Q4 & Preliminary Full-Year 2021

Presentation

February 18, 2022

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PCI Biotech

Q&A session through teleconference and webcast console

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When prompted, provide the confirmation code or event title.
Confirmation Code: 436187
Event title: Quarterly Report - Q4
This information is also available in the Q4 Report press release.

Also possible to post questions through the webcast console.

PCI Biotech

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Highlights

2021

Highlights

2021

fimaCHEM

- The RELEASE trial 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
- Approximately 30% of the 41 enrolled patients will continue to receive study treatments for up to 6 months, enabling a swift wind-down of the trial
- The trial results will be analysed to evaluate how the data can be utilised going forward

Highlights

2021

fimaVACC

- The programme is progressing towards initiation of a Phase II clinical proof-of-concept study, with product definition and overall study design clarified following comprehensive consultations with international experts
- US patent granted for the use of **fimaVACC** in combination with immune checkpoint inhibitors

Highlights

2021

fimaNAc

- Focused development plan initiated based on strategic research and collaborations, targeting applications suited to the specific strengths of the PCI technology
- Encouraging data on enhanced delivery of mRNA for various medical applications presented at the UK based 12th Annual RNA Therapeutics Virtual Conference
- Established extensive research collaboration with the South Korean company OliX Pharmaceuticals, a leading developer of RNAi therapeutics
- In January 2022, PCI Biotech entered into a preclinical collaboration with the South Korean company MDimune, developing innovative drug delivery technologies for modifying cellular and disease processes

Highlights

2021

Corporate

- Significantly strengthened the organisation with three highly skilled individuals; an experienced clinical operational leader, and two key employees within clinical science and business development focusing on **fima*VACC*** and **fima*NAC***

Pipeline

LEVERAGING THE PCI TECHNOLOGY PLATFORM WITHIN IMMUNOTHERAPY & NUCLEIC ACID THERAPEUTICS

Development programmes

Programme	Indications/Therapeutics	Preclinical	Phase I	Phase II
fimaVACC	Therapeutic cancer vaccines			
fimaNAc	Nucleic acid therapeutics			

Photochemical internalisation (PCI) is a platform technology with two ongoing programmes targeting an attractive and growing oncology market

