PCI BIOTECH - Company presentation at Jefferies

November, 2019

Dr Per Walday, CEO

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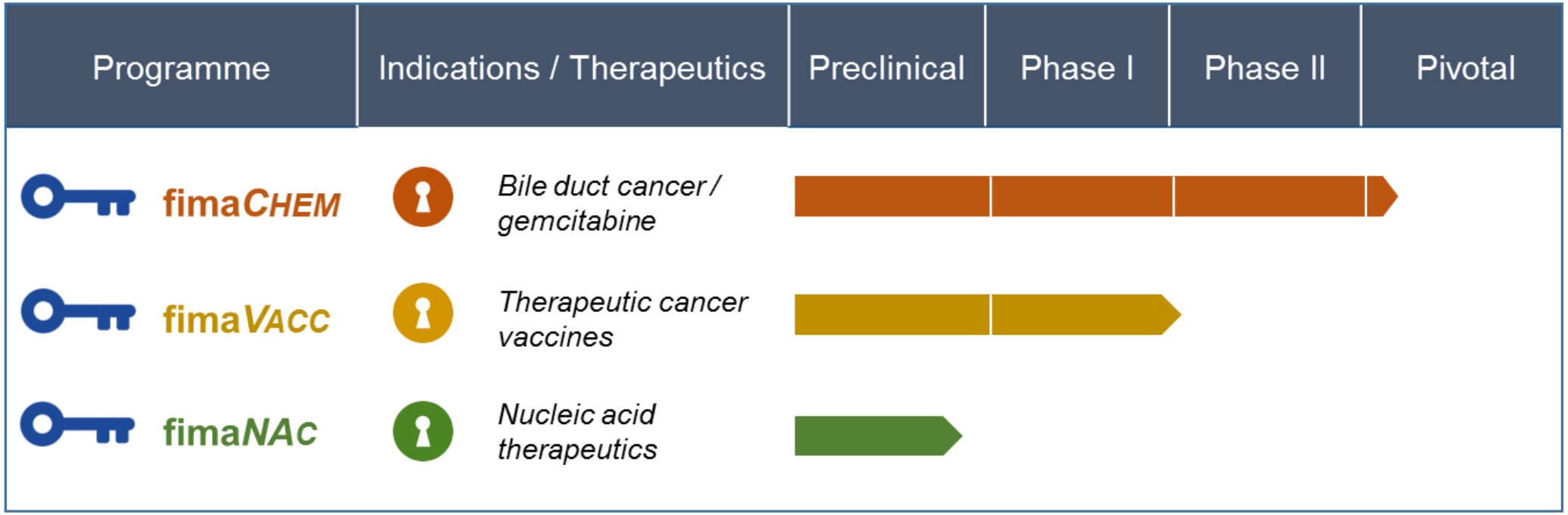
PCI BIOTECH AT A GLANCE

► *Unlocking the potential of innovative medicines*

► **A listed (PCIB:NO) cancer-focused biotech company with three well differentiated assets**

► **Photochemical internalisation ("PCI") platform technology**

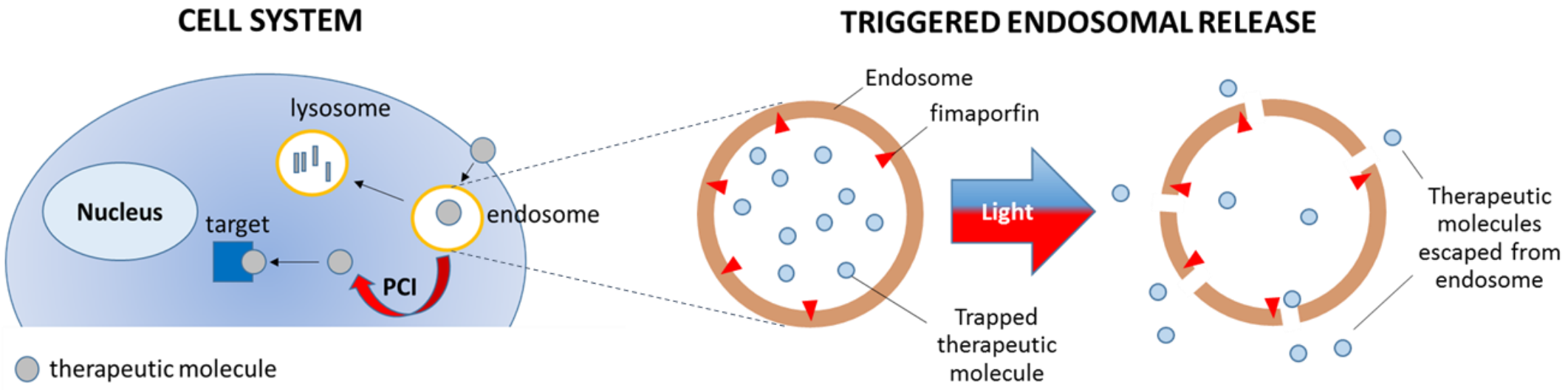
► **Mrkt Cap of approx. €100 mill, with €30 mill in cash per Q2 2019**



