

PCI Biotech

ABGSC Life Science Summit, May 2022

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PCI Biotech

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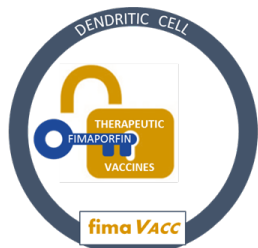
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PCI BIOTECH IN BRIEF

PCI Biotech is an **innovation-driven company with an oncology-focused pipeline**

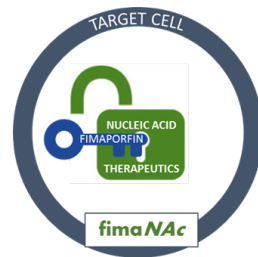
Our vision is to **develop and commercialise novel therapeutic solutions** to address unmet medical needs for patients

Our photochemical internalisation (PCI) **technology platform enables drugs to reach intracellular therapeutic targets**



PCI Biotech's lead programme **fimaVacc** applies a **unique mode of action to enhance the essential cytotoxic effect of therapeutic cancer vaccines** to turn immune cold tumours hot

- Phase 2 study planned to initiate in Q1 2023 in Europe; results anticipated H1 2024
- **Innovative and versatile** platform for immunotherapy

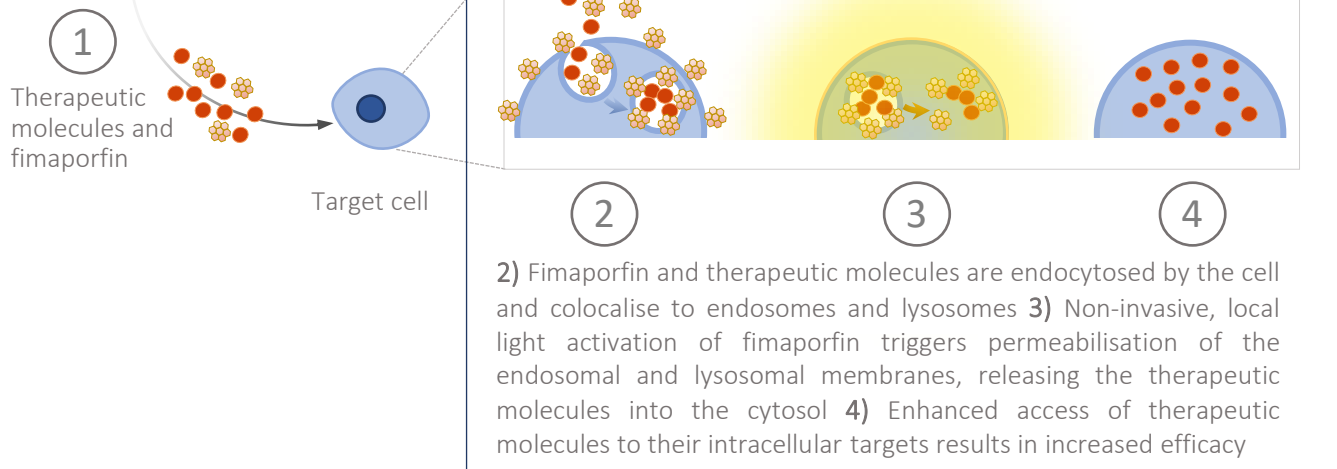


fimaNAc provides **intracellular delivery of nucleic acids**, such as mRNA and siRNA therapeutics, thereby addressing one of the major bottlenecks facing this emerging and promising field

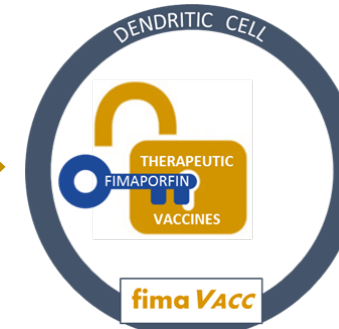
- Targeting **applications suited to the specific strengths** of the PCI technology
- **Collaborative approach** with key players

A BROAD INNOVATION PLATFORM

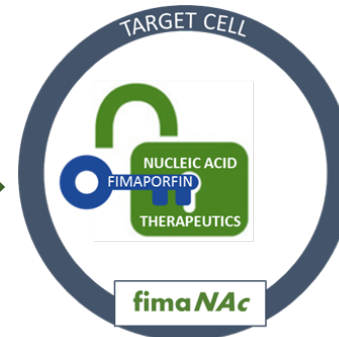
Unique MoA to enhance access of therapeutic molecules



