PCI Biotech - Q1 2022 Interim Report

Presentation May 11, 2022

Per Walday, CEO
Ronny Skuggedal, CFO
Amir Snapir, CMO

PCI Biotech

Q&A session through teleconference and webcast console

Norway +47 2195 6342
Sweden +46 4 0682 0620
Denmark +45 7876 8490
United Kingdom +44 2037 696 819
United States +1 646 787 0157

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Table of Contents

Highlights

Q1 2022

fima VACC

- Progressing towards initiation of a Phase II clinical proof-of-concept study
- Established group of international clinical experts to provide clinical guidance and support the development and performance of the trial
- Good project readiness – preparation of clinical trial application and sourcing of study treatments ongoing, and selection of clinical sites in EU5 started

Highlights

Q1 2022

fimaNAc

- Progressing the focused development plan, targeting applications suited to the specific strengths of the PCI technology
- Established a preclinical collaboration with the South Korean company MDimune, developing innovative drug delivery technologies for modifying cellular and disease processes

Highlights

Q1 2022

fimaCHEM

- RELEASE was closed to recruitment in January 2022 due to changes in the competitor situation that renders the trial challenging to complete and potentially inadequate for approval
- Available data from RELEASE have been reviewed – there is not sufficient data to show differences between the treatment arms and last patient will leave the study in May
- RELEASE will be closed as quickly as possible, with an expected future cash effect of up to NOK -10 million

Highlights

Q1 2022

Corporate

- Per Walday will step down as CEO at the end of May 2022 and Ronny Skuggedal, CFO, is appointed as Interim CEO effective 1st June
- The CBO, Ludovic Robin, will leave the company in May 2022
- The organisation has been reduced by 4 FTE (25%), with notice periods ending during Q2. The financial runway, with current commitments, is estimated to be towards the end of 2023
- Further strengthened the Scientific Advisory Committee with Prof. Ernst Wagner at the Ludwig-Maximilians-Universität (LMU) and Center of Nanoscience in Munich, Germany, contributing expertise in the field of targeted delivery of nucleic acids and protein therapeutics

Pipeline

Development programmes

Leveraging the PCI technology platform within Immunotherapy & nucleic acid therapeutics

Programme	Therapeutics	Preclinical	Phase 1	Phase 2
fimaVACC	Therapeutic cancer vaccines			
fimaNAc	Nucleic acid therapeutics			

