5th Annual Cancer BioPartnering & Investment Forum

28 March, 2017

Per Walday, CEO

PCI Biotech

PCI BIOTECH

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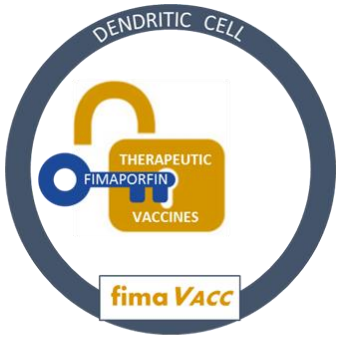
PCI BIOTECH AT A GLANCE

► Unlocking the potential of innovative medicines

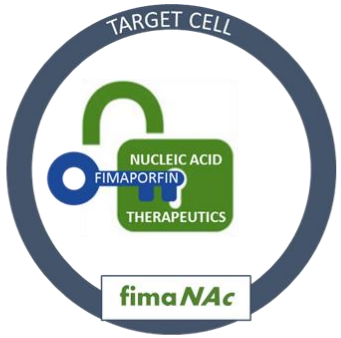
- A listed (PCIB:NO) cancer-focused biotech company
- Photochemical internalisation ("PCI") technology, originating from the Norwegian Radium Hospital
- Clinical programmes
  - **fima CHEM** – fimaporfin (Amphinex®) for the orphan indication inoperable bile duct cancer, Phase I completed
  - **fima VACC** – 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 four 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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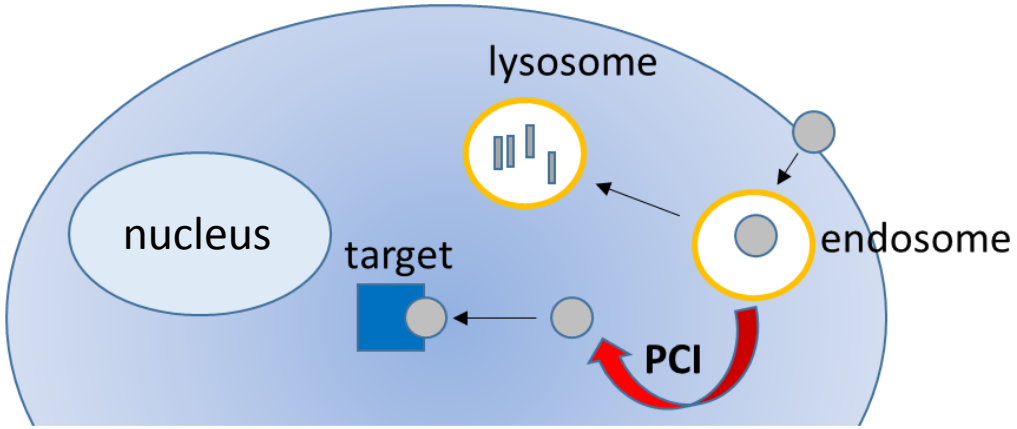
- Enabling drugs to reach intracellular therapeutic targets