PCI TECHNOLOGY

- Enabling drugs to reach intracellular therapeutic targets

Mode of action



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

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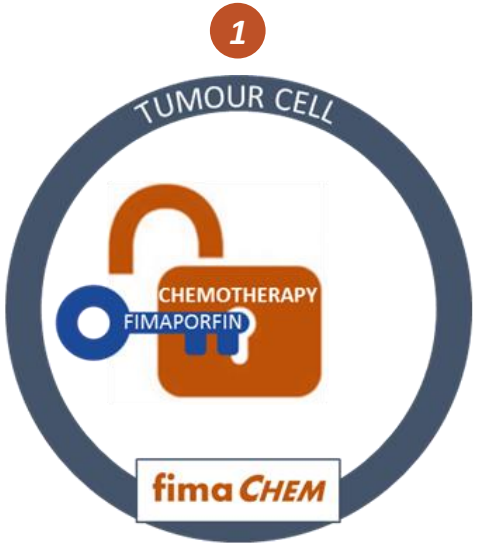
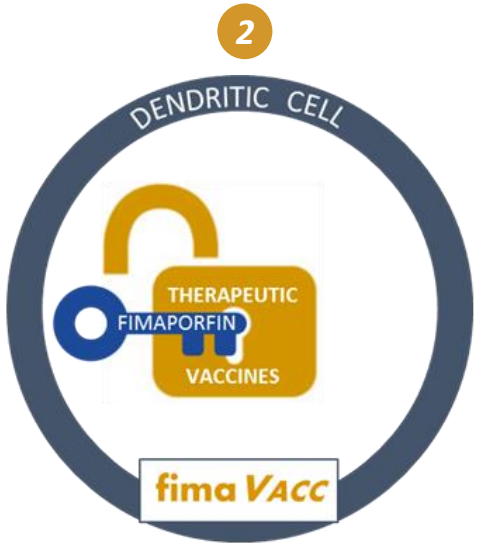
PCI TECHNOLOGY

- Broad application

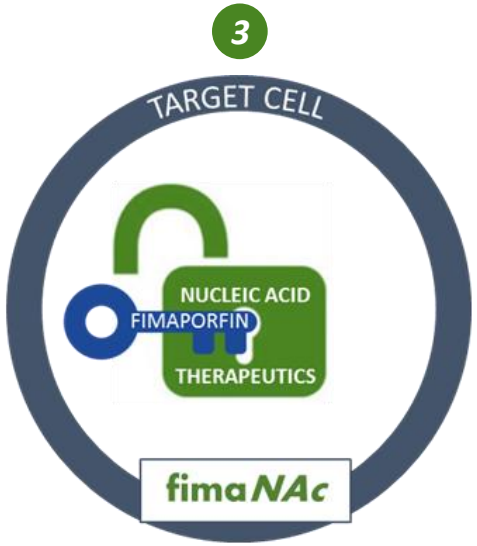
The solution to a key challenge for several modalities



Enabling approved drugs to fulfil unmet local treatment need



Enhancing cellular immune responses important for therapeutic effect

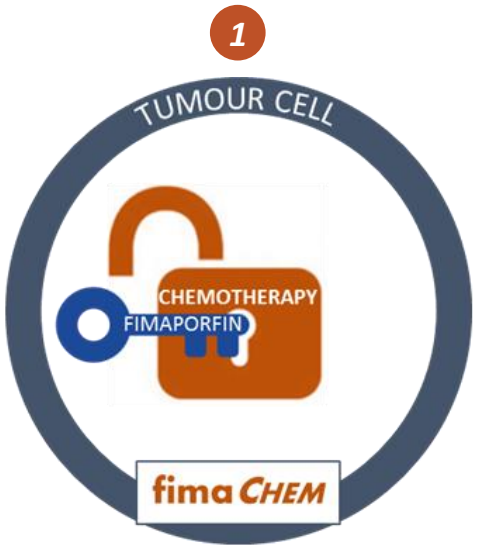


Providing a delivery solution for nucleic acid therapeutics

PCI TECHNOLOGY

- Broad application

The solution to a key challenge for several modalities



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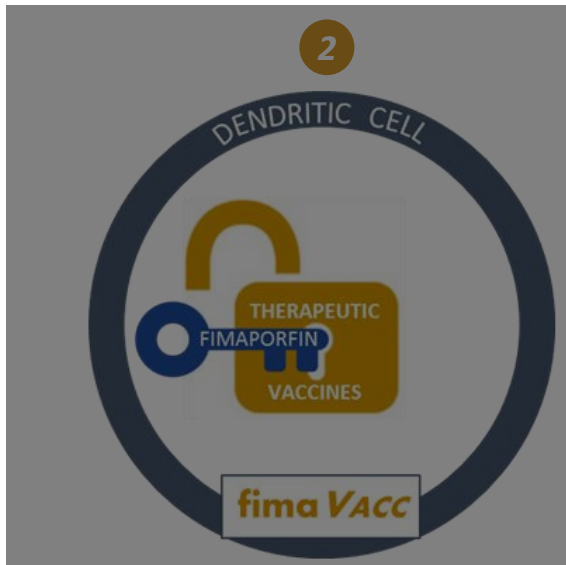