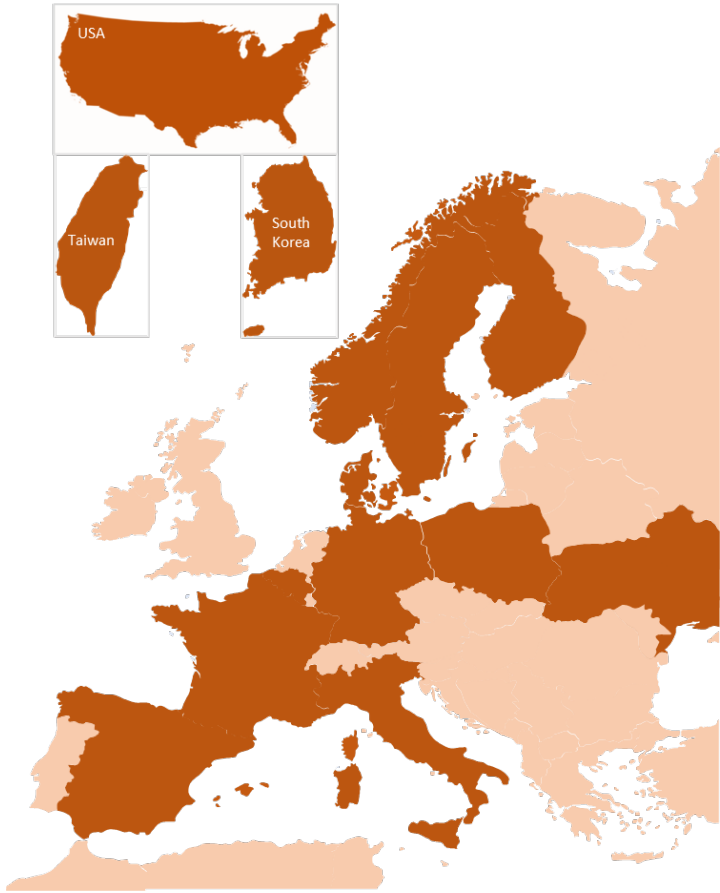
Operational review

by programme

fimaCHEM

Operational review

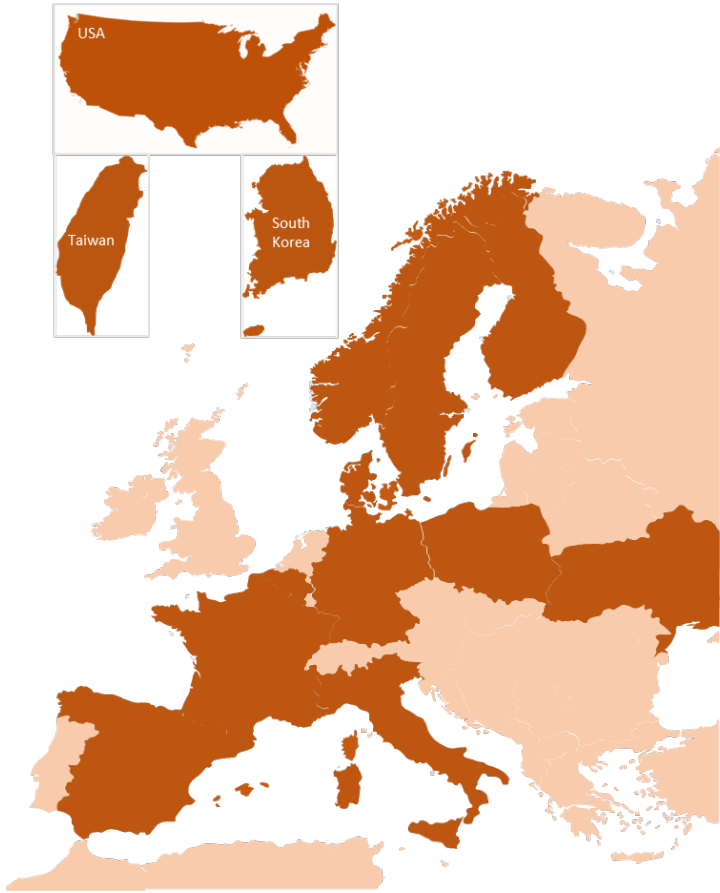
- Recruitment to the RELEASE study has been closed following presentation of results from the randomised Phase III TOPAZ-1 study at ASCO GI Jan. 20-22, 2022
- The TOPAZ-1 study demonstrated that a combination of immune checkpoint inhibition with gemcitabine and cisplatin provides a significant survival benefit to patients with advanced biliary tract cancer
- The results are expected to rapidly change the first line standard treatment for patients with unresectable perihilar or distal bile duct cancer, which is the intended patient population of the RELEASE trial



fimaCHEM

Operational review

- Such a change in the standard of care treatment will render the RELEASE trial challenging to complete and potentially inadequate for approval and will significantly diminish the opportunity for PCI Biotech's treatment approach in this patient population
- PCI Biotech will now focus on a swift and cost-efficient closing process of the trial – work in progress with CRO
- Almost 60% of the sites are being closed immediately, while efficacy will be monitored and collected for earliest possible closure of all other sites
- The results will be compiled and analysed for assessment of how they can be utilised going forward



fima VACC

Operational review

Leveraging the PCI technology platform within immunotherapy

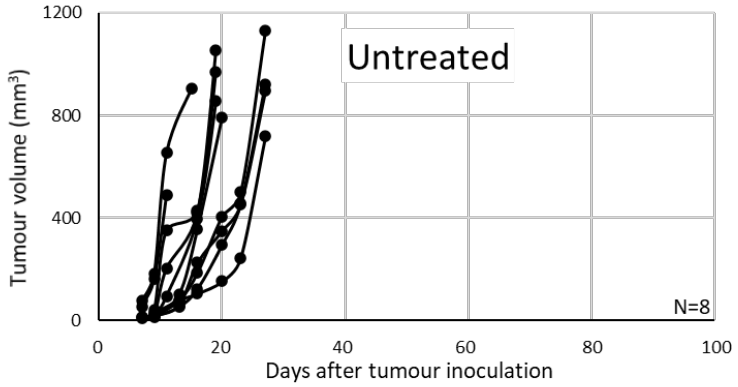
- Compelling preclinical results with unique mode of action
  - Particularly strong CD8 T-cell immune responses
- Successfully translated into humans
  - Phase I study in healthy volunteers – results published
- Versatile vaccination platform
  - Potential use with several modalities
- US patent granted for combination with immune checkpoint inhibitors
  - Covering important foreseen development combinations