PCI technology



- ▶ Enhances the essential cytotoxic effect of therapeutic cancer vaccines
- ▶ Generates more disease specific cytotoxic T-cells
- ▶ Strong anti-tumour responses
- ▶ Innovative and versatile platform for immunotherapy



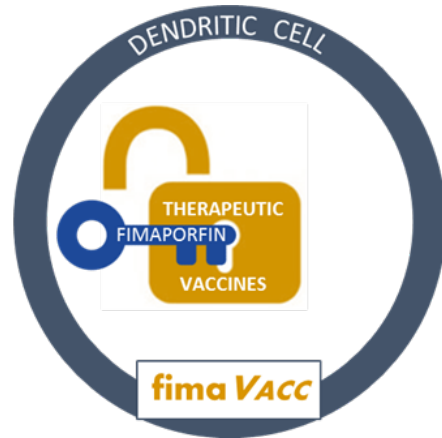
- ▶ Enhances the therapeutic effect of nucleic acids
- ▶ Overcomes the challenge of endosomal escape in nucleic acid delivery
- ▶ Preclinical data includes mRNA, plasmids and oligonucleotides

PIPELINE LEVERAGING THE PCI TECHNOLOGY PLATFORM WITHIN IMMUNOTHERAPY & NUCLEIC ACID THERAPEUTICS

Programme	Therapeutics	Preclinical	Phase 1	Phase 2	Planned next milestone
fima VACC	Therapeutic cancer vaccines				Initiate Phase 2, head and neck cancer
fima NAc	Nucleic acid therapeutics				Enabling technology, dermatology applications

PCI TECHNOLOGY

- ▶ An innovative platform technology that enables intracellular delivery



Enhancing cellular immune responses important for therapeutic effect

- Compelling preclinical results
- Safety and encouraging immune response with peptide vaccine antigens demonstrated in a phase 1 study¹
- Moving towards a phase 2 study