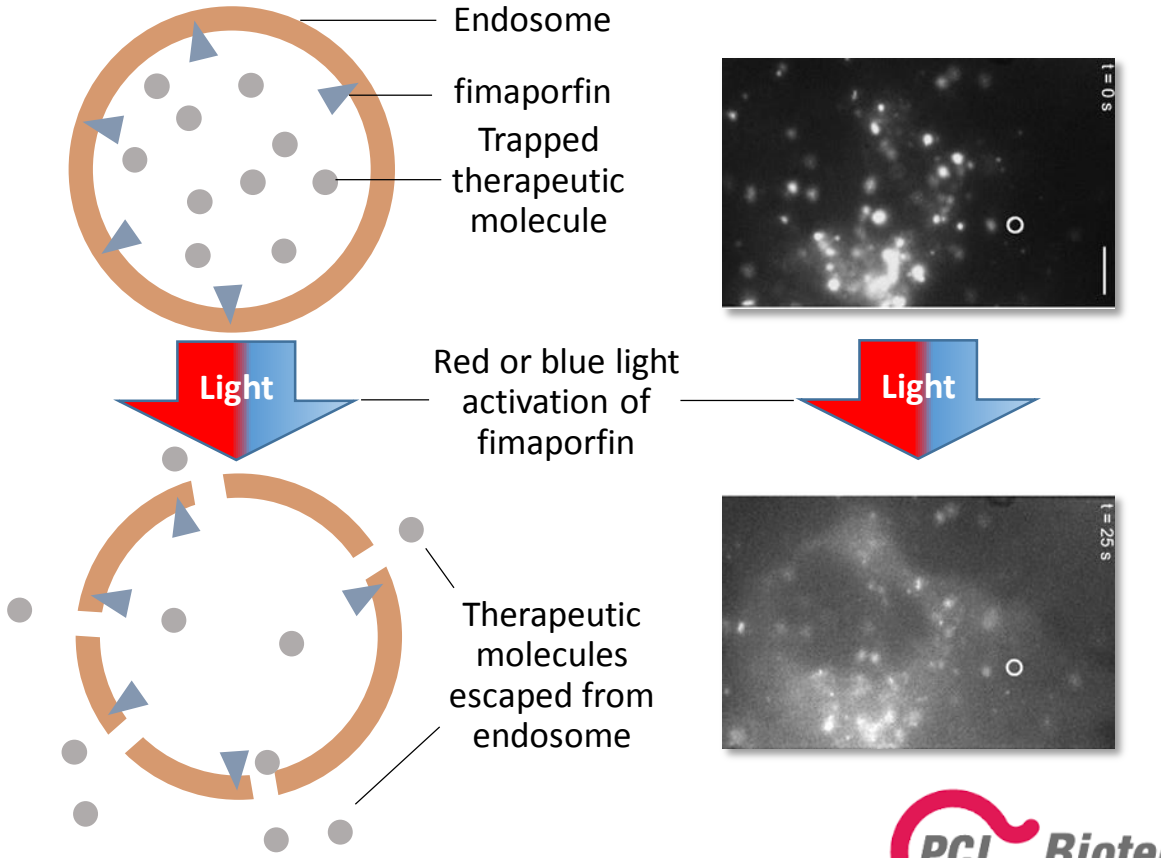
CELL SYSTEM



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

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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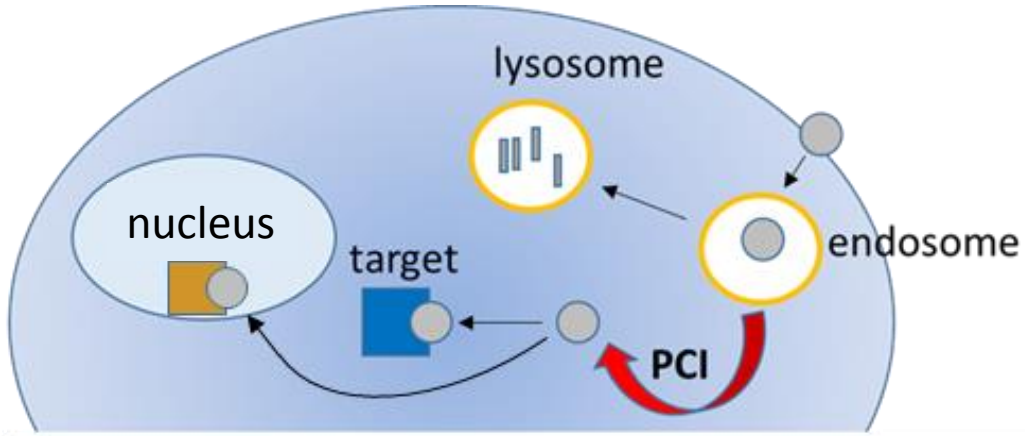
PCI TECHNOLOGY

▶ fimaCHEM – mode of action

Cancer cell



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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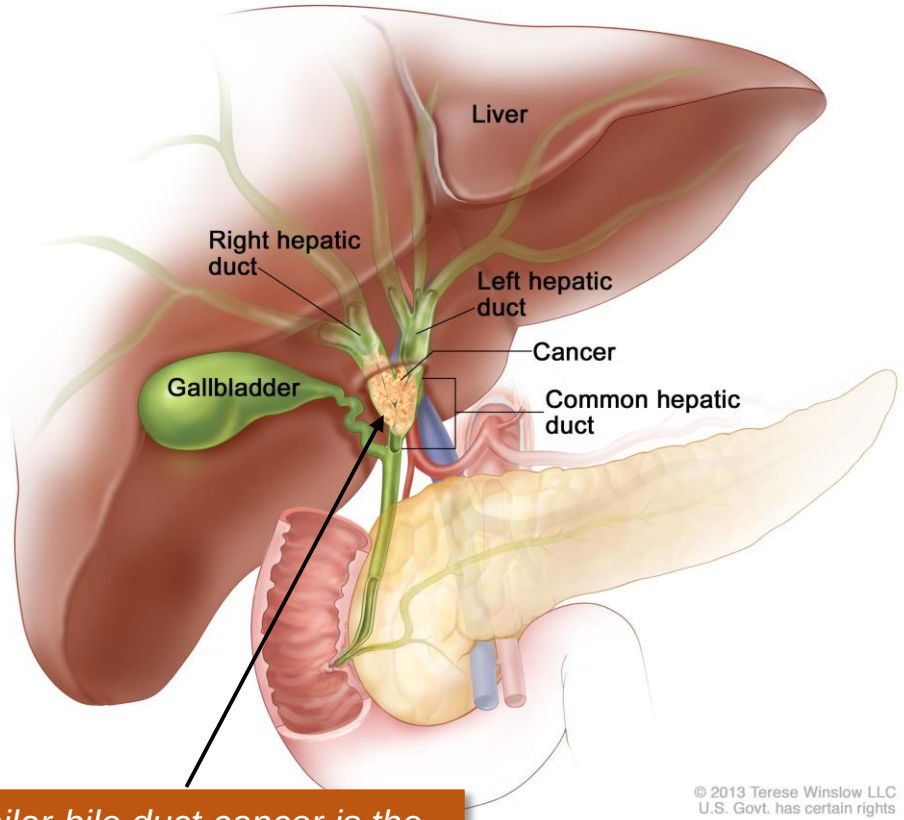
BILE DUCT CANCER

► Location and classification

- Often referred to as cholangiocarcinoma
- The cancer cells originates from the cells inside the bile duct (called cholangiocytes)
- Cholangiocarcinoma includes:
  - Intrahepatic tumours (10%*)
  - Perihilar tumours (60-70%*)
  - Distal tumours (20-30%*)
  - Different incidence, pathobiology and management