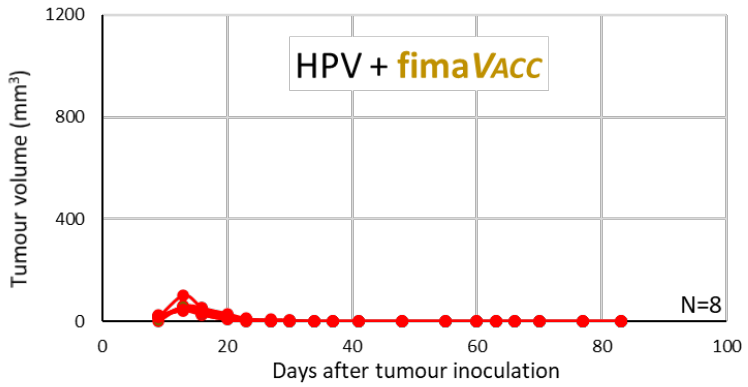
fima VACC

Operational review - preclinical

Compelling preclinical results

Intradermal therapeutic vaccination with **fima VACC** induces strong anti-tumour response





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

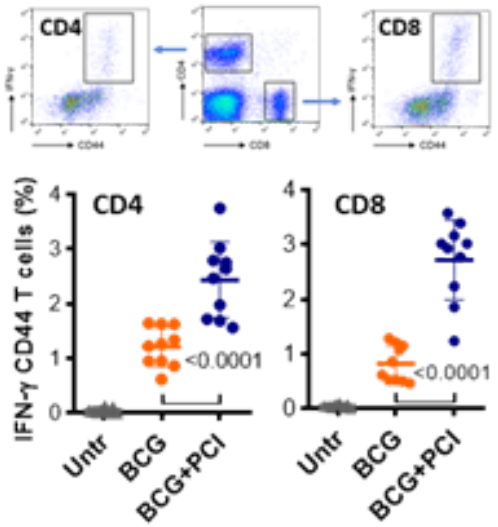
- **fima VACC** (PCI + poly(I:C) adjuvant) with HPV long peptide antigen vaccinated i.d. on Days 8, 13 and 22 (after tumours were established)
- Mice became tumour free and were immune to a new challenge with tumour cells

fima VACC

Operational review - preclinical

Versatile vaccination platform

- In January 2022, positive results from preclinical studies on BCG vaccination performed in collaboration with The University of Zurich and ETH Zurich were accepted for publication in Frontiers in Immunology, a high impact immunology journal
- The article* title is "Photochemically-mediated inflammation and cross-presentation of Mycobacterium bovis BCG proteins stimulates strong CD4 and CD8 T-cell responses in mice"
- The results support our general understanding of **fima VACC**'s mode of action and the potential of the technology



fima VACC significantly enhances both cytotoxic (CD8) and helper (CD4) T-cell responses to BCG vaccination in mice, which are important responses in tuberculosis vaccination and treatment

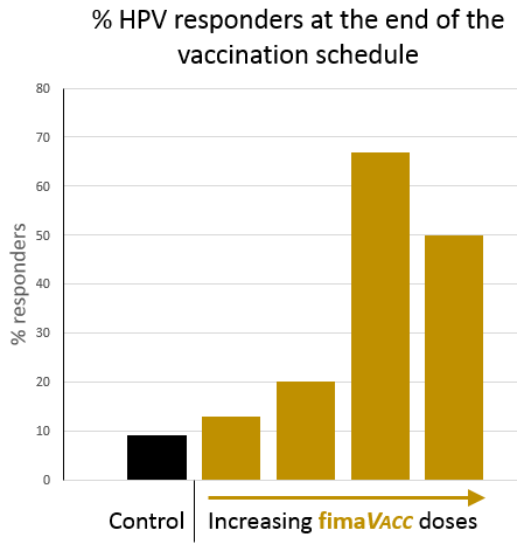
*Waeckerle-Men, Y. *et al.* 2022. Frontiers in Immunology 13, Article 815609

