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PCI Biotech

PCI BIOTECH

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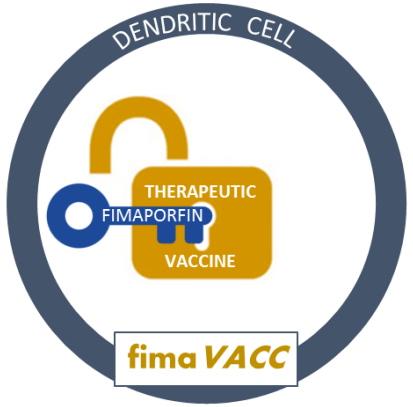
PCI BIOTECH AT A GLANCE

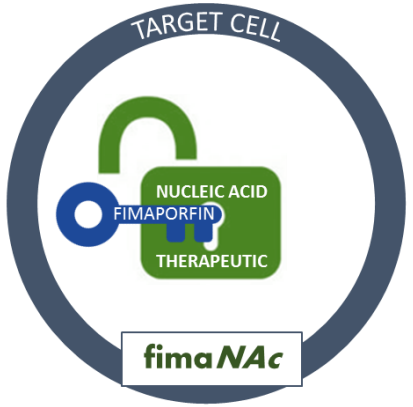
▶ Unlocking the potential of innovative medicines

- 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
  - **fima*NAc*** – Efficient intracellular delivery of nucleic acid therapeutics

Bile duct cancer study with promising early signs of efficacy in Phase I and Phase II about to start



Proprietary vaccination technology moving towards clinical validation, and one active research collaboration



Preclinical program with two active research collaborations, one with top tier pharma

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PHOTOCHEMICAL INTERNALISATION

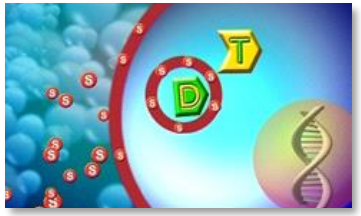
► Triggered endosomal release through illumination

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

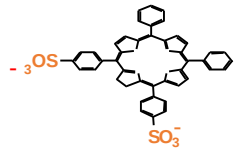
The active molecule

- 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

Worth more than
$10bn
across the 7 major markets

PCI may enhance approximately
20%
of relevant approved chemotherapies

Niche indications allow for
ORPHAN DRUG
applications

- fimaCHEM 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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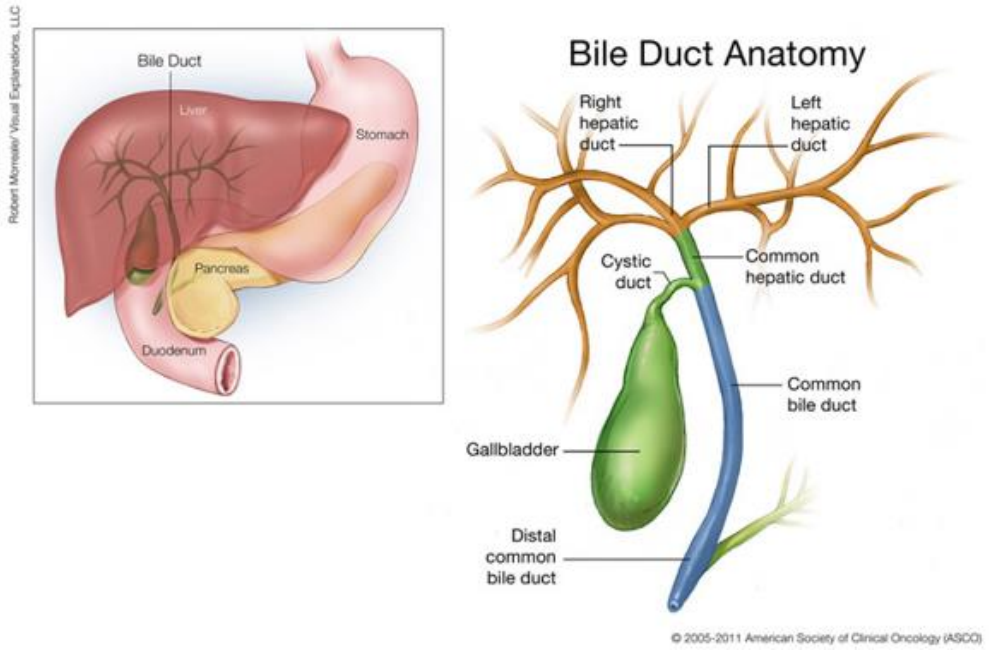
BILE DUCT CANCER