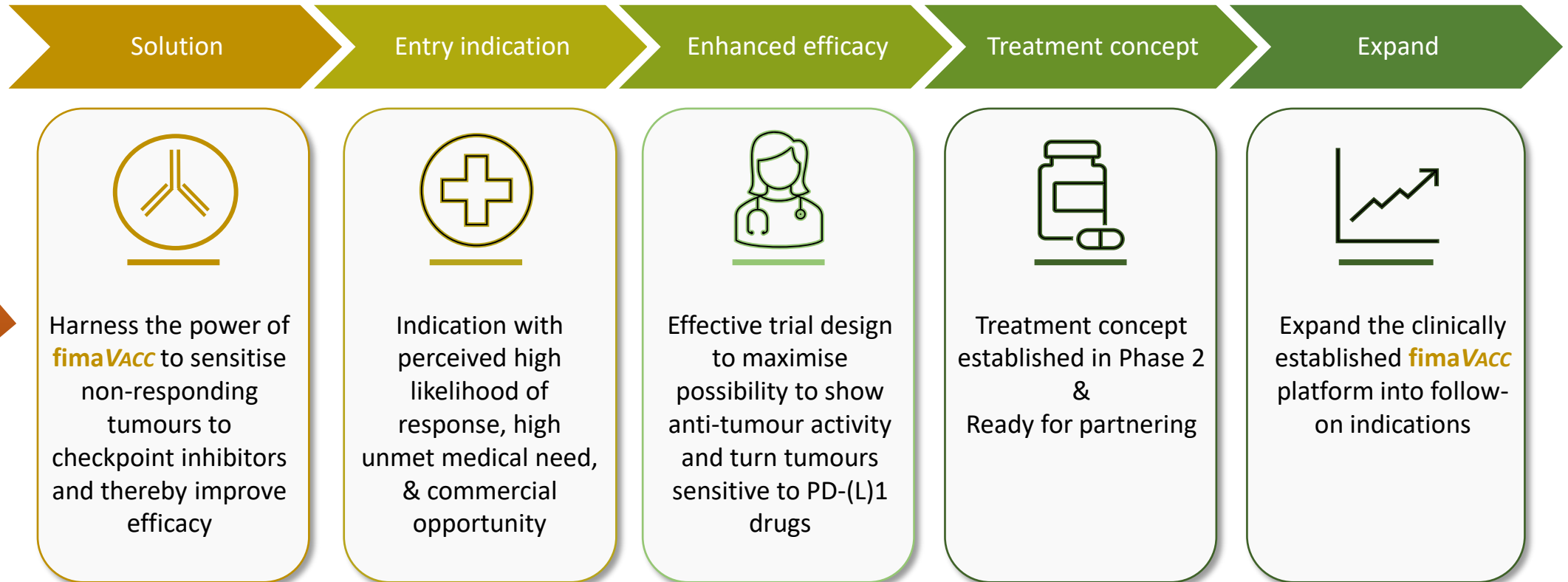


¹ Otterhaug et al (2021) Frontiers In Immunology 11: 576756

HARNESS THE POWER OF **fimaVacc** TO ENHANCE IMMUNOTHERAPY

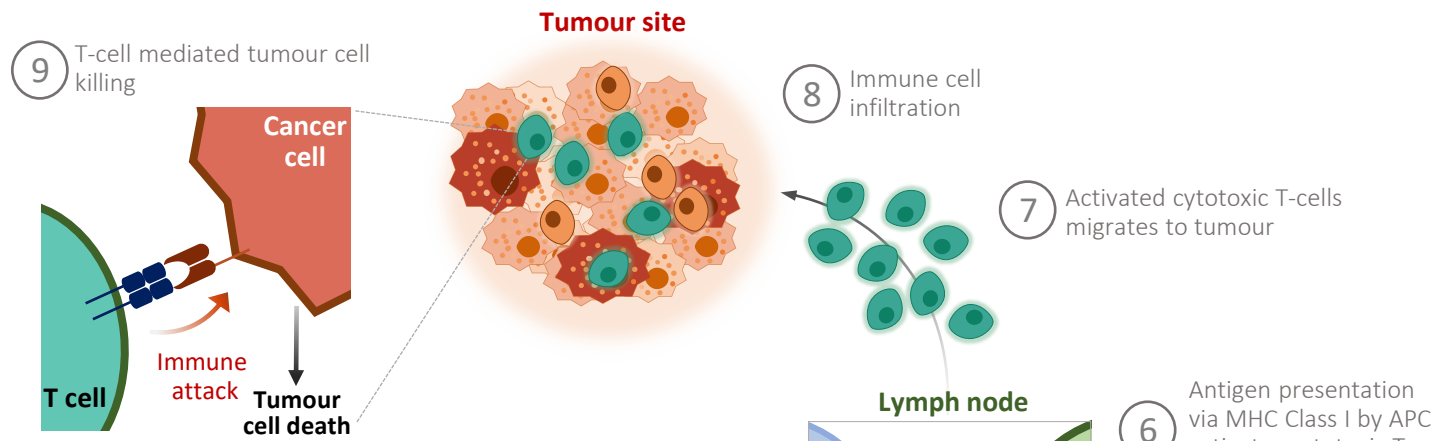
► Strategy

- PD-(L)1 checkpoint inhibitors are dominating the immunotherapy market
- Many patients have limited responses to checkpoint inhibitors
- Attractive opportunity space to leverage the **fimaVacc** platform