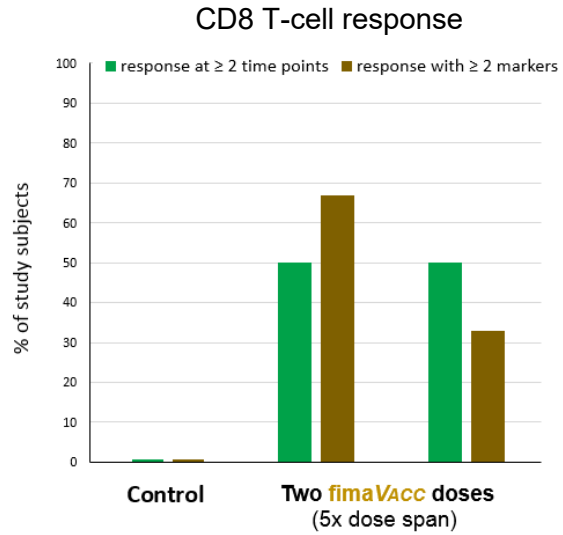
fimaVACC

Operational review - clinical

Phase I study shows enhanced immune responses compared to a state-of-the-art adjuvant

- Addition of 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
  - Increased functionality of the induced CD8 T-cells
- Highly desired features for therapeutic vaccination





fima VACC

Operational review - clinical

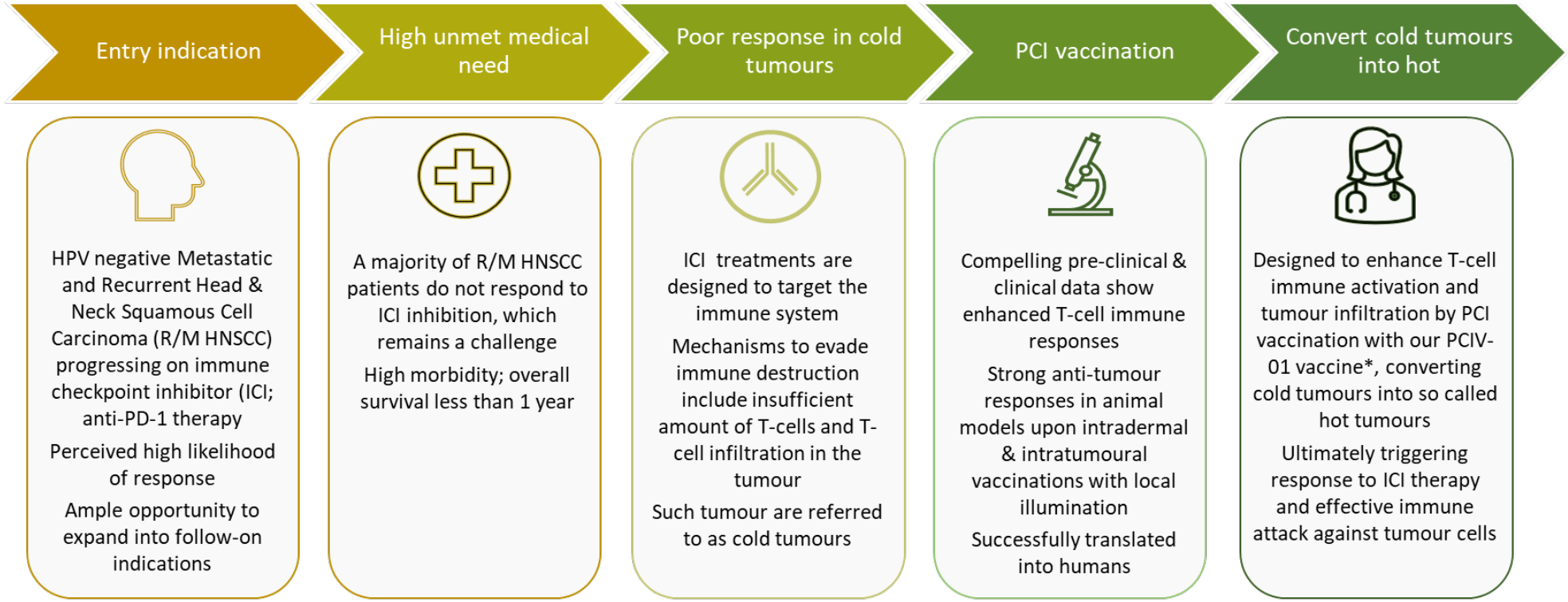
Progressing towards initiation of a Phase II clinical proof-of-concept study