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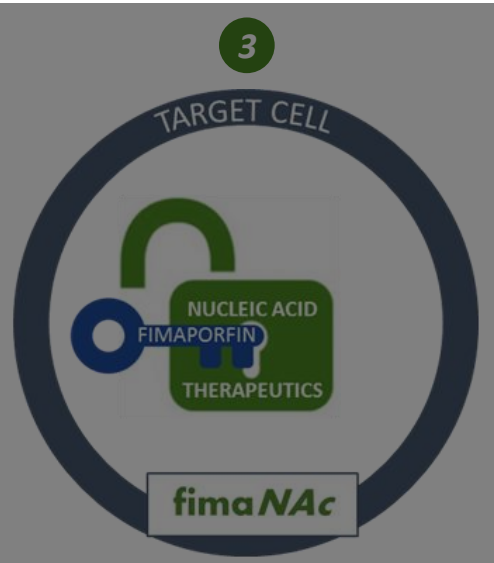
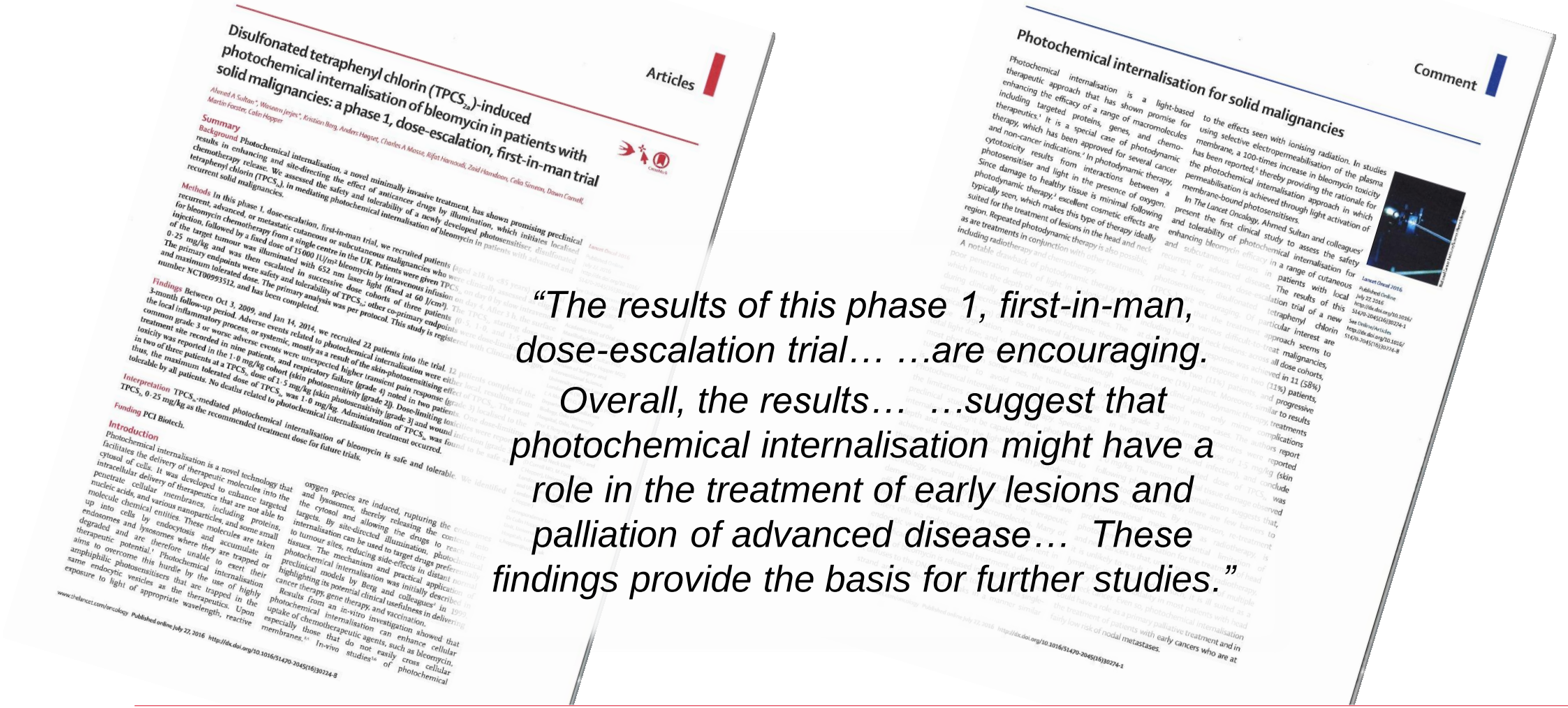


Providing a delivery solution for nucleic acid therapeutics

First-In-Man Study Published in Lancet Oncology[1]

- With independent expert commentary[2]



Articles

Disulfonated tetraphenyl chlorin ($TPCS_{2a}$)-induced photochemical internalisation of bleomycin in patients with solid malignancies: a phase 1, dose-escalation, first-in-man trial

Ahmed A Sultan*, Wassesen Jerjes*, Kristian Berg, Anders Hagget, Charles A Mosse, Rifat Hamoudi, Zaid Hamdoon, Celia Simeon, Dawn Carnell, Martin Forster, Colin Hopper

Summary

Photochemical internalisation for solid malignancies

Comment

"The results of this phase 1, first-in-man, dose-escalation trial… …are encouraging. Overall, the results… …suggest that photochemical internalisation might have a role in the treatment of early lesions and palliation of advanced disease… These findings provide the basis for further studies."

[1] Sultan et al (2016) Lancet Oncology 17(9):1217-1229
[2] Madsen (2016) Lancet Oncology 17(9):1173-1174