Operational review

fimaCHEM

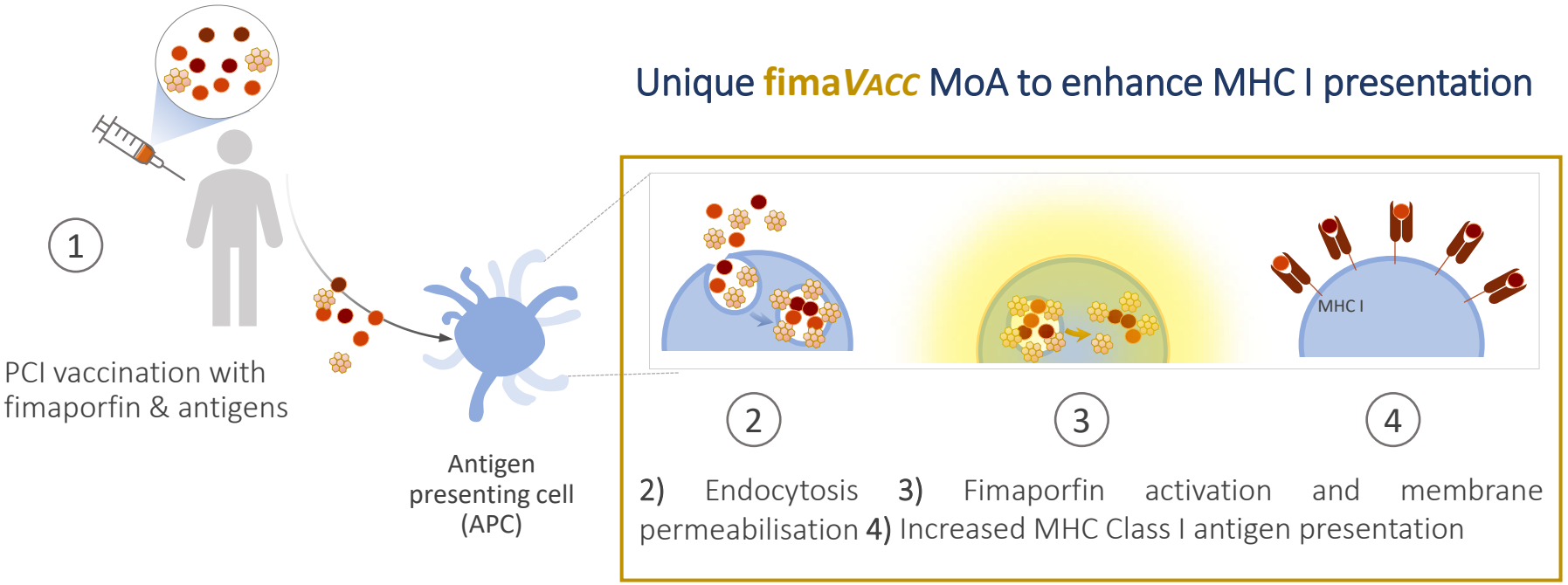
Operational review

- RELEASE recruitment closed in January 2022
  - Expected rapid change in SoC
  - Trial challenging to complete as a result of the expected change in SoC, and potentially inadequate for approval
- Available data reviewed
  - Radiographic data from 34 out of 41 enrolled patients evaluated for PFS/ORR
  - Data are not sufficient to allow conclusion
- All further follow-up assessments ceased
  - Enables swift and cost-efficient closing process
  - Last patient will leave the study in May

fima VACC

Innovative and versatile platform for immunotherapy
Unique MoA to enhance cytotoxic effects of therapeutic cancer vaccines