- Start small and build upon the results
- Study in cancer patients with a goal to demonstrate anti-tumour activity
- Recurrent/metastatic head and neck cancer – perceived high likelihood of response and high unmet medical need
- Combine different therapeutic approaches to achieve maximal immunotherapy effect – converting cold tumours into hot
- Work closely with international experts in the fields of the disease and immunotherapy

fimaVACC

Operational review - clinical

Harness the power of fimaVACC to address unmet medical needs



**PCIV-01: anti-cancer vaccine with peptide antigens and fimaporfin*

fima VACC

Operational review - status

- Ongoing activities focusing on preparation of the study protocol, CMC and operational activities
- A forum of clinical investigators has been established to support the preparations and conduct of the study
- Further information will be announced when all key aspects of the study have been discussed and endorsed by the clinical expert group

fimaNAc

Operational review

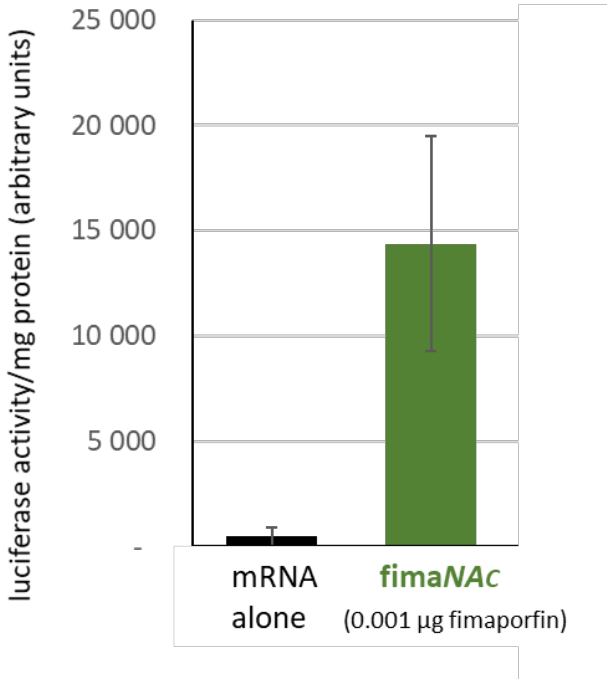
Providing an intracellular delivery solution for nucleic acid therapeutics

- 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 a range of partnerships in key areas

fimaNAc

Operational review - strategy

- Initial focus will be on easily illuminable clinical conditions with supporting preclinical results
  - Skin applications where preclinical experiments suggest substantial enhancement of delivery and transfection, with excellent spatial specificity



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

fimaNAc

Operational review - status

- Encouraging collaborative data on enhanced delivery of mRNA for various medical applications presented at the UK based 12th Annual RNA Therapeutics Virtual Conference
  - The data suggest that **fimaNAc** provides an appealing intracellular delivery solution for certain applications within the emerging class of nucleic acid therapeutics
- These results have helped boost further interest in the technology and two collaborations were initiated with South Korean companies

Research collaborations

Operational review

- Research collaborations offer valuable scientific knowhow, encouraging results and intellectual property
- Currently six collaborations, spanning across different classes of drugs and therapeutic applications
- The most recently established collaboration is with MDimune, a South Korean biotech company developing innovative drug delivery technologies
- PCI Biotech continues to pursue new and value-adding collaborative opportunities

Key financials
Outlook
Q&A

Finance

- **Estimated financial run-way well into 2023**
  - Current cost base for RELEASE will be reduced over time
  - Closure process for RELEASE under review
  - Potential capital need for next clinical phase of fimaVACC under evaluation
- **Decision to close RELEASE is a non-adjusting after the reporting date event**
  - Laser devices to be fully depreciated in Q1 2022, without cash-flow effect