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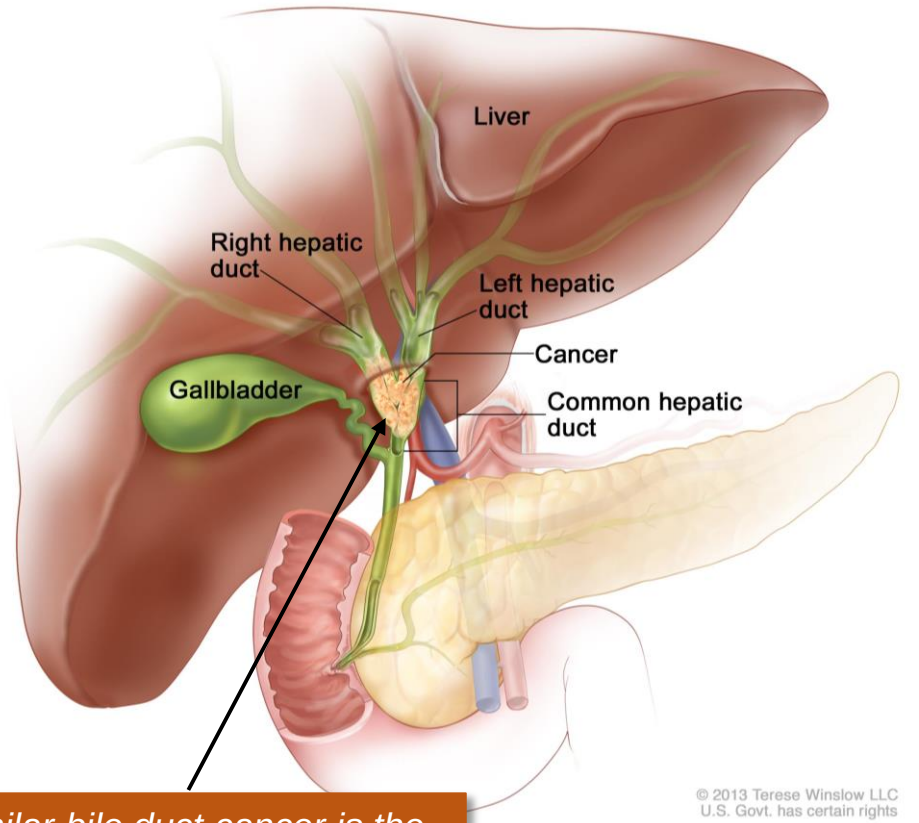
BILE DUCT CANCER

► 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%[1])
  - Perihilar tumours (60-70%[1])
  - Distal tumours (20-30%[1])
  - Different incidence, pathobiology and management



Perihilar bile duct cancer is the initial target for PCI treatment

1) Bile duct cancer, American Cancer Society, 30 October 2013

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BILE DUCT CANCER – EXTRAHEPATIC INOPERABLE

- Excellent fit between medical need and **fimaCHEM**

Enhancing the active and recommended chemotherapy

Easy illumination through standard endoscopic methods

Boosting chemotherapy effect where it is most needed

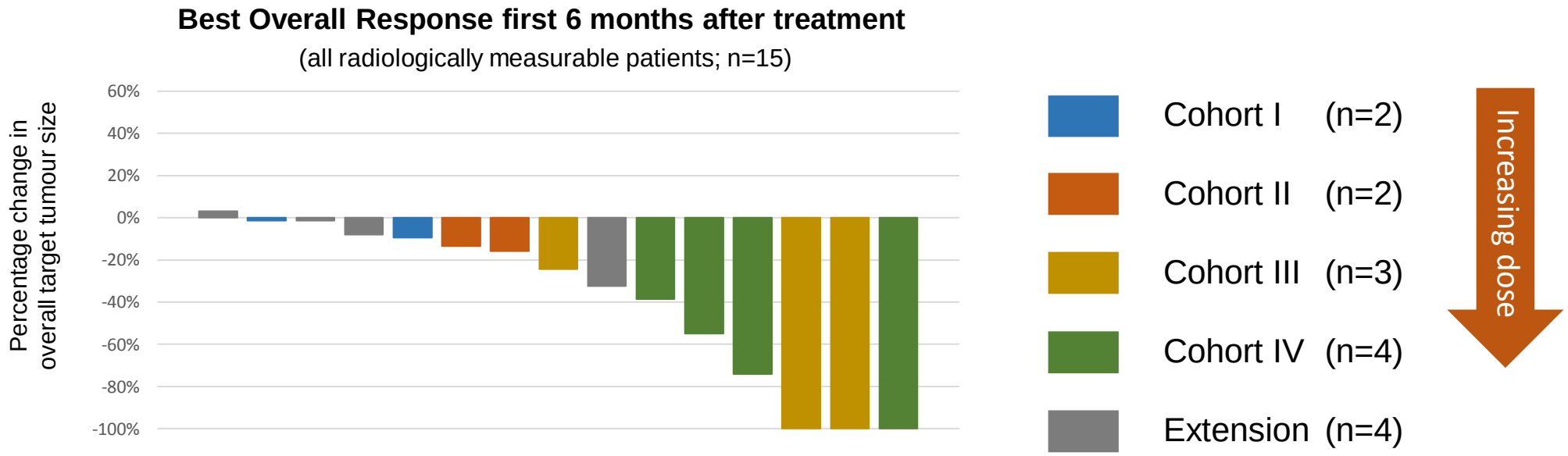
- Orphan indication
- Average survival inoperable: 11-12 months[1]
- Current management
  - Surgery
    - – Only potentially curative treatment
    - – Less than ⅓ are resectable at presentation
  - Stenting
    - – **Endoscopic** stenting for palliative biliary drainage
  - Chemotherapy
    - – No approved chemotherapy
    - – Recommended: **gemcitabine** and cisplatin

[1] N Engl J Med 2010;362:1273-81

BILE DUCT CANCER – PHASE I RESULTS

▶ Best Overall Response - patients with measurable disease in all cohorts

- Dominated by significant target tumour reduction in the first 6 months
- >20% reduction in tumor size was observed in 17 out of 19 target lesions in cohorts III and IV at 6 months, of these,12 lesions became undetectable (independent centralised read)
- Positive early signs of efficacy – mOS a of 21.7 months at selected dose in Cohort IV (n=6), with half of the patients surviving >30 months