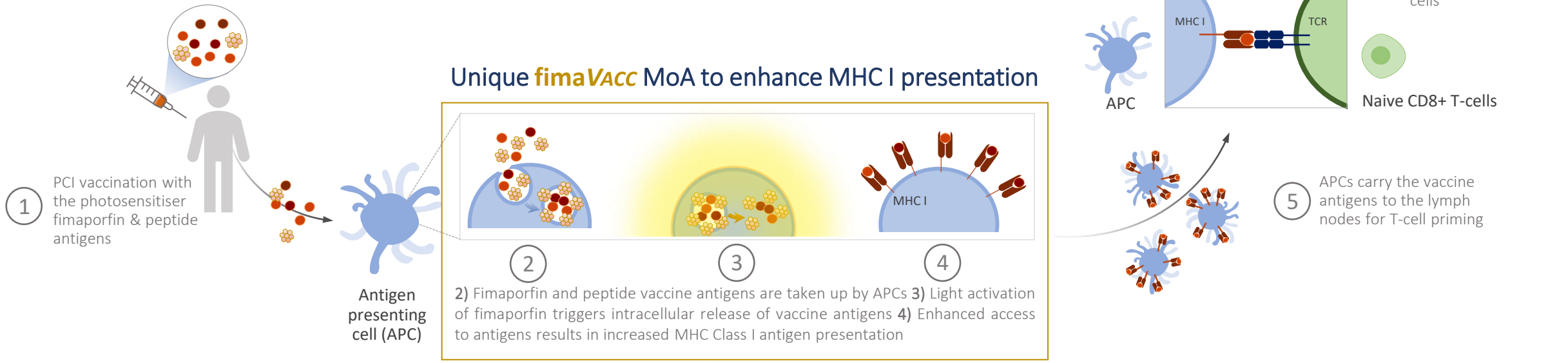


fimaVacc - UTILISING THE IMMUNE SYSTEM TO FIGHT CANCER

- CD8+ cytotoxic T-cells are the preferred immune cells for targeting cancer and require MHC Class I antigen presentation to be induced
- A major hurdle in cancer vaccination programmes have been to achieve MHC class I antigen presentation
- **fimaVacc** platform overcomes this challenge by strongly **enhancing MHC class I antigen presentation, activating and inducing infiltration of cytotoxic T-cells** into the tumour, resulting in **tumour cell killing**