- A rare but fatal disease



- **Five year survival less than 5%**
- **Remarkable resistance to chemotherapy**
- **Estimated market potential of up to USD 500m for efficacious treatment**
- **Phase I/II trial ongoing with fimaprofin**
  - combination with gemcitabine
  - open-label, multi-center trial in up to 45 patients
  - activation of fimaporfin by intraluminal illumination

BILE DUCT CANCER – CLINICAL PHASE I/II STUDY

- Preliminary response data

- **6 months radiology (CT) data from 3 dose cohorts**

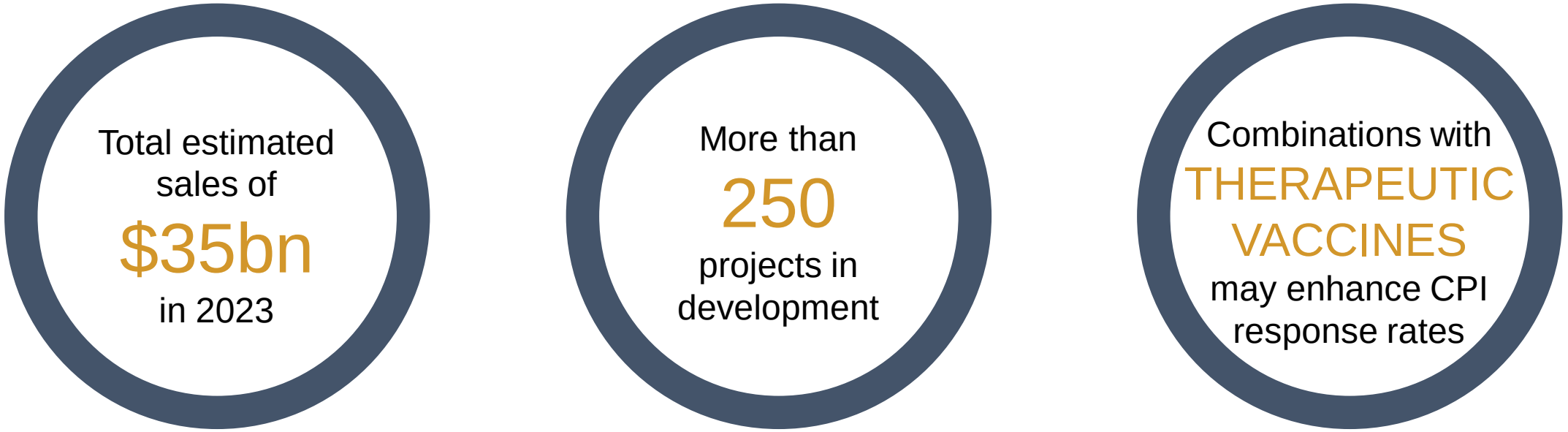
	PD	SD	PR	CR	NA*
Cohort 1	1	1			1
Cohort 2		1			2**
Cohort 3		1	1	1	
Cohort 4	Not yet available – subjects on-going				