[a] mOS – median overall survival

BILE DUCT CANCER – RELEASE STUDY DESIGN

- Randomised study with interim analysis for potential accelerated/conditional approval

- **Orphan designation granted in both the US and EU**
- **Fastest way to market determined through regulatory interactions with authorities**

- 1st line treatment of patients with inoperable extrahepatic bile duct cancer
- Approx. 40 key hospitals (Europe & USA)
- Formal interim analysis of PFS after approximately 60 progression events
- Approx. 36 months to interim and 50 to final analysis from initiation
- Randomisation (1:1) of 186 patients
- Primary endpoint: PFS[a], with OS[b] as key secondary
- Interim analysis primary endpoints: PFS followed by ORR[c]
- Regular IDMC[d] review, but no formal futility stop

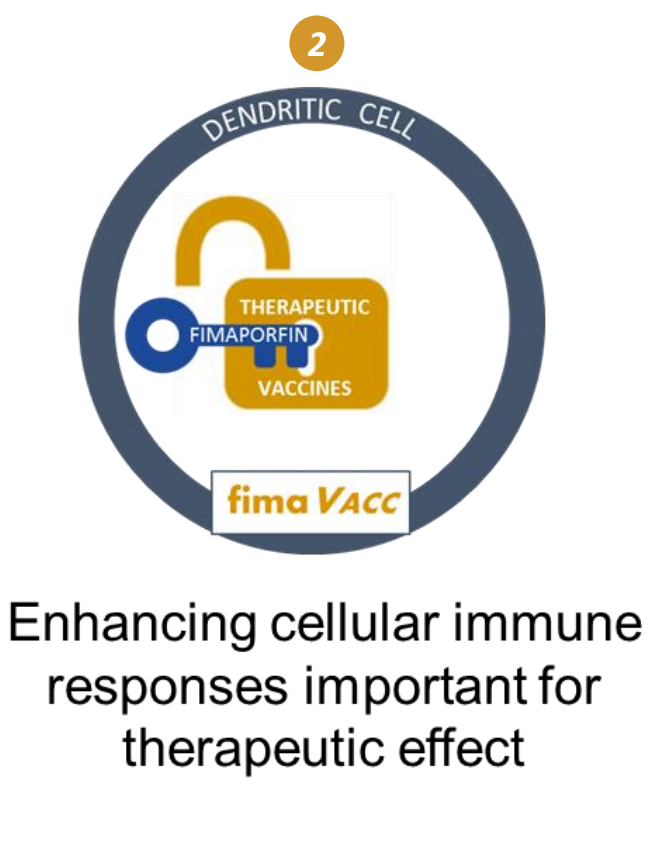
- **First patient included in Europe May 2019**
- **Prevalence of bile duct cancer is higher in Asia – planned expansion to Asian sites**

[a]PFS: Progression Free Survival; [b]OS: Overall Survival; [c]ORR: Objective Response Rate; [d]IDMC: Independent Data Monitoring Committee

PCI TECHNOLOGY

- Broad application

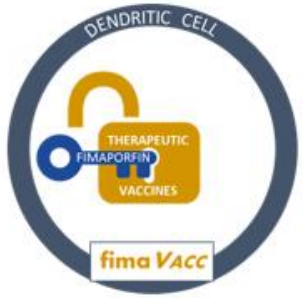
The solution to a key challenge for several modalities



fima VACC TECHNOLOGY – STRONG POTENTIAL

- Opportunity to play a key role in second generation immunotherapy

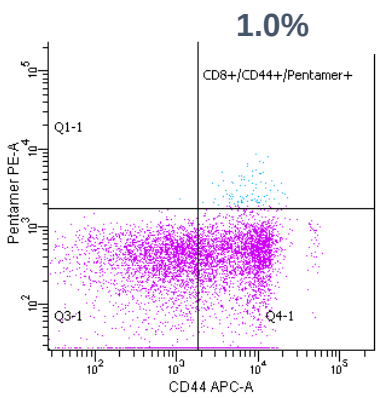
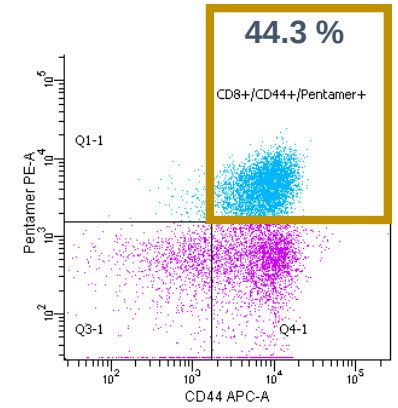
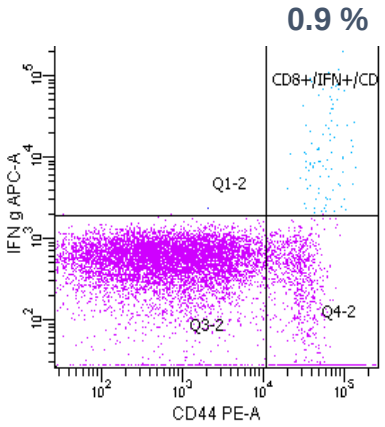
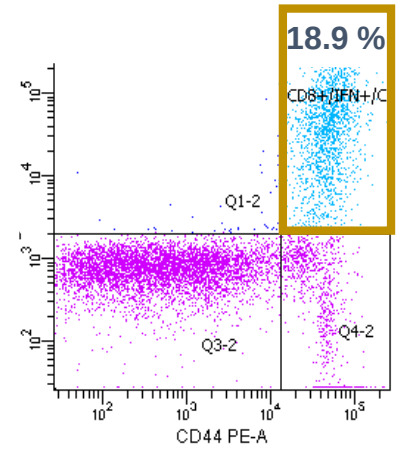
- Unique mode of action for CD8 T-cell induction
  - CD8 induction by MHC class I antigen presentation in dendritic cells and macrophages
- Broad applicability
  - Peptide and protein antigens - prophylactic & therapeutic vaccination
- Excellent stability of fimaporfin
  - Stable at room temperature in solution and can be autoclaved
- Strong preclinical data set
  - Clear understanding of mode of action for CD8 induction
- Completed Phase I clinical study with more than 90 subjects enrolled
  - Safety of intradermal administration established across a wide range of doses
  - Successful clinical proof of concept with enhanced immune responses