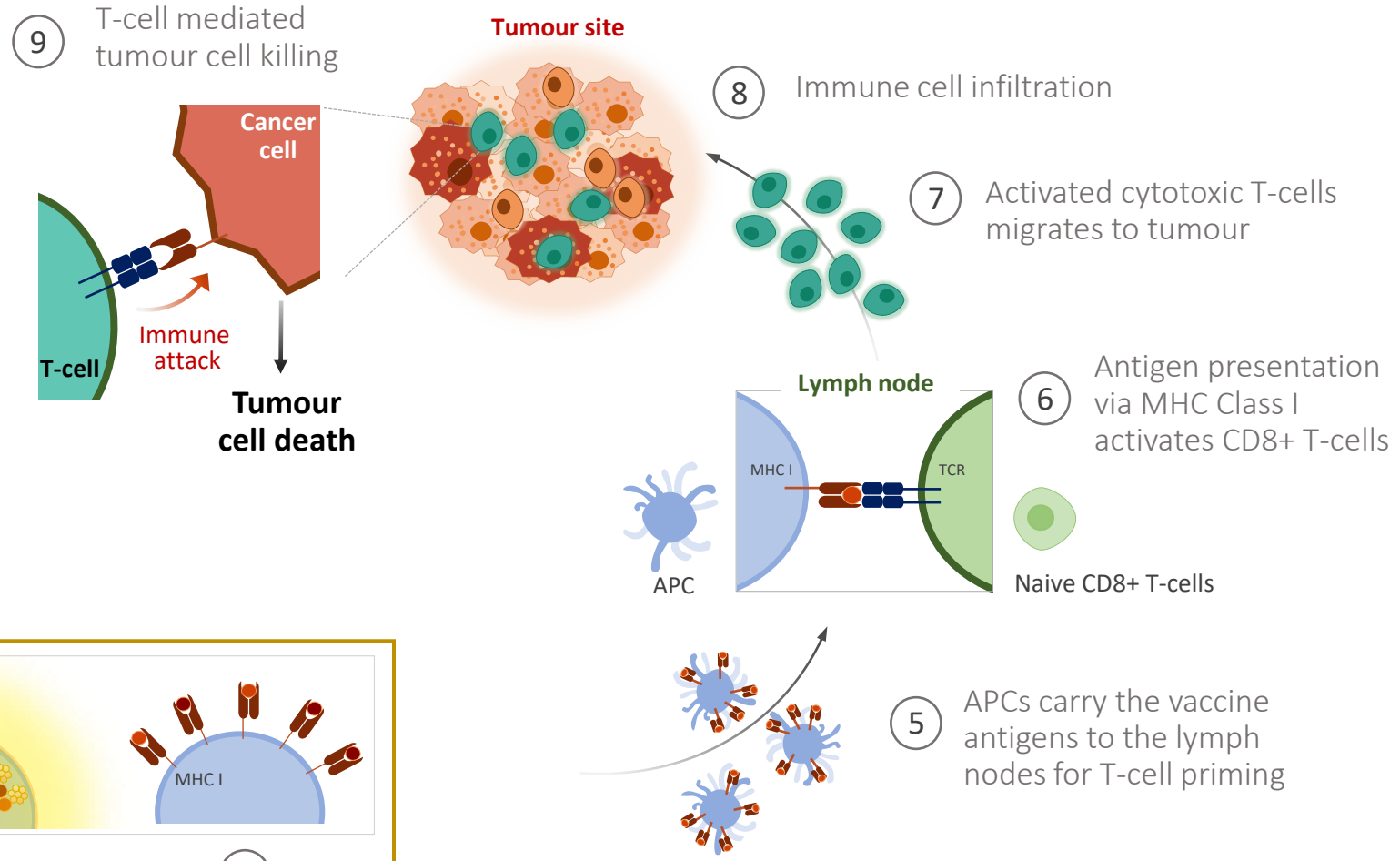
Operational review



fima VACC

Operational review

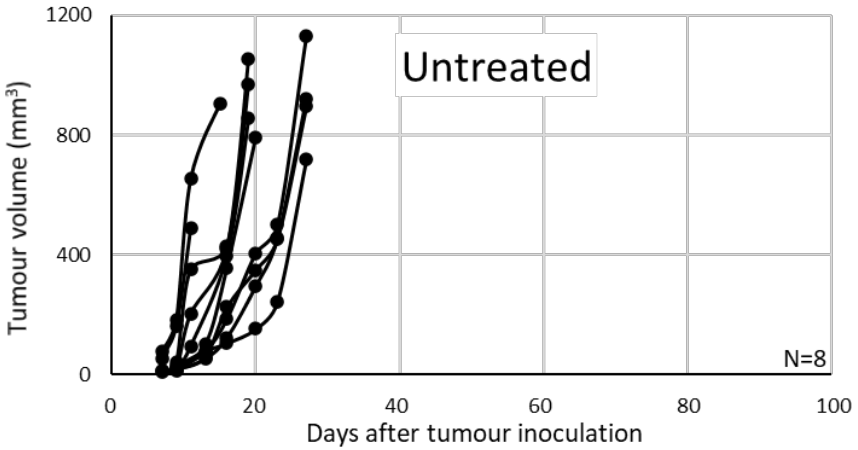
Induced cytotoxic CD8+ T-cells attack cancer cells