* 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

IMMUNOTHERAPY

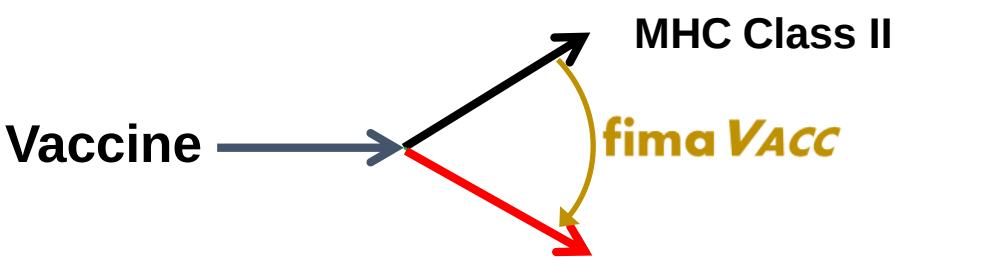
- A new hope for millions of patients



- fima VACC enhances cellular immune responses important for therapeutic effects
- Moving towards clinical validation, potentially in healthy volunteers
- Opportunity to develop own therapeutic vaccination products

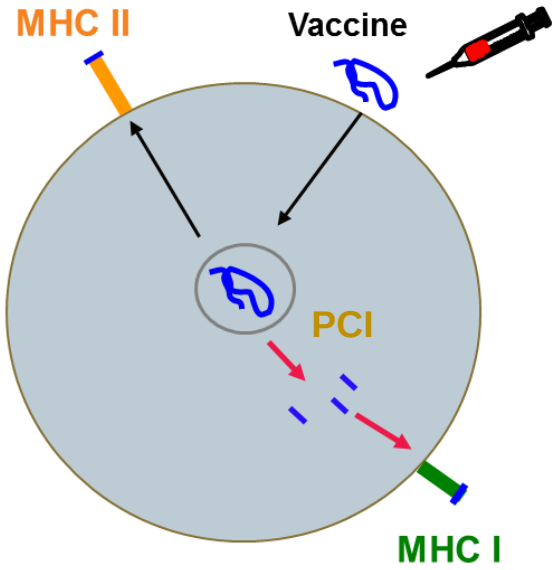
PCI FOR VACCINATION

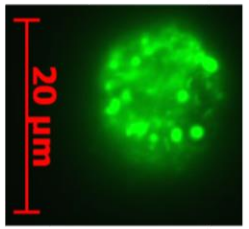
- Enhancing cytotoxic T-cell response by light-induced cross presentation



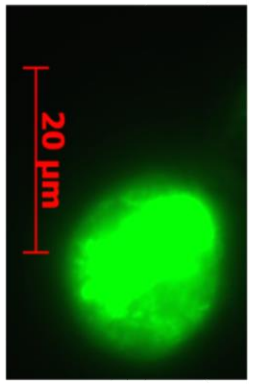
Generate more disease specific cytotoxic T-cells