Enhancing cellular immune responses important for therapeutic effect

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

Source: PCI Biotech data

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SUCCESSFUL CLINICAL PROOF OF CONCEPT

- Phase I study in healthy volunteers – vaccination with HPV E7 long peptides

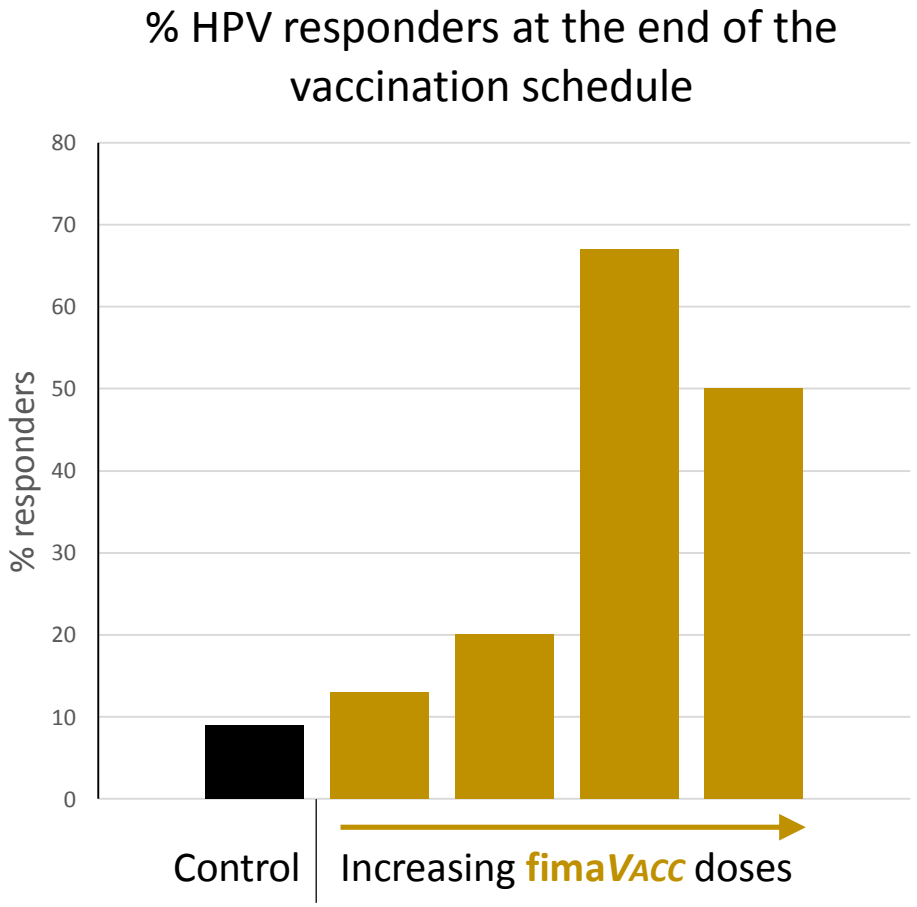
- **Compared to control (Hiltonol) fimaVACC induces:**
  - **Substantial increase in number of T-cell responders to HPV E7 peptides**
  - **Clearly enhanced overall T-cell responses**
  - **More robust CD8 T-cell responses (notoriously difficult to induce with E7)**
  - **Increased functionality of the induced CD8 T-cells**

fimaVACC provides:

- ✓ ***Increased number of responders***
- ✓ ***Enhanced T-cell responses***
- ✓ ***Improved T-cell functionality***

OVERALL T-CELL RESPONSES – HPV E7 PEPTIDES

- Substantial increase in the percentage of subjects responding to vaccination



fimaVACC induces more overall T-cell (CD4 + CD8) responders than the control with a state of the art adjuvant technology (Hiltonol), after completion of the HPV E7 vaccination schedule

SOLID PROGRESS OF THE fimaVACC PROGRAMME

► Successful clinical proof of concept

- The Phase I study provides successful clinical proof of concept for **fimaVACC**
  - Proof of concept and efficacy in terms of intradermal dosing in humans
  - A positive overall characterisation of tolerability, with efficacy seen across a wide tolerable dose span
- Strategy for **fimaVACC** is two-pronged; utilising the Phase I results in direct partnering efforts and plan for clinical proof-of-concept in a disease setting