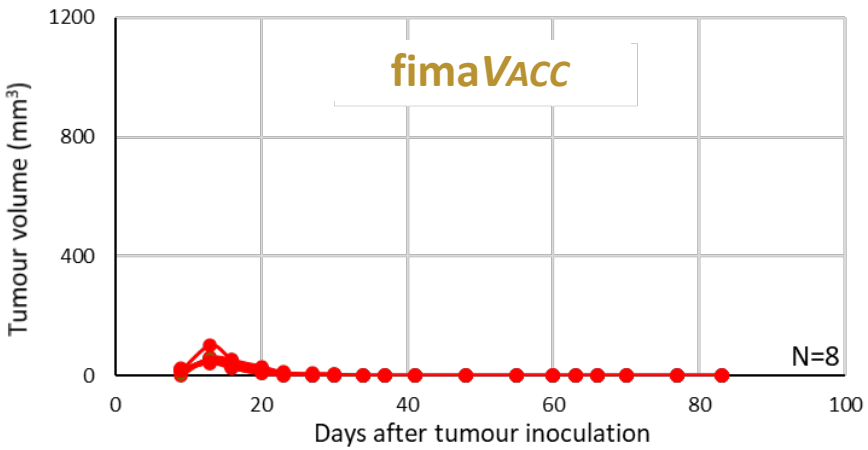


fima VACC

Intradermal vaccination with fimaVACC induces strong anti-tumour response

Operational review





- TC-1 tumours inoculated in animals without subsequent vaccination
- Aggressively growing tumours established in all animals, with no animals surviving beyond Day 30

- **fimaVACC** (fimaporfin + HPV long peptide antigen) with polyIC adjuvant vaccinated i.d. on days 8, 13, and 22 after tumour established
- Mice became tumour-free and were immune to a new challenge with tumour cells

fima VACC

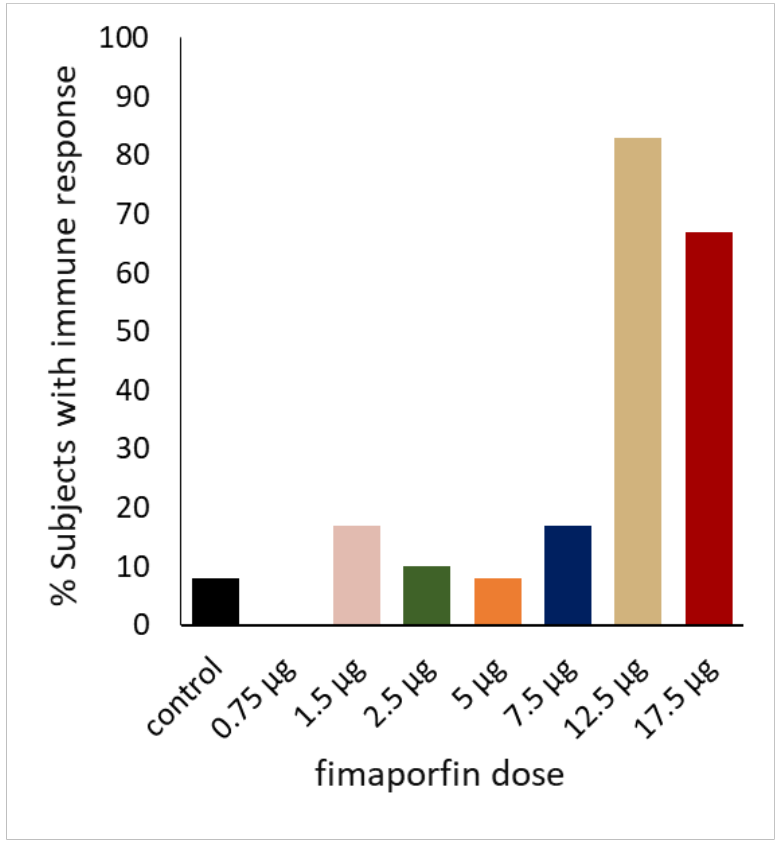
Scientifically validated platform – Clinical evidence in Phase I study

Operational review

- Phase I in healthy subjects showed increased T-cell responses
- Good safety and tolerability
- PCI Recommended Phase 2 dose determined

Phase 1 trial results showed a good safety profile and increase in immune response at the recommend phase 2 dose