Key financial figures

(figures in NOK 1,000)	Q4 2021	Q4 2020	FY 2021	FY 2020
Other income (public grants)	1 188	1 567	6 273	7 368
Operating results	-23 272	-21 361	-86 029	-82 121
Net financial result	-1 776	-5 104	-2 362	9 881
Net profit/loss	-25 048	-26 464	-88 391	-72 239

(figures in NOK 1,000)	Q4 2021	Q4 2020	FY 2021	FY 2020
Cash & cash equivalents	116 118	187 967	116 118	187 967
Cash flow from operating activities	-17 492	-16 020	-68 307	-77 391

Outlook

Enabling intracellular delivery

fimaVACC

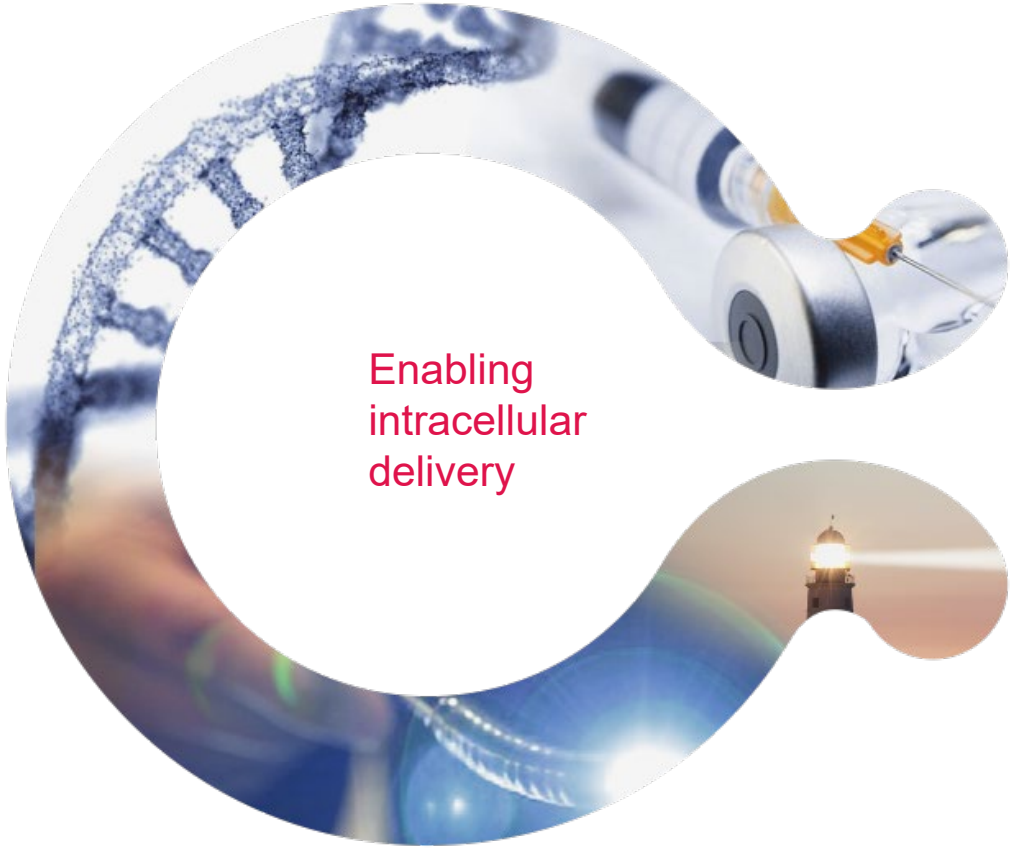
- Progressing towards initiation of a Phase II clinical proof of concept study
- Aiming to improve the response to immune checkpoint inhibitors in recurrent/metastatic head and neck cancer patients
- Clinical expert group supporting the clinical development
- Versatile vaccination technology available for partnering and licensing

fimaNAC

- Development of treatment applications in the most attractive areas for the technology
- Pursuing collaborations and out-licensing opportunities

fimaCHEM

- Swift and cost-effective closing of the RELEASE study
- Compile and analyse results for evaluation of potential value



Q&A

PCI Biotech

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