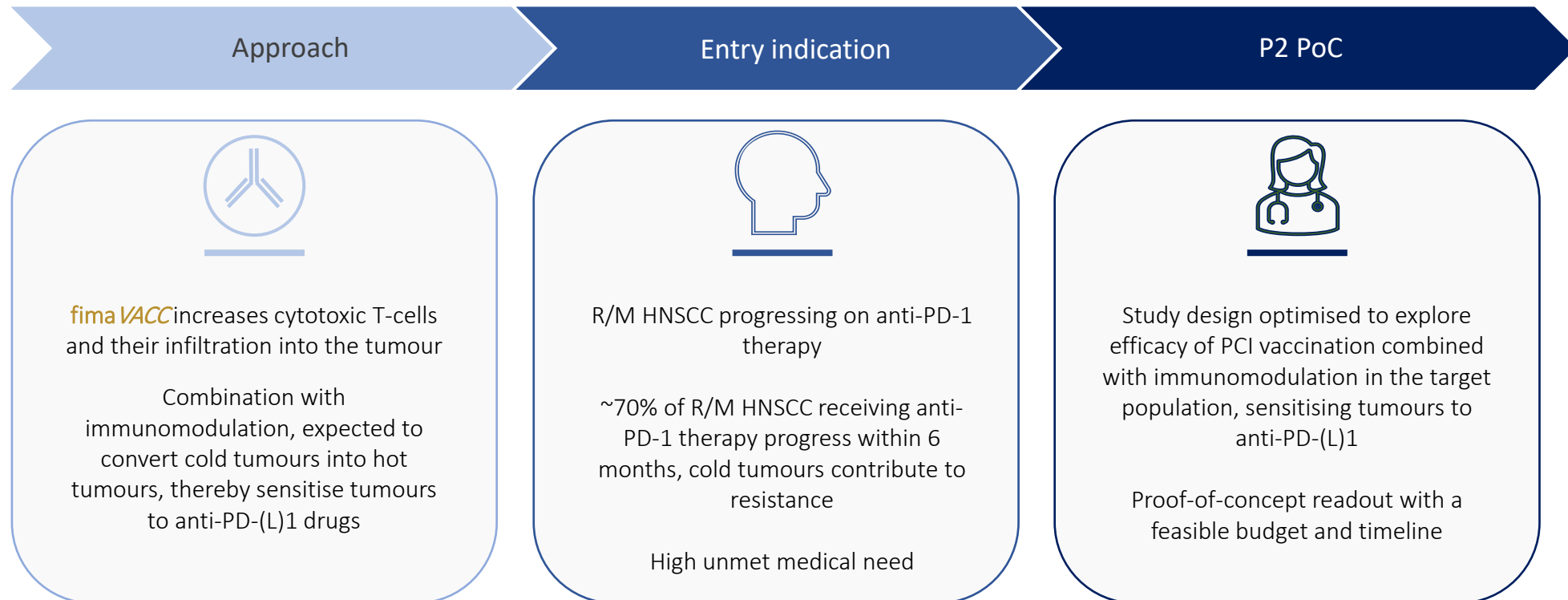


Unique fimaVacc MoA to enhance MHC I presentation



PLANNED PHASE 2 STUDY: OVERALL STRATEGY

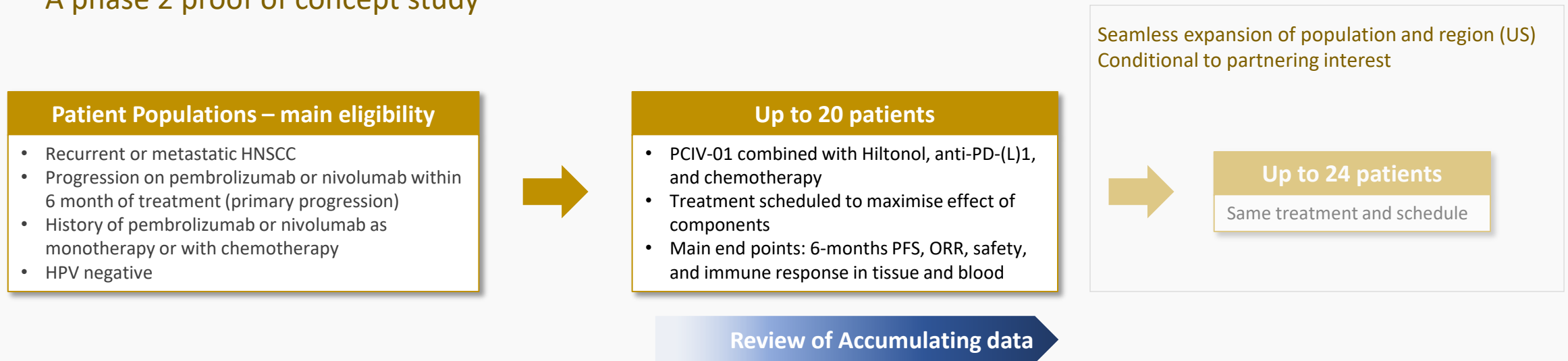
- ▶ Safety and efficacy of PCI enhanced vaccination combined with immunomodulation for the treatment of R/M HNSCC that is resistant to immunotherapy



PLANNED PHASE 2: STUDY DESIGN

- ▶ Safety and efficacy of PCIV-01 combined with immunomodulation for the treatment of R/M HNSCC that is resistant to immunotherapy; A multi-centre, open-label, non-randomised, phase 2 study

A phase 2 proof of concept study



- *International, multicenter study, ~8-12 clinical sites*
- *Core clinical investigators and external experts engaged with the program, including **Prof. Kevin Harrington**, Institute of Cancer Research, UK and **Prof. Ezra Cohen**, University of California, San Diego, US*

TIMELINES AND POTENTIAL TIME POINTS FOR PARTNERING

- ▶ Planned phase 2 study, expected upcoming catalysts & milestones

2022	2023	2024
Q4	Q1	H1
CTAA submission	First patient enrolled	Top line results



- Open treatment study enables news-flow as results accumulate
- Strong core clinical group of KOLs established to support study protocol development and effective study execution

PLANNED PHASE 2 STUDY: FOCUSED OPPORTUNITY POSITIONED TO DRIVE VALUE

Solid foundation

- Solid preclinical data including anti-tumour responses
- Strongly enhanced T-cell immune responses
- Successful proof-of concept of immune response demonstrated in healthy subjects in Phase 1 study

Scientific rationale

- PCIV-01 vaccination expected to induce T-cells necessary for anti-PD-(L)1 to work
- Aim to turn cancers sensitive to anti-PD-(L)1 drugs by conversion of cold to hot tumours
- Trigger effective immune attack against tumour cells

Broad IP portfolio

- Patent for vaccine technology in combination with TLR agonists granted in key markets
- Patent on combination with checkpoint inhibitors granted in US, pending ROW
- IPs extend into 2036, facilitates the opportunity to develop own vaccination product and pipeline

Entry indication

- Perceived high likelihood of response to study treatment
- High unmet medical need
- Ample opportunity for value growth

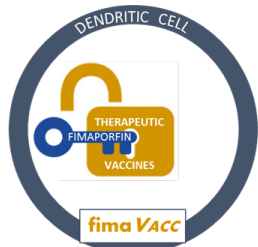
Expertise

- Deep expertise via internal clinical development team
- Close collaboration with core clinical experts
- Concept and clinical study endorsed by international, renowned KOLs

PCI PROVIDES EFFICIENT INTRACELLULAR DELIVERY OF NUCLEIC ACIDS

Entry into the cell cytosol is necessary for nucleic acid based drugs to exert their therapeutic effect. This is a **major hurdle** for these drugs, as they are not able to freely pass the cell membrane. Nucleic acids are taken up into cells by endocytosis but are then trapped in endosomes within the cell.