~10x increase in immune responders



fima VACC

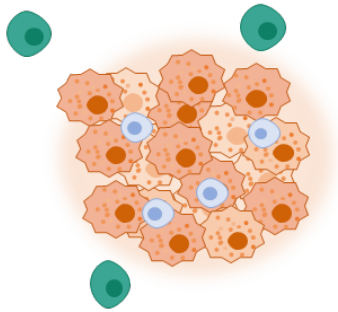
Converting cold tumours to hot

Operational review

Immune checkpoint inhibitors are effective treating hot tumours

Cold Tumour

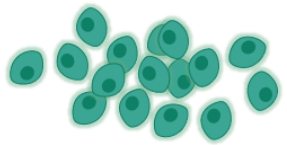
- Few T-cells and low infiltration of T-cells in the tumour
- Immunosuppressive cells present
- Poor response to anti-PD-(L)1 drugs



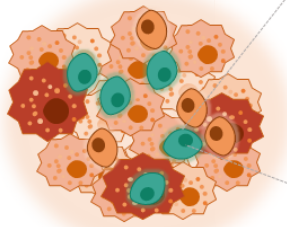
Conversion into hot tumour in the PoC study

- CD8+ T-cells are activated and infiltrate the tumour
- Suppression of immunosuppressive cell types
- Sensitisation to anti-PD-(L)1 drugs

Intradermal vaccination

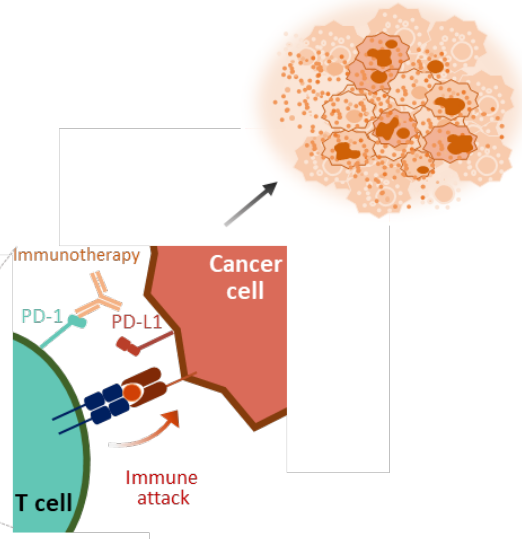


Vaccination activates CD8+ T cells which migrate to the tumour

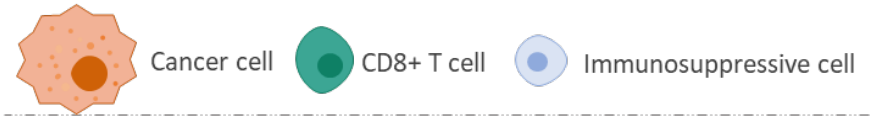


Tumour site

Immune cell infiltration and reduction of immune suppressive cells by immunomodulator