Perihilar bile duct cancer is the initial target for PCI treatment

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

BILE DUCT CANCER

▶ The unmet need

- Rare disease, yearly 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 – average approx. 12 months survival
- Current management
  - Surgery
    - Only potentially curative treatment
    - Less than ⅓ are resectable at presentation
  - Stenting
    - **Endoscopic** stenting for palliative biliary drainage
  - Chemotherapy
    - No approved chemotherapy
    - Recommended chemotherapy: **gemcitabine** and cisplatin

Excellent technology fit with PCI

Targeted illumination is done using standard endoscopic procedure

The active chemotherapy gemcitabine is significantly enhanced by fima CHEM

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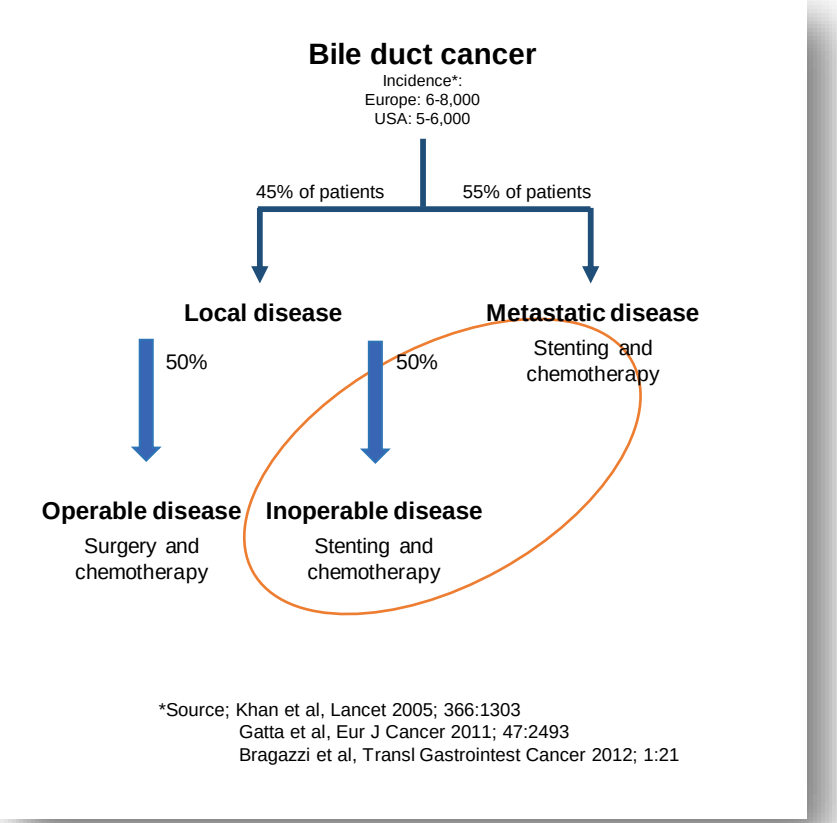
Bile Duct Cancer

A sizeable orphan market potential

- **Immediate target market is as first line treatment**
  - Incidence is close to 15,000 across Europe and the US
  - Immediate target is inoperable patients with primary hilar disease
  - Approximately 3,000 assumed to be eligible for fimaCHEM
  - Possible upside in distal and more advanced metastatic disease
  - Higher incidences in Asia
- **Attractive price potential**
  - Lack of approved medicinal treatment options
  - Diseases with <10,000 in US support annual pricing >$100,000[1]
- **Potential significant majority share of the market**
  - Anticipated benefits
    - No competing marketable treatment alternatives
    - Greater efficacy due to local chemotherapy boost
    - Easy light access through established standard procedures



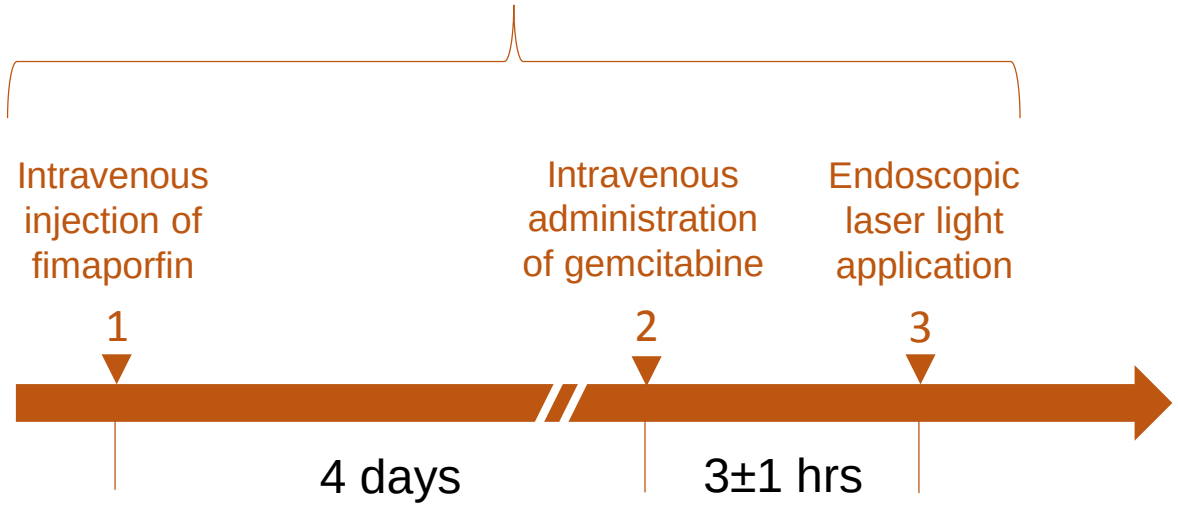
[1] LifeSciCapital, OD Market Sector Analysis 2016