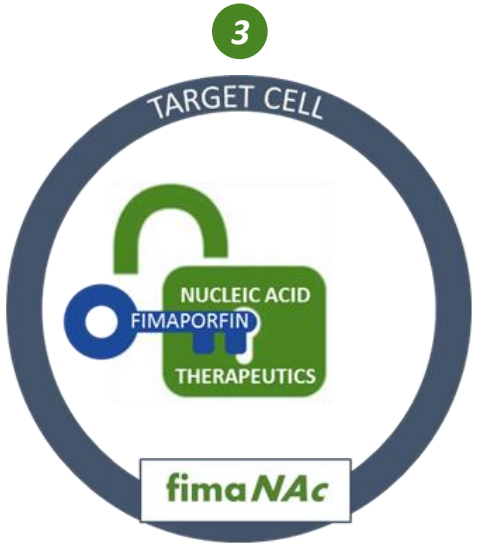
PCI TECHNOLOGY

- Broad application

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

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

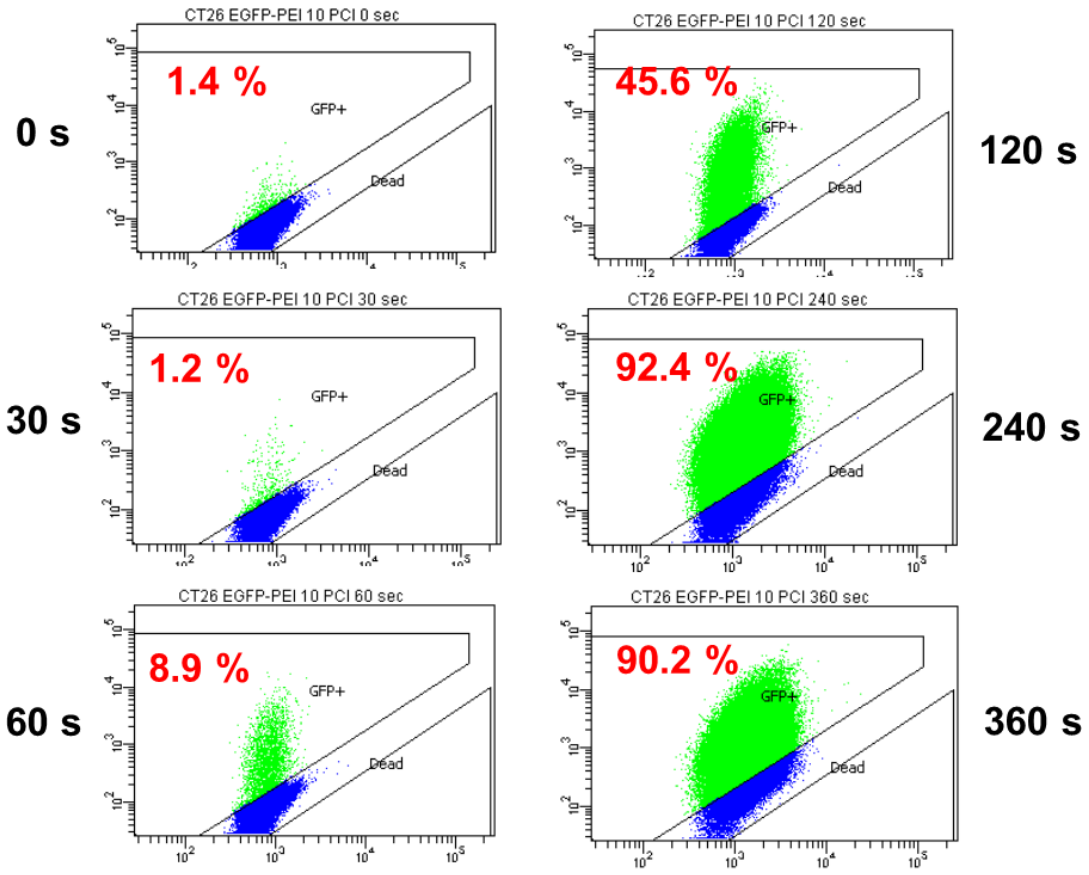
Type of nucleic acid	Delivery vehicle
Plasmids	PEI, cationic peptides, cationic lipids, polylysine ++ Targeting to EGF-R, transferrin-R
siRNA	PEI, cationic peptides, dendrimers, lipofectamine, DOTAP, nanogels, chitosan ++
PNA (peptide nucleic acids)	None, cationic amino acids attached
mRNA	None, PEI,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

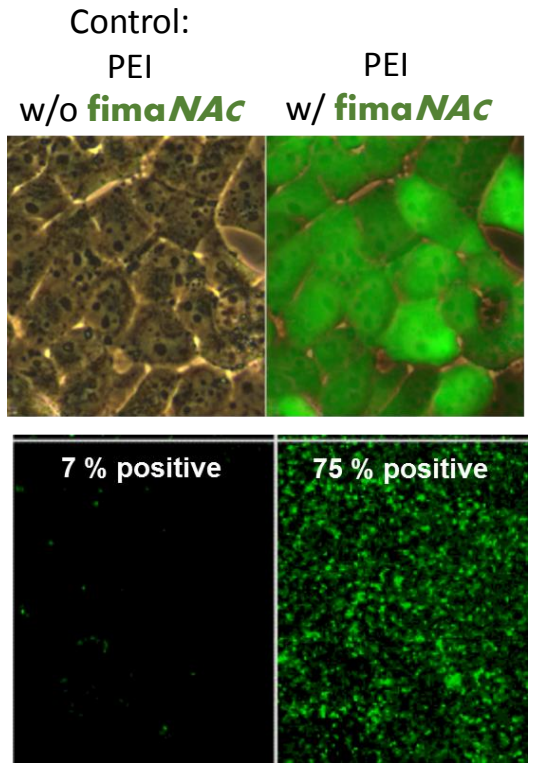
Pursuing collaboration and partnering opportunities with major players at minimal internal resources