Anti-cancer immune response and sensitisation to anti-PD-(L)1 drugs

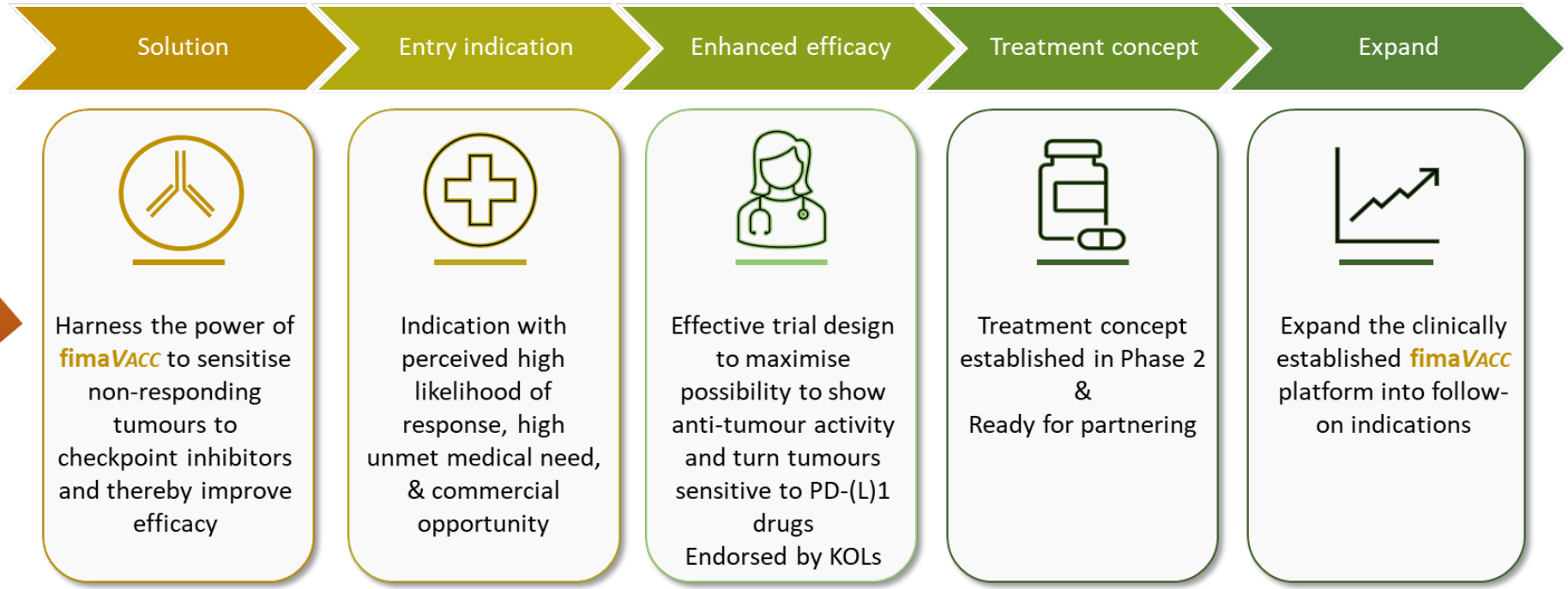


fima VACC

Operational review

Harness the power of fimaVacc to enhance immunotherapy by turning cold tumors into hot

- 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



fima VACC

Phase 2 PoC study

Operational review

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

Approach	Entry indication	P2 PoC
		
fima *VACC* increases cytotoxic T-cells and their infiltration into the tumour Combination with immunomodulation, expected to convert cold tumours into hot tumours, thereby sensitise tumours to anti-PD-(L)1 drugs	R/M HNSCC progressing on anti-PD-1 therapy ~70% of R/M HNSCC receiving anti-PD-1 therapy progress within 6 months, cold tumours contribute to resistance High unmet medical need	Study design optimised to explore efficacy of PCI vaccination combined with immunomodulation in the target population, sensitising tumours to anti-PD-(L)1 Proof-of-concept readout with a feasible budget and timeline

fima VACC

PoC treatments

Operational review

PCI vaccination (PCIV-01 plus light) with an adjuvant to increase cytotoxic T-cell immune activation and tumour infiltration while downregulating immunosuppressive cells with an additional immunomodulator Anti-PD-(L)1 are effective treating hot tumours

PCIV-01	Vaccine adjuvant	Additional immunomodulator	Immune checkpoint inhibitor
Definition			
Fimaporfin & a mix of peptide antigens*	Hiltonol	Chemotherapy	Anti-PD(L)1
Rationale			
• HNSCC-associated antigens presented on the cancer cell's surface • A CD4+ helper T-cell stimulator peptide • The combination is expected to induce cytotoxic T-cell priming & tumour infiltration, and trigger an anti-cancer immune response	• Increase immune response • Documented preclinical and validated clinical value in combination with PCI vaccination	• Decrease immunosuppressive cells to enhance immunotherapy efficacy during the initial treatment cycles • Expected to increase clinical benefit from the study treatments	• Anti-PD-(L)1 drugs have good efficacy in patients were the tumour has been converted from cold to hot

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PoC study design

Operational review

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

Patient Populations – main eligibility

- Recurrent or metastatic HNSCC
- Progression on pembrolizumab or nivolumab within 6 month of treatment (primary progression)
- History of pembrolizumab or nivolumab as monotherapy or with chemotherapy
- HPV negative