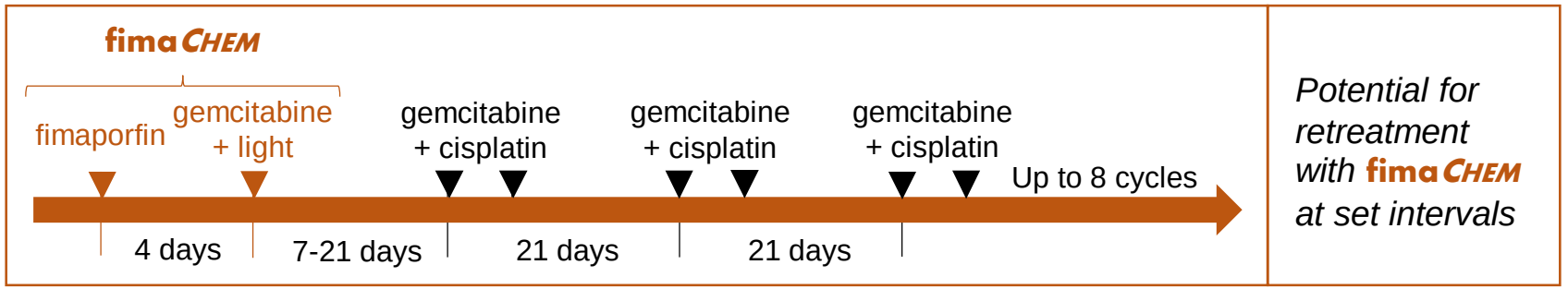
BILE DUCT CANCER

- A proven technology with excellent fit to standard procedures

fima CHEM

A three step treatment procedure





Potential for retreatment with fima CHEM *at set intervals*

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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 are 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, as this is an expected requirement from regulatory authorities

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BILE DUCT CANCER – CLINICAL PHASE I/II STUDY

- Six month radiology data – central read confirms promising early tumour response

Cohort III & IV – RECIST classification of patients

RECIST	PD	SD	PR	CR	NA*
Central read	2**	1	2	2	2

* Not measurable / Not radiologically evaluable
** Progressive disease due to appearance of new lesions

PD: Progressive disease (>20% growth)
SD: Stable Disease
PR: Partial Response (>30% shrinkage)
CR: Complete Response (no visible tumour)

Cohort III & IV – response at single lesion level

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

Phase I results presented as late-breaking news at United European Gastroenterology Week

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BILE DUCT CANCER

► Status and strategy going forward

- **Phase I completed with good tolerability and very promising early signs of efficacy**
  - No serious unexpected safety findings and no apparent increase in adverse reactions with increasing doses
  - Very promising early signs of efficacy – significant tumour shrinkage observed radiologically
  - Results verified at central evaluation by study-independent external radiological experts in RECIST
- **Orphan designation**
  - Granted Orphan Drug Designation in EU
  - Open IND in US – Orphan Drug application in process
- **Regulatory interactions with EU and US authorities, to determine fastest way to market**
  - Promising signs of efficacy in a life threatening orphan indication without approved treatment alternatives
  - May allow for marketing authorisation based on restricted data, e.g. a pivotal phase II study

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*** response rates

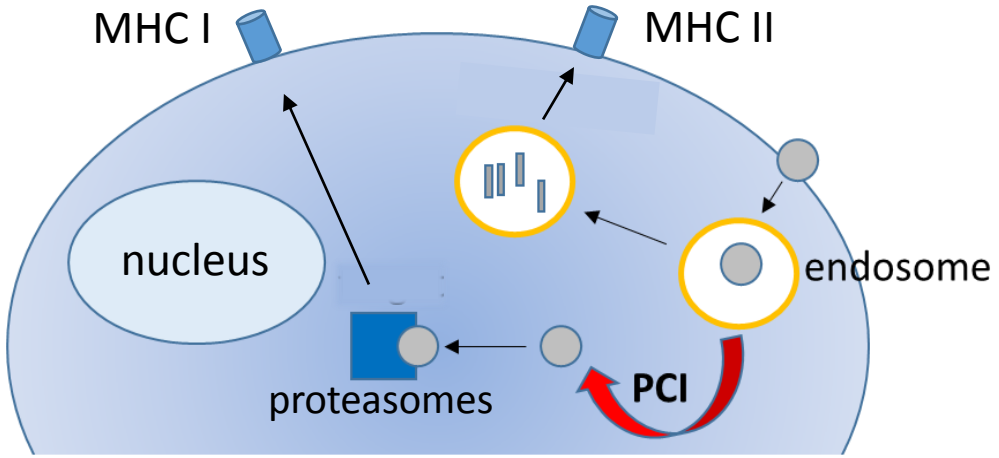
- **fima VACC** enhances cellular immune responses important for therapeutic effects
- Initiated Phase I study in healthy volunteers for clinical validation
- Aim is to out-license the technology on non-/semi-exclusive basis
- Opportunity to develop own therapeutic vaccination products