Attack cancer and virus-infected cells more efficiently





Antigen in endosomes



After fima VACC treatment

Ovalbumin antigen in JAWSII dendritic cells

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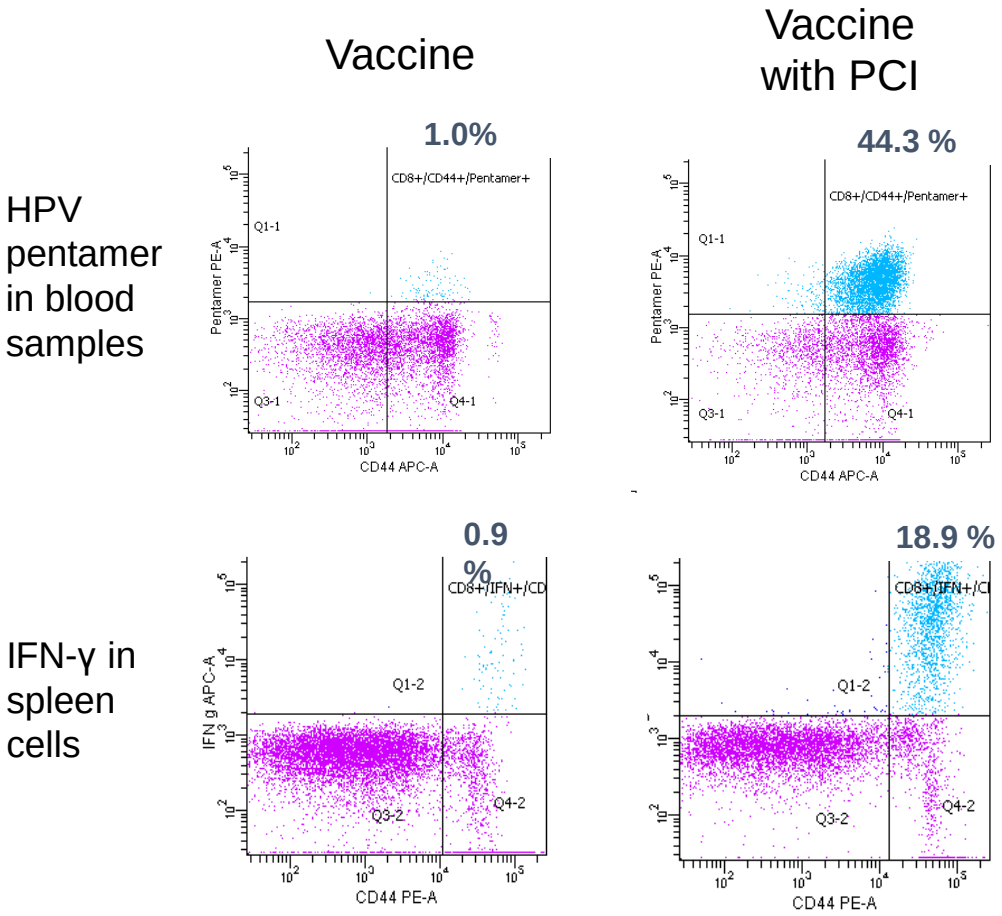
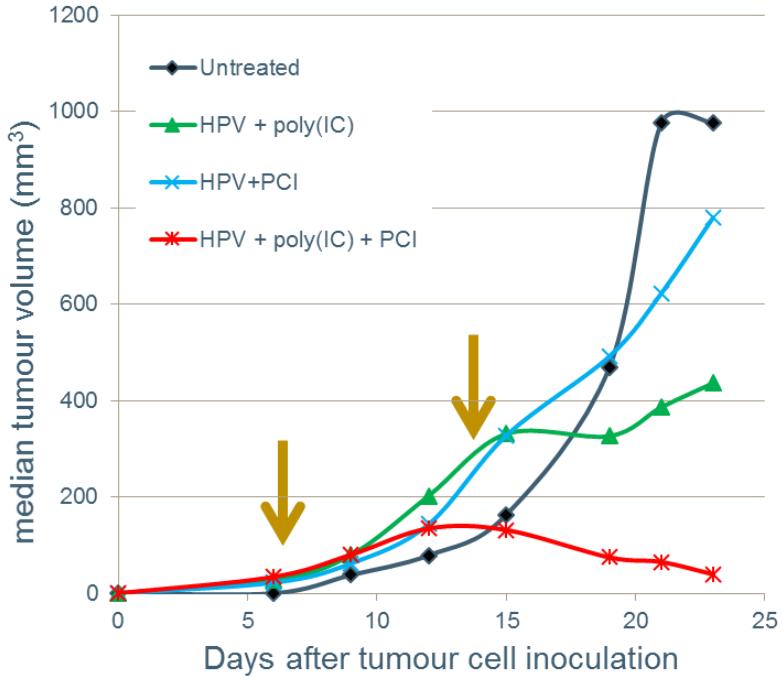
THERAPEUTIC VACCINATION