Up to 20 patients

- PCIV-01 combined with Hiltonol, anti-PD-(L)1, and chemotherapy
- Treatment scheduled to maximise effect of components
- Main end points: 6-months PFS, ORR, safety, and immune response in tissue and blood

Seamless expansion of population and region (US)
Conditional to partnering interest

Up to 24 patients

Same treatment and schedule

Review of Accumulating data

- 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
- Study planned to start in 2023

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Operational review

P2 PoC: Status and project readiness

- Ongoing activities focusing on preparation of the clinical trial application, CMC, and study operations
  - Peptide manufacturer identified and manufacturing ongoing
  - Sourcing of other study treatments in progress
- A group of international clinical experts established to provide guidance and support the development and performance of the trial
- Selection of clinical sites in EU5 started

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P2 PoC: Focused opportunity positioned to drive value

Operational review

Solid foundation	• Solid pre-clinical 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 2037, 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 consultancy • Concept and clinical study endorsed by international, renowned KOLs

fima VACC

P2 PoC expected upcoming catalysts & milestones

Operational review

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

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

fimaNAc

Operational review

Providing an intracellular delivery solution for nucleic acid therapeutics

- Compelling preclinical results
  - Strong data for a range of nucleic acid therapeutics
- Addressing a major hurdle for this class of drugs
  - Intracellular delivery remains a major obstacle
- Focused development targeting applications suited to the strength of the platform
  - Strategy to build partnerships in key areas
- Collaboration established with MDimune in Q1, a South Korean biotech company developing innovative drug delivery technologies

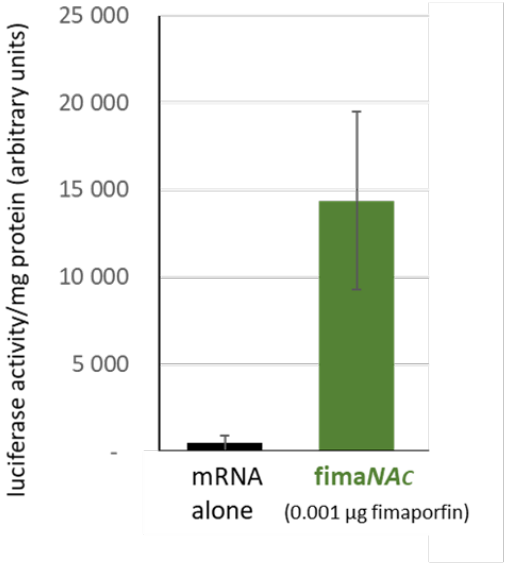
fima*NAc*

Operational review - status

Excellent technological fit with dermatological diseases

- ✓ Substantial enhancement of intracellular nucleic acid delivery in skin
- ✓ **fima*NAc*** provides excellent spatial specificity of nucleotides
- ✓ Easy illumination access and possible topical application

- Large market and opportunity space with several companies developing nucleic acid therapeutics for dermatological applications
- Research collaboration with the South Korean company OliX



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

fima*NAc*

Operational review - strategy

Focused development of user-friendly application

- Intend to initiate collaborative development of integrated delivery solution for dermatological applications
  - Topical **fima*NAc*** formulation
  - Skin illumination device
- Aim to be applied across dermatology applications
- Expanding the collaborative opportunity space

Corporate

Key financials

Outlook

Q&A

Corporate

Organisational changes

- Organisational changes - 25% reduction by end of June
  - Clinical team
  - CBO
  - CEO to assume a new position
  - Ronny Skuggedal, Interim CEO effective 1 June
  - Research and Development team fit for purpose

- Conferences
  - LSX World Congress, London, May 2022
  - TIDES USA, Boston, May 2022
  - ABGSC Life Science Summit, May 2022

Finance

- **Financial run-way estimated towards the end of 2023**
  - RELEASE closure, estimated future cash effect up to NOK -10 million
  - Organisational changes
  - Preparations for the fima*VACC* PoC study continue while financing opportunities are being explored