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

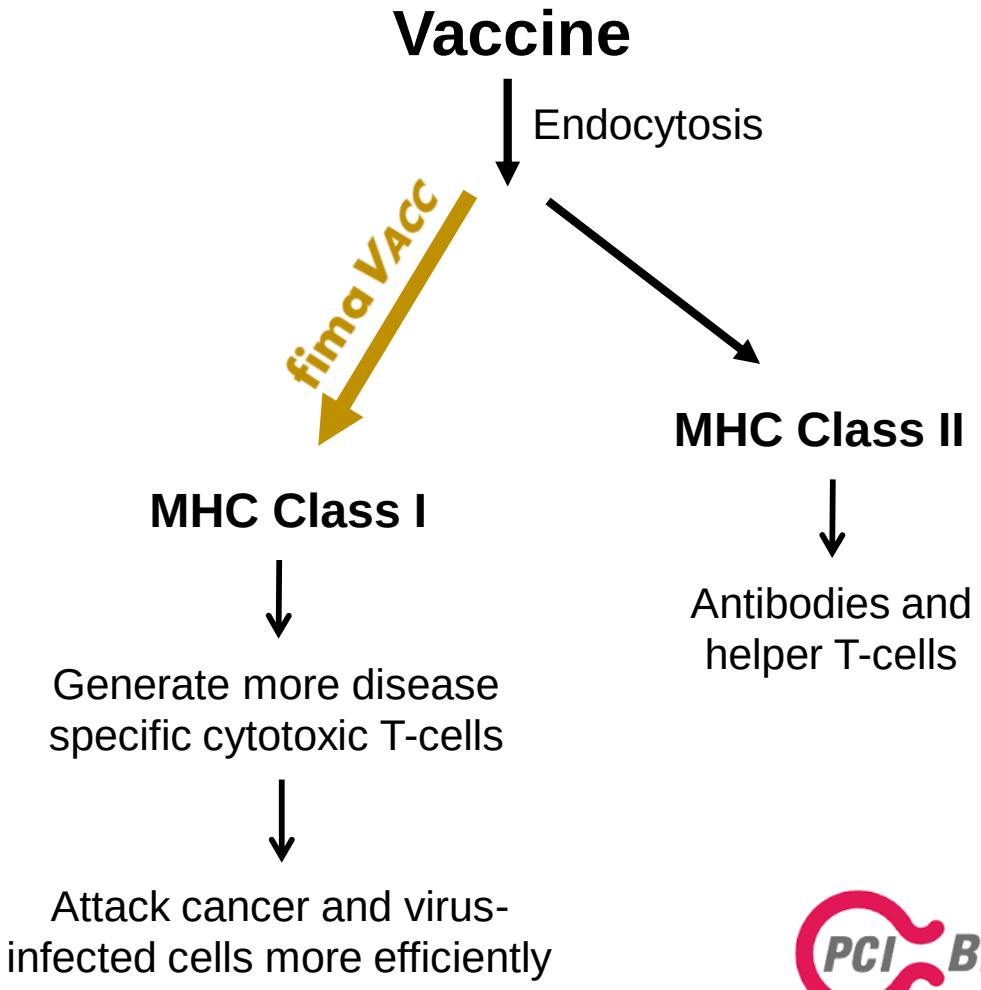
PCI TECHNOLOGY

▶ fima VACC – mode of action

Dendritic cell

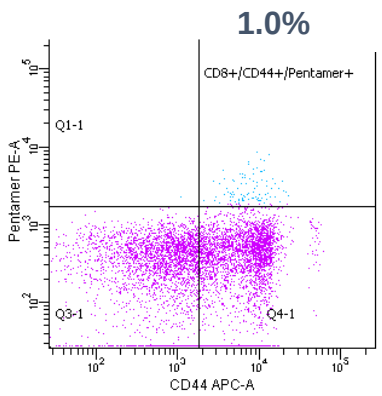
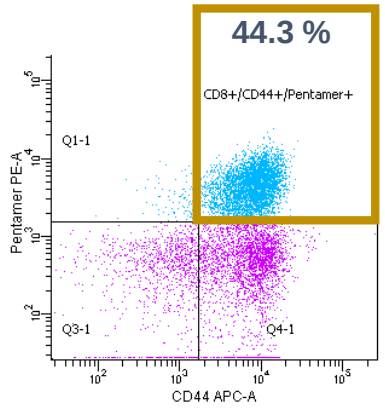
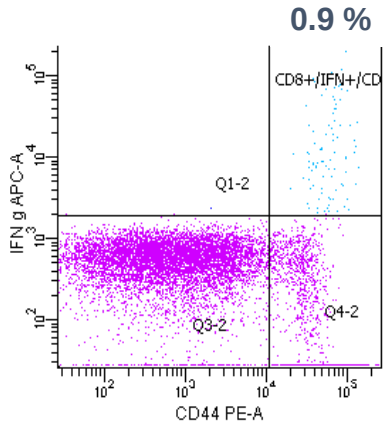
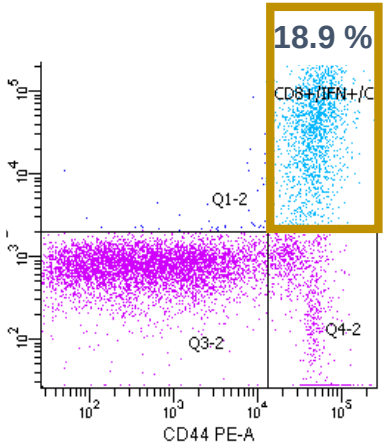