The **PCI technology can effectively** release these drugs from the endosomes, thereby addressing one of the major bottlenecks facing this emerging and promising field. This application can **enhance nucleic acid** delivery to any target site that is accessible to illumination, with **targeted delivery** to the illuminated site only.



In the **fimaVacc** programme, the PCI technology is developed for **intratumoural delivery of nucleic acids** for immunotherapeutic purposes

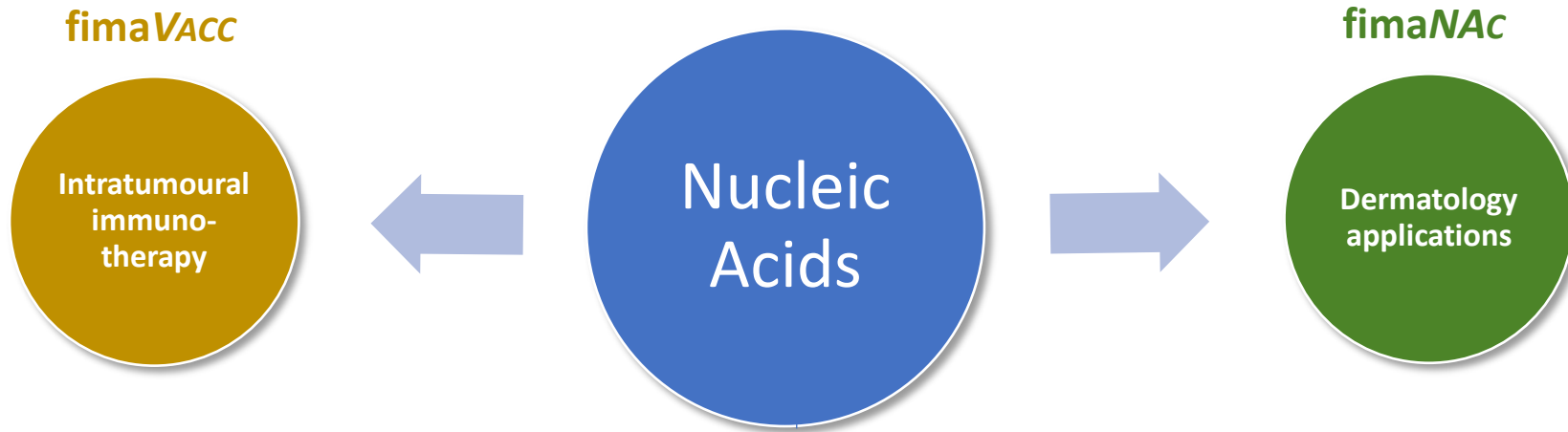
- Evidence of strong enhancement of mRNA transfection **without off-target delivery**
- **Compares beneficially to LNPs** for this application (both wrt transfection and off-target effects)
- Systemic effects upon treating one tumour have been demonstrated with the PCI technology



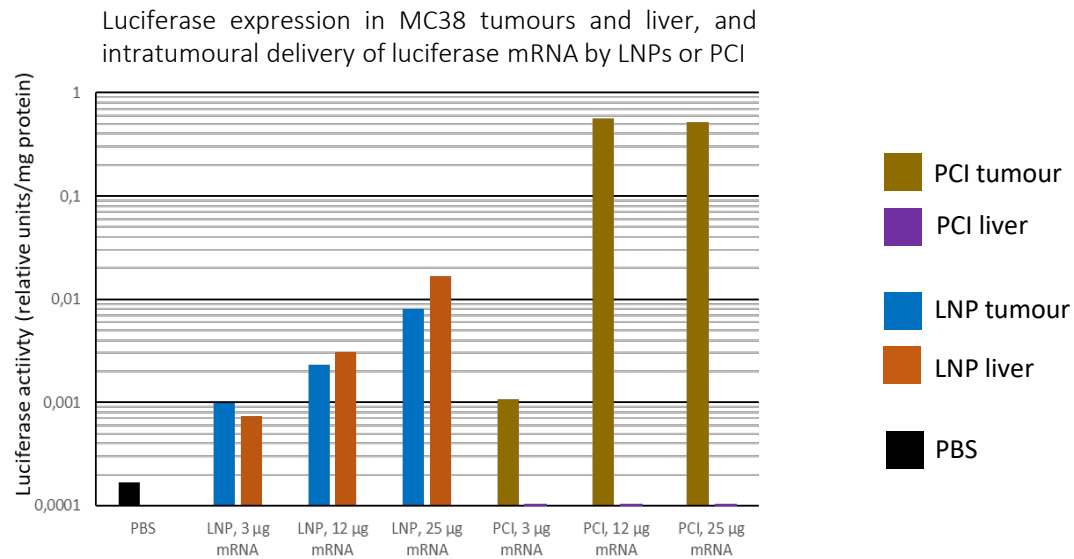
fimaNAc provides intracellular delivery of nucleic acids, such as mRNA and siRNA therapeutics, for all other applications