- *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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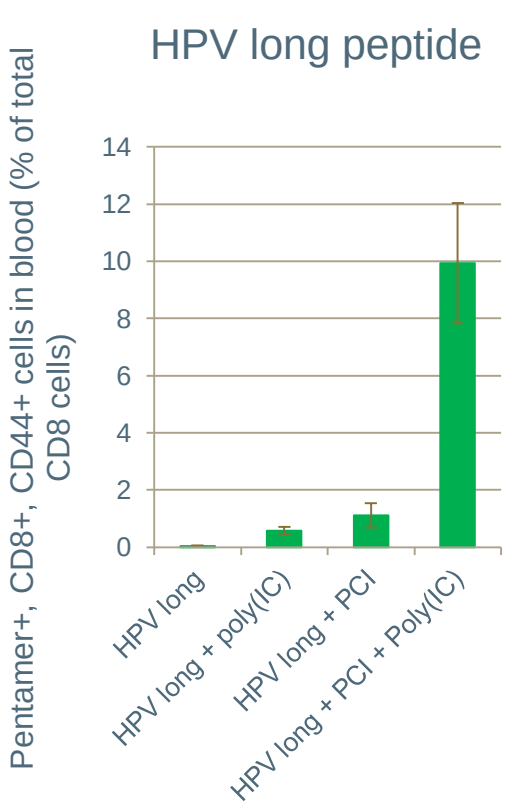
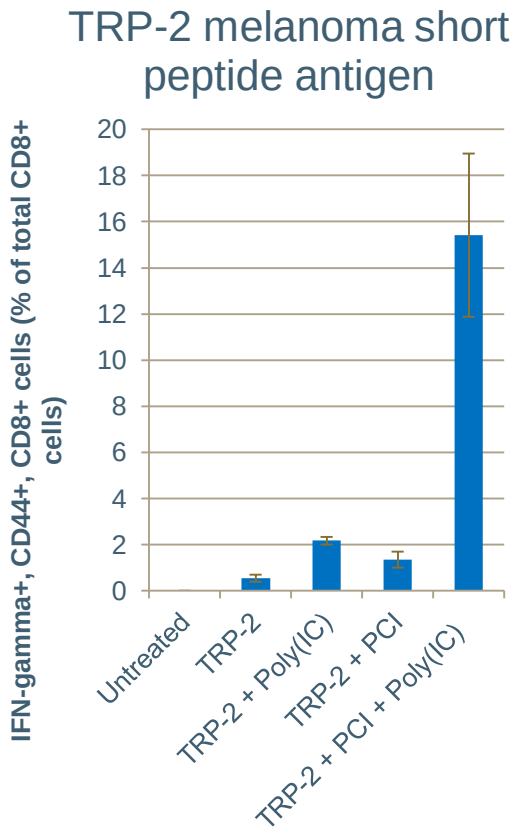
SYNERGY WITH OTHER TECHNOLOGIES

- 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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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

- fimaNAc may provide a delivery solution for many nucleic acid therapy applications
- Opportunistic collaborative approach

