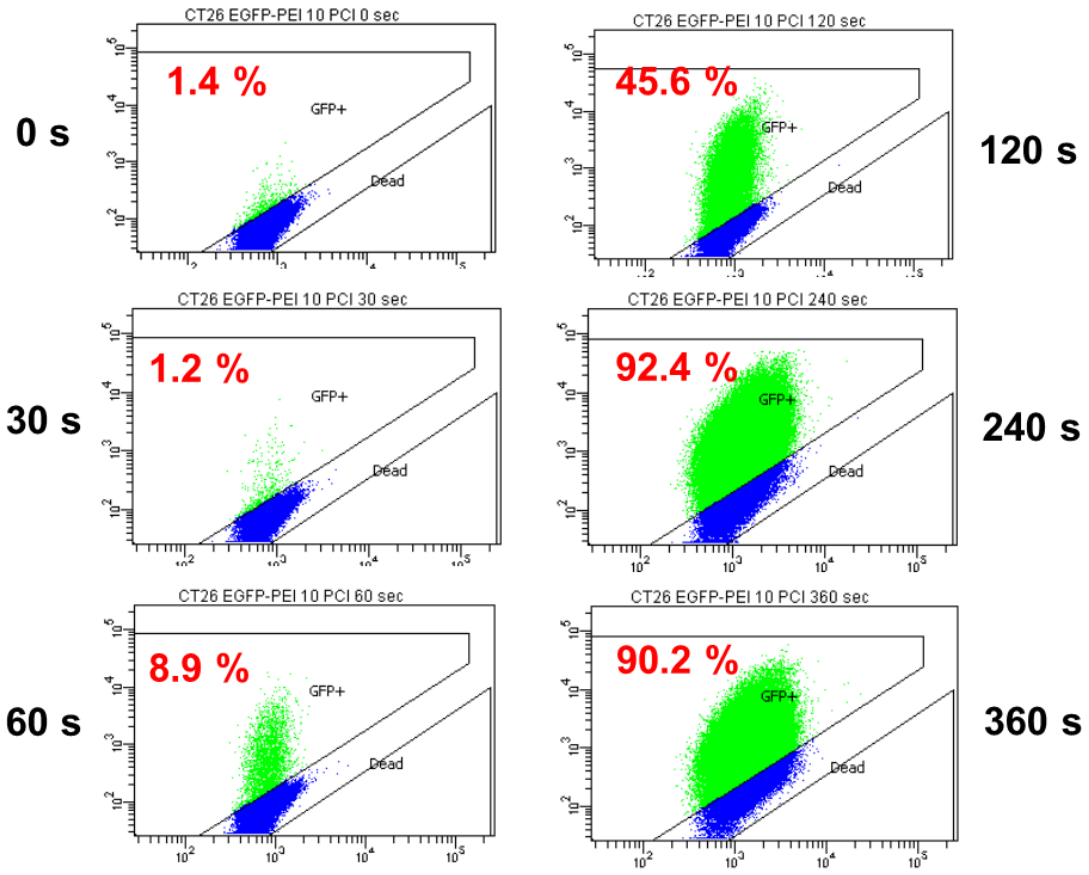
Nucleic Acid Therapeutics

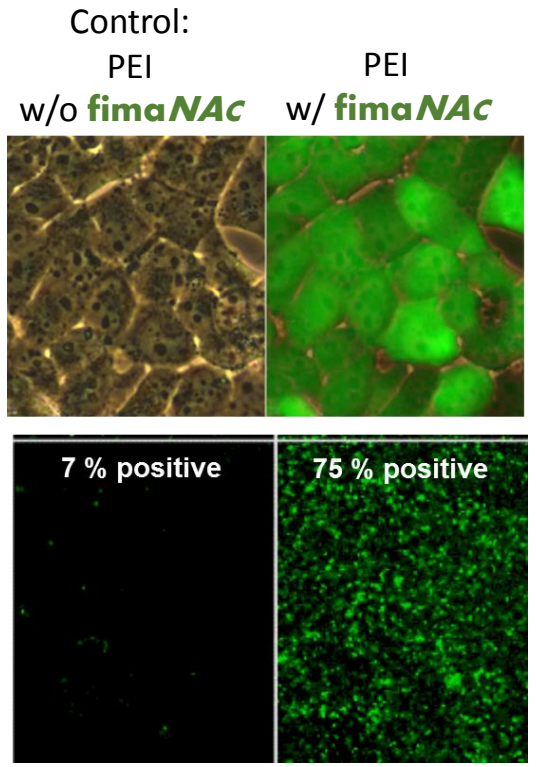


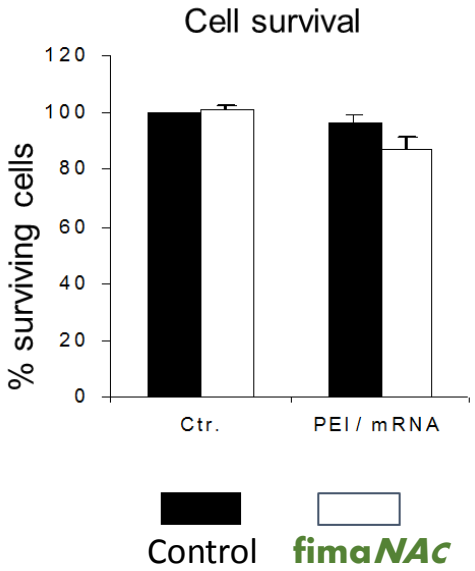
ENHANCING mRNA DELIVERY

- 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

RXi Pharmaceuticals

- Initiated 2Q 2015
- Listed on Nasdaq
- Innovative therapeutic siRNA
- Clinical programs in dermatology and ophthalmology

Top-10 large pharma

- Initiated 3Q 2015
- A global leader in nucleic acid therapeutics
- Collaborative research funded by partner
- Evaluate synergistic effects between companies' technologies

fimaVACC

BioNTech

- Initiated 3Q 2016
- German biotechnology company developing individualised cancer immunotherapies
- Clinical programmes in melanoma, head & neck, breast, ovarian and pancreatic cancer

Ultimovacs

- Initited 1Q 2016
- Norwegian immunotherapy company
- Therapeutic cancer vaccine against human telomerase
- Clinical programs in prostate and lung cancer

DEVELOPMENT PIPELINE

- Unlocking the true potential of innovative medicines

Programme	Therapeutic agents	Preclinical	Phase I	Phase II	Status
fimaCHEM	*Chemotherapeutics*				Phase I in the orphan indication bile duct cancer completed with promising early signs of efficacy
fimaVACC	*Therapeutic cancer vaccines*				Phase I study ongoing One active R&D collaboration
fimaNAc	*Nucleic acid therapeutics*				Three active R&D collaborations

An oncology focused company with three well differentiated assets

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