vaccine antigen



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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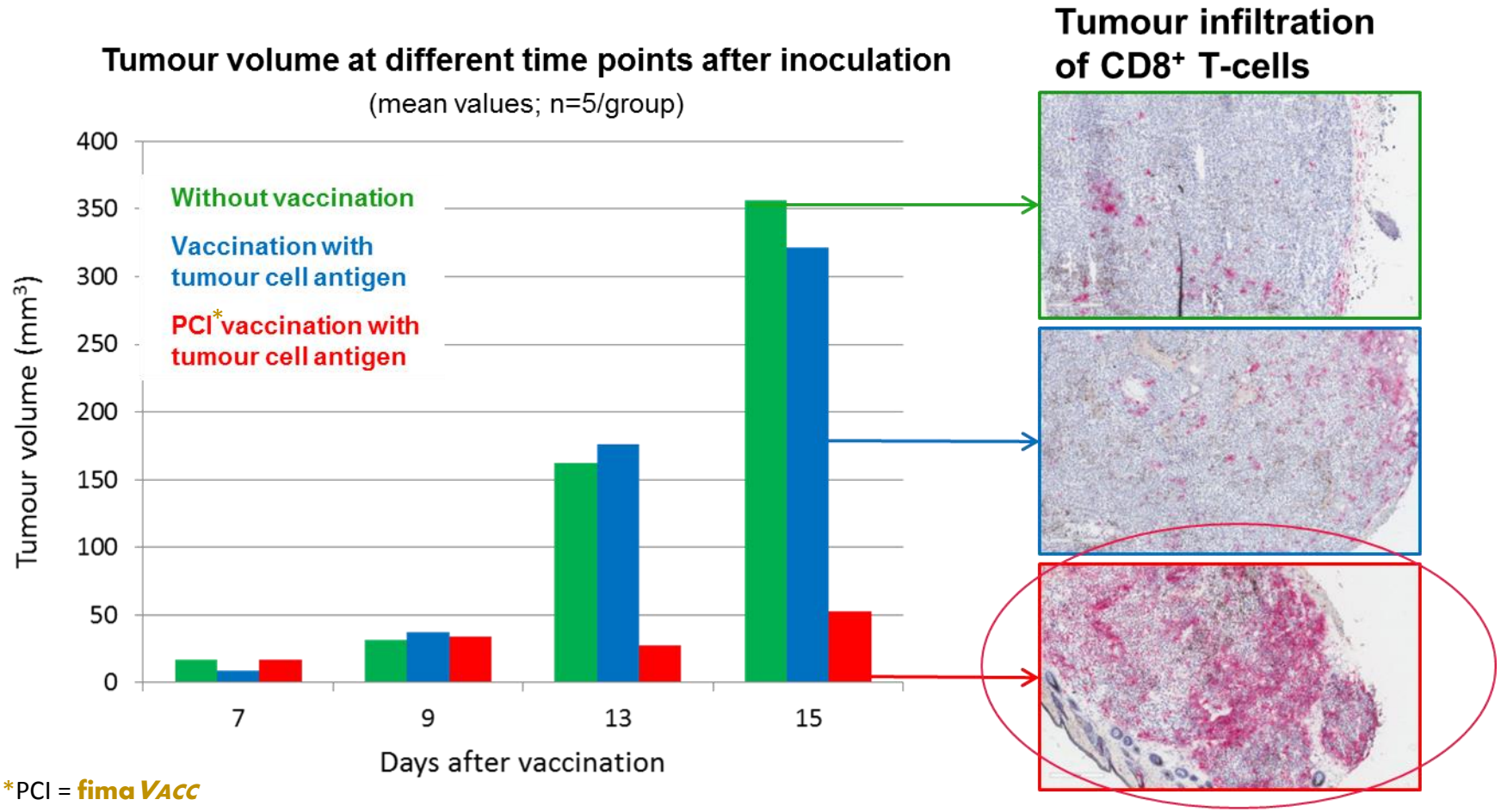
THERAPEUTIC VACCINATION IN TUMOUR MODEL

- **fima VACC** induces cytotoxic T-cells that infiltrate tumours

Therapeutic fima VACC vaccination with OVA in animal tumour model (B16-OVA melanoma/OT-1)



*PCI = fima VACC

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
- Ease of use
  - fimaporfin mixed with vaccine
  - intradermal vaccination
- Broad applicability
  - peptide and protein antigens
  - particulate antigen formulations
  - prophylactic & therapeutic vaccination
- Excellent stability and cost effective synthesis
- Phase I study in healthy volunteers initiated 3Q 2016

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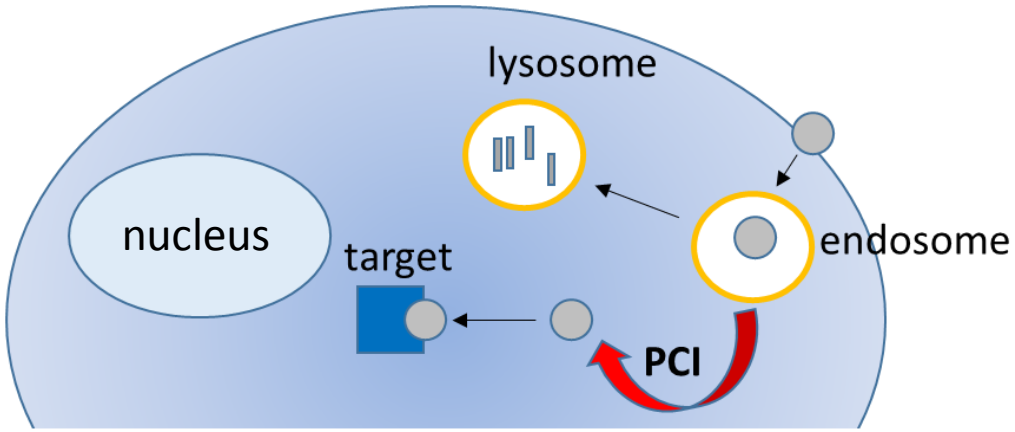
* Research and Markets “RNAi therapeutics market”. Dec 2015