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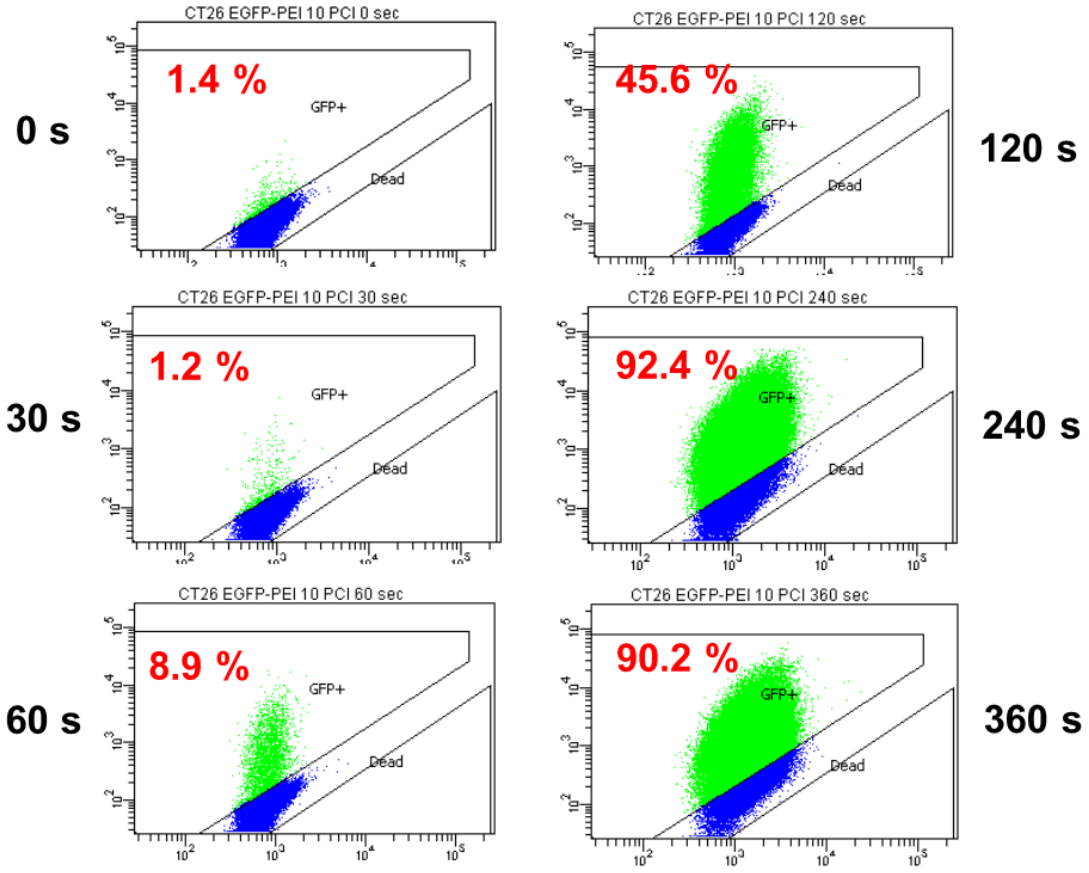
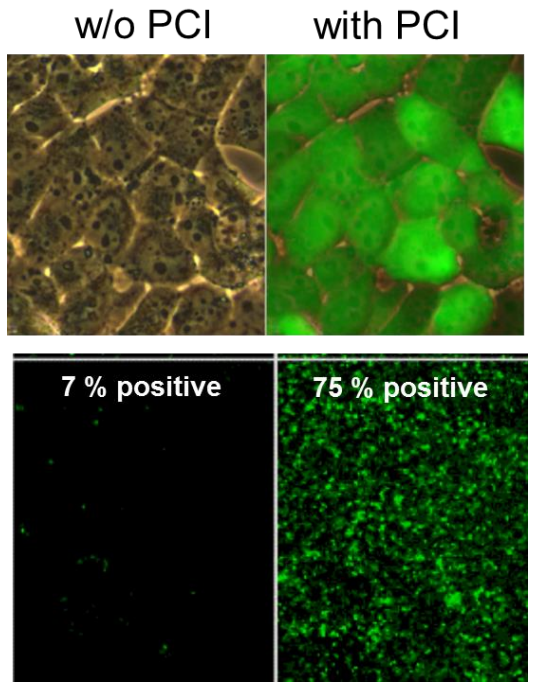
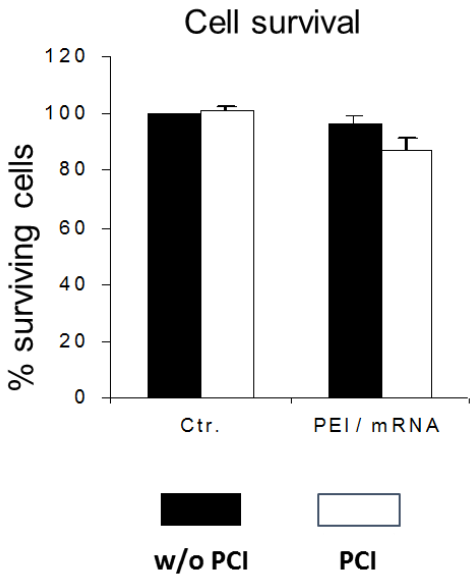
ENHANCING mRNA DELIVERY

- Strongly increased GFP synthesis with increasing light doses

fimaNAc with polyethylenimine vehicle







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KEY MILESTONES THROUGH 2018

- Unlocking the true potential of innovative medicine