Key financial figures

(figures in NOK 1,000)	**Q1 2022**	**Q1 2021**	**FY 2021**
Other income (public grants)	1 188	1 588	6 273
Operating results	-22 801	-21 171	-86 029
Net financial result	-212	-2 602	-2 362
Net profit/loss	-23 012	-23 773	-88 391

(figures in NOK 1,000)	**Q1 2022**	**Q1 2021**	**FY 2021**
Cash & cash equivalents	93 680	164 298	116 118
Cash flow from operating activities	-21 592	-20 621	-68 307

Outlook

Enabling intracellular delivery

fima VACC

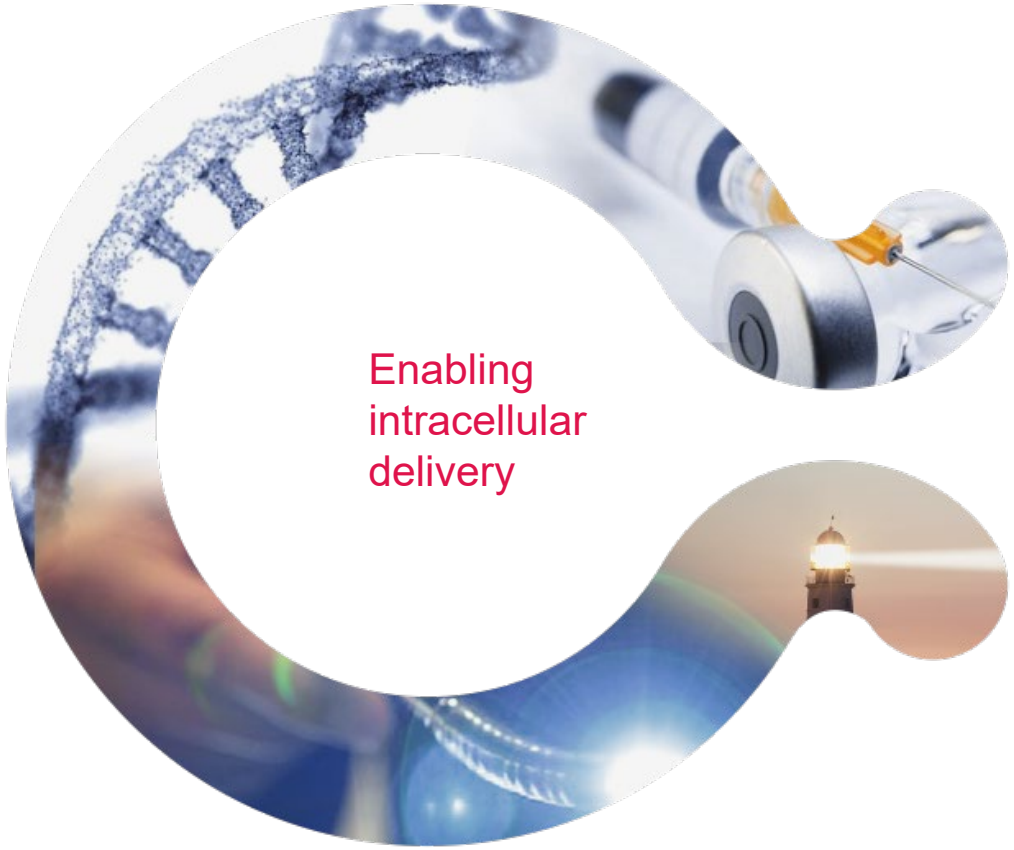
- Progressing towards initiation of Phase II
- Aiming to convert cold tumours to hot and improve the response to ICIs in head and neck cancer
- Good project readiness: clinical expert group established and clinical sites in EU5 selected
- Versatile vaccination technology available for partnering

fima NAC

- Development of treatment applications in dermatology
- Pursuing collaborations and out-licensing opportunities

fima CHEM

- Swift and cost-effective closing of the RELEASE study



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For enquiries:

Per Walday, CEO
Mobile phone: +47 917 93 429
E-mail: pw@pcibiotech.com

Ronny Skuggedal, CFO
Mobile phone: +47 940 05 757
E-mail: rs@pcibiotech.com