- Targeting **dermatology**, an application suited to the specific strengths of the PCI technology
- Easy illumination access and potential for diseases with limited treatment options
- Plan to develop **topical application** and custom-made **light device**

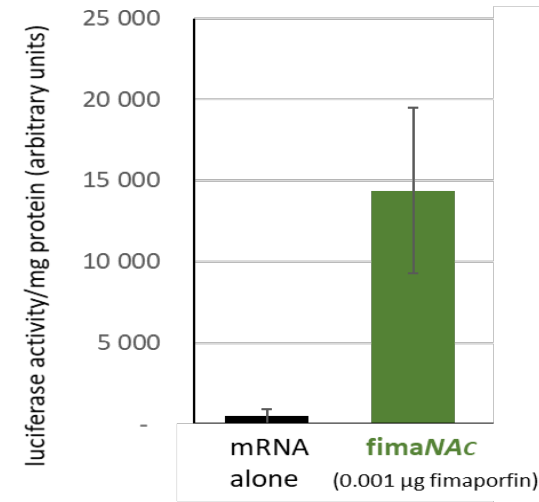
DEVELOPMENT PROGRAMMES— PCI ENHANCED NUCLEIC ACIDS DELIVERY



Efficient PCI-mediated delivery of nucleic acids in animal experiments



Enzymatic luciferase activity in skin samples after intradermal injection of luciferase mRNA



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RESEARCH COLLABORATIONS

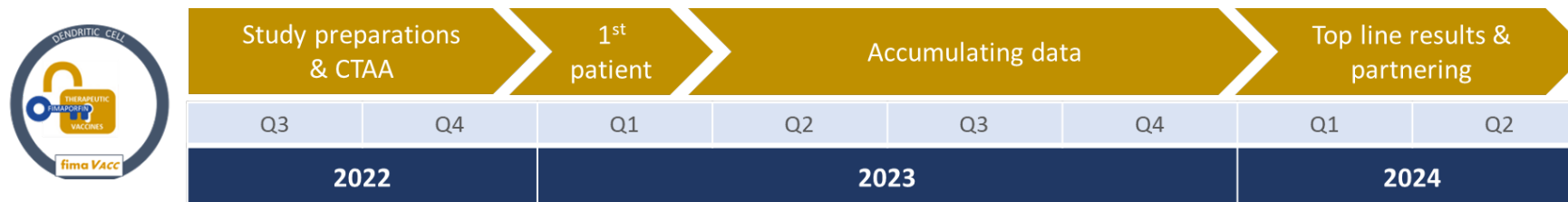


- ▶ Offer valuable scientific knowhow, encouraging results and intellectual property
- ▶ Current collaborations spanning different classes of drugs and applications
- ▶ Pursuing new and value-adding collaborative opportunities

INVESTMENT HIGHLIGHTS

Broad innovation platform	Proprietary PCI platform technology with programmes targeting rapidly growing markets Our vision is to bring innovation with impact for conditions with limited treatment options
Pipeline opportunities	fima VACC – a clinical stage vaccination technology with a novel mechanism of action fima NAc – a nucleic acids delivery solution with established preclinical research collaborations
Compelling data	Clinical evidence of increased immune responses and preclinical evidence of effective and durable anti-tumour responses with fima VACC vaccination technology
Clinical development strategy	fima VACC lead Phase II programme endorsed by KOLs in EU and US Focused opportunity with efficient clinical translation and ample opportunity for value growth
Strong leadership	Experienced team in drug discovery, development and commercialisation across a range of medical development and commercial areas

Clinical development plan





Enabling
intracellular
delivery

PCI Biotech

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