PCI TECHNOLOGY

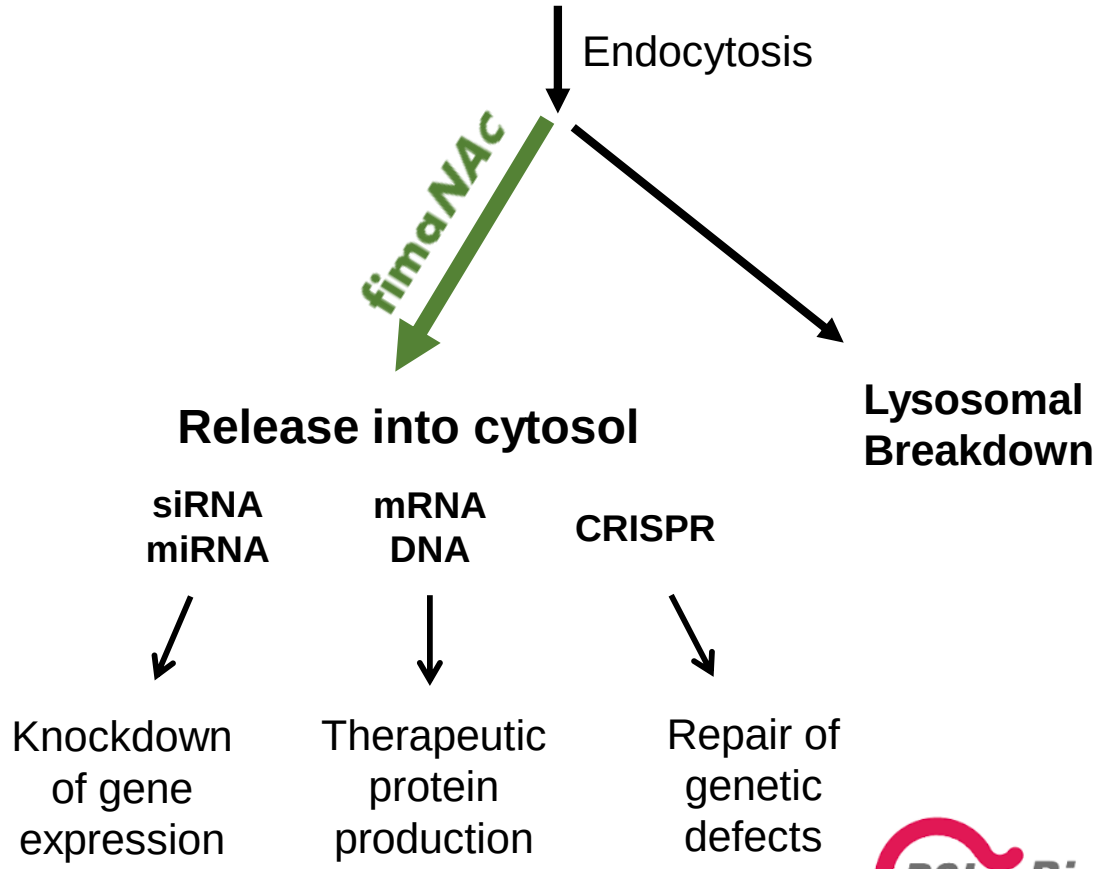
▶ fimaNAc – mode of action

Target cell



nucleic acid therapeutic

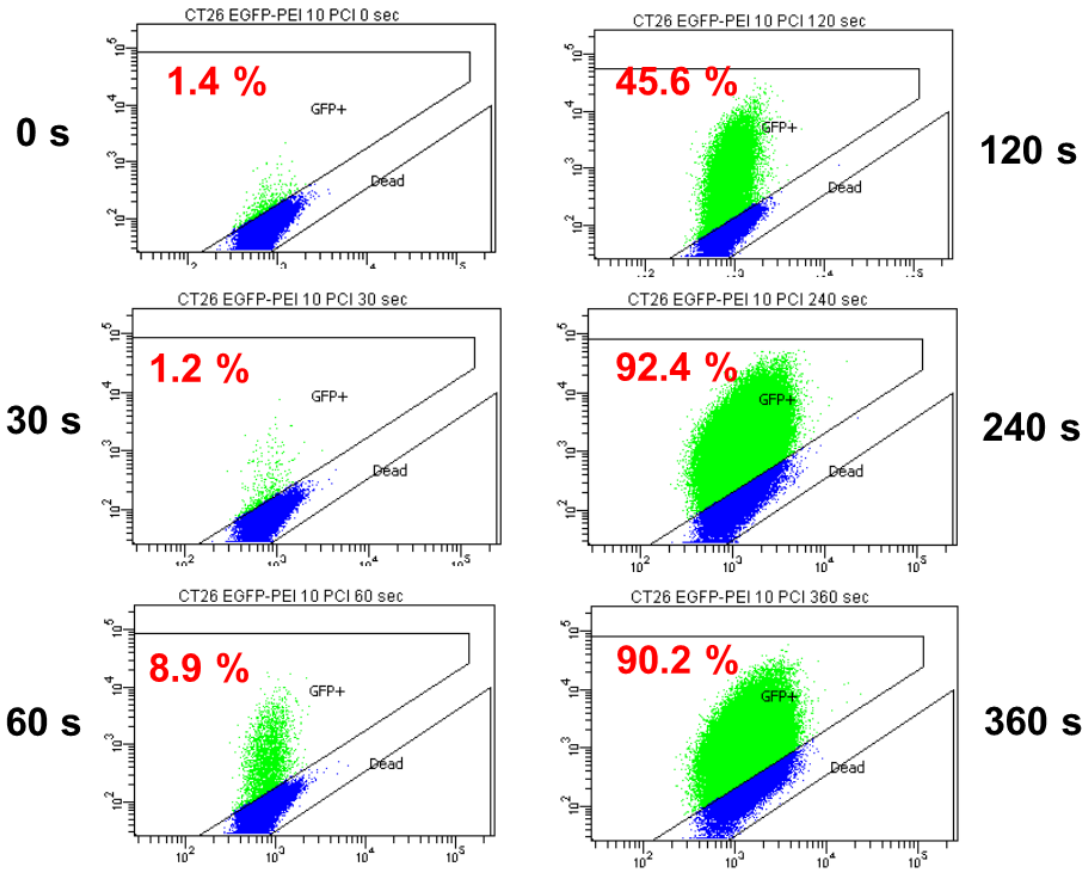
Nucleic Acid Therapeutics

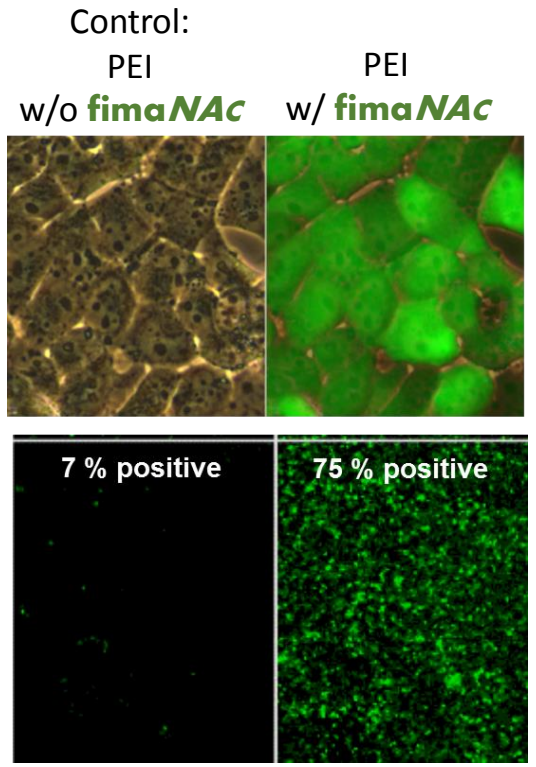


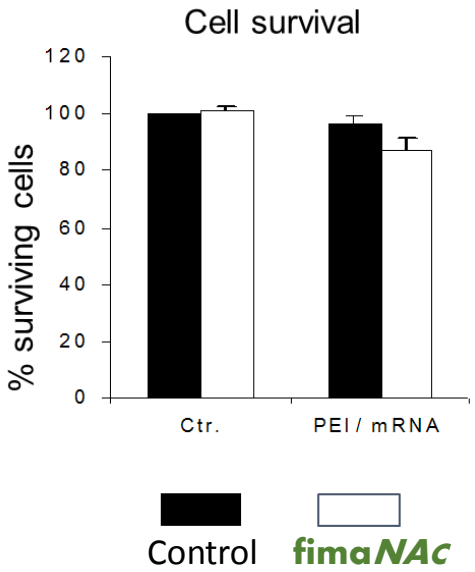
ENHANCING mRNA DELIVERY

- Strongly increased GFP synthesis with increasing light doses

fimaNAc with polyethylenimine (PEI) vehicle







VERSATILITY OF fimaNAc

- Delivery of many types of nucleic acid with many different vehicles *in vitro*

- **Main bottleneck in the field is delivery**
- fimaNAc can deliver many types nucleic acids
- Enhancement by fimaNAc is best under conditions favourable for vehicle safety
  - Low ratio of vehicle to nucleic acid
  - Low concentration of vehicle/nucleic acid complex
- Especially advantageous *in vivo*
  - Difficult to achieve a high concentration of vehicle/nucleic acid complex in target cells
  - Toxicity may limit the amount of vehicle used

Nucleic acids successfully delivered by fimaNAc

Type of nucleic acid	Delivery vehicle
Plasmids	PEI, cationic peptides, cationic lipids, polylysine ++ Targeting to EGF-R, transferrin-R
siRNA	PEI, cationic peptides, dendrimers, lipofectamine, DOTAP, nanogels, chitosan ++
PNA (peptide nucleic acids)	None, cationic amino acids attached
mRNA	PEI, Protamine
Adenoviral vectors	None, cationic polymers
AAV vector	None

Opportunistic approach – pursuing collaboration and partnering opportunities

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RESEARCH COLLABORATIONS

- Four active collaborations within nucleic acid therapeutics

fimaNAc

RXi Pharmaceuticals

- Initiated 2Q 2015
- Listed on Nasdaq
- Innovative therapeutic siRNA
- Clinical programmes 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

BioNTech

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

eTheRNA

Boosting the human immune system to fight diseases

- Initiated 4Q 2016
- Belgian immunotherapy company
- Proprietary TriMix platform programming dendritic cells with synthetic mRNA
- Clinical programmes in melanoma and triple negative breast cancer

Research collaborations aim to evaluate synergies between the fima platform and partner technologies, with the potential for further partnerships

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*				Four active R&D collaborations

An oncology focused company with three well differentiated assets

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