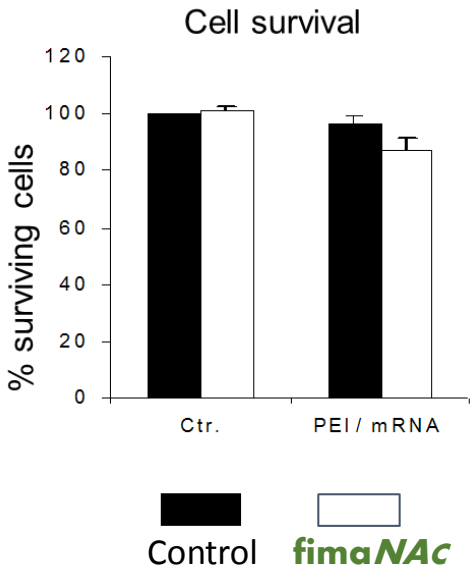
ENHANCING mRNA DELIVERY

- Strongly increased GFP synthesis with increasing light doses

fimaNAc with polyethylenimine (PEI) vehicle







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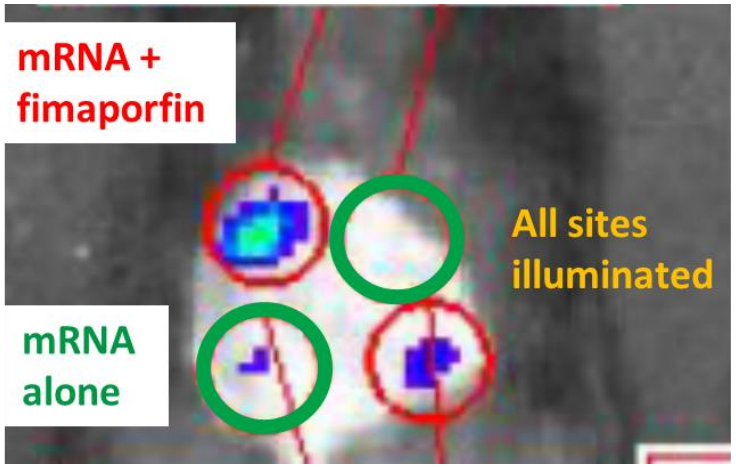
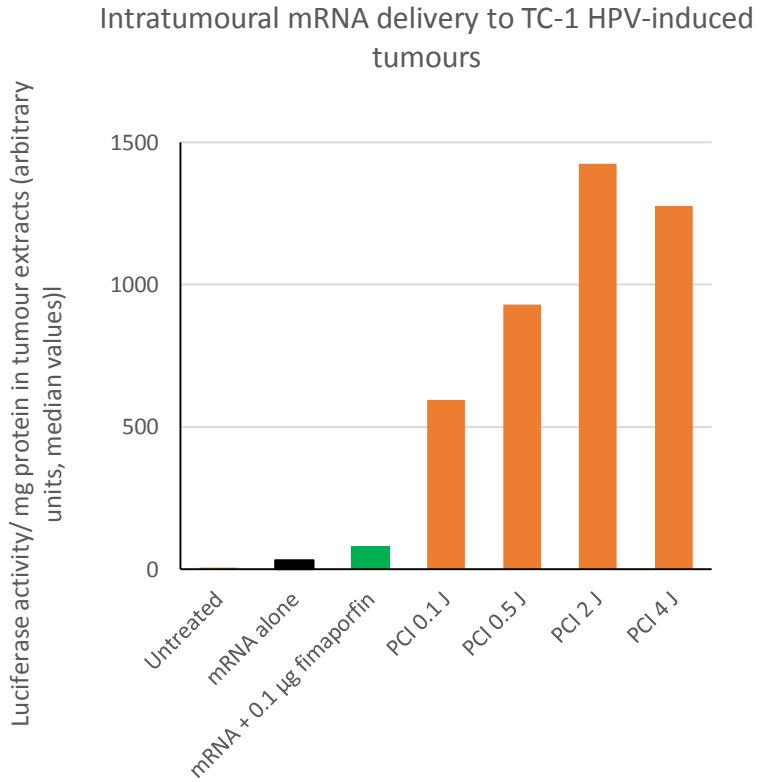
ENHANCING mRNA DELIVERY

- Strongly enhances delivery of mRNA *in vivo*

- Luciferase mRNA injected intradermally
- 2 control sites (mRNA alone) and 2 test sites (mRNA + fimaporfin)
- All sites illuminated simultaneously
- Animals injected with luciferin 24 hours after illumination.





- At best light dose (2 J) nearly 50 x enhancement as compared to naked mRNA alone

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RESEARCH COLLABORATIONS

- Six collaborations established with key players in nucleic acid therapeutics

fimaNAc

- Established research collaborations to evaluate the synergistic potential of **fimaNAc** with partners nucleic acid technologies

Top-10 large pharma

IMV IMMUNOVACCINE

Phio PHARMACEUTICALS

BAVARIAN NORDIC

eTheRNA

BIONTECH

PCI Biotech

GOOD PROGRESS AND EXCITING OUTLOOKS

fimaCHEM

Progressing development in bile duct cancer towards marketing authorisation application

- Encouraging tumour response and survival data from Phase I
- Orphan drug status granted in EU and USA
- Fastest way to market determined through regulatory interactions with authorities
- Pivotal RELEASE study with interim read for accelerated approval enrolled first patient in May 2019

fimaVACC

Successful clinical PoC with enhanced immune responses – two-pronged strategy

- Vaccination technology available for licensing
- Plan for clinical proof of concept in a disease setting

fimaNAc

Collaborative strategy

- Strong preclinical data on intracellular delivery of nucleic acid therapeutics
- Research collaborations with key players in the field

PCI BIOTECH HOLDING ASA

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