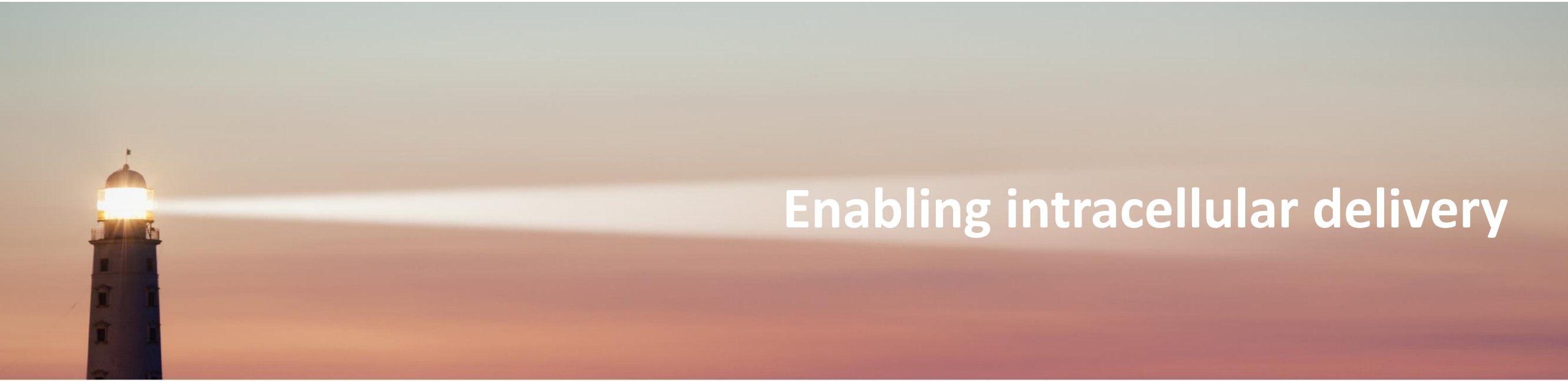
PCI Biotech



Q3 2021 PRESENTATION

November 17, 2021

Per Walday, CEO
Amir Snapir, CMO
Anders Høgset, CSO
Ronny Skuggedal, CFO

PCI BIOTECH

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This information is also available in the Q3 Report press release, and on the webpage https://www.pcibiotech.no/webcasts

Also possible to post questions through the webcast console.

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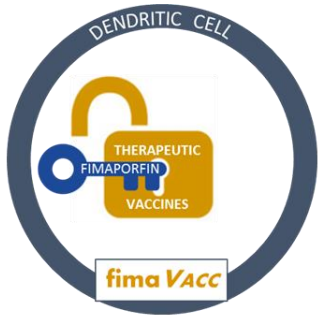
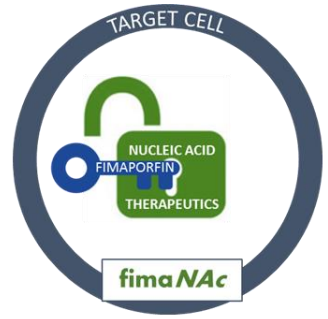
Enabling approved drugs to fulfil unmet local treatment need



Enhancing cellular immune responses important for therapeutic effect



Providing a delivery solution for nucleic acid therapeutics

Q3 2021 HIGHLIGHTS

- fimaCHEM

RELEASE – enrolment fluctuations continues

- Enrolment of patients into the RELASE study is still challenging and fluctuating – Covid-19 has a continued negative impact on the study and with August being a low recruitment month due to the holiday season, only five patients were enrolled in Q3
- Three patients were enrolled into the RELEASE study in October and the company continues to have a strong focus on recruitment, with the emphasis on regular trial management, including overall performance evaluation and site replacement

Q3 2021 HIGHLIGHTS

- fimaCHEM

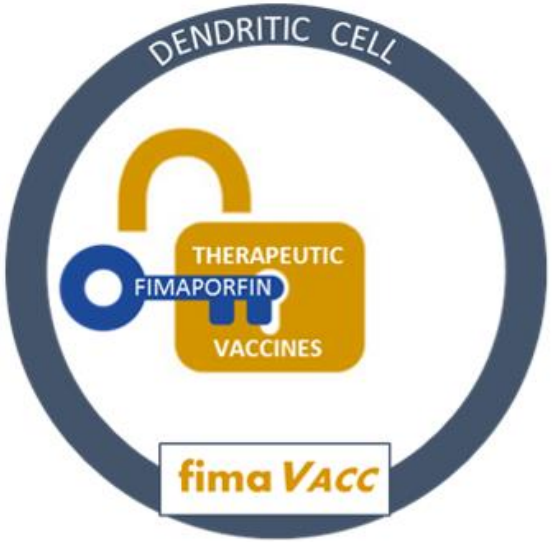
RELEASE – pursuing strategies to address recruitment and retention

- Thirty patients have per end of October been included in the RELEASE study and the expected timeline for interim analysis remains 2H 2023
- Proactively pursuing strategies to address recruitment and retention, including interactions with FDA and EMA about an alternative study design

Q3 2021 HIGHLIGHTS

- **fimaVACC**

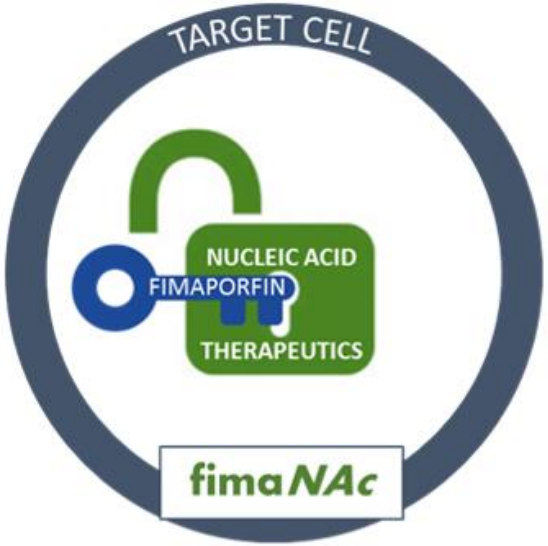
  - The **fimaVACC** programme is progressing towards initiation of a Phase II clinical proof-of-concept study, with product definition and study design clarified following comprehensive consultations with international experts



Q3 2021 HIGHLIGHTS

- **fimaNAc**

  - Development plan initiated based on strategic research and collaborations, targeting applications suited to the specific strengths of the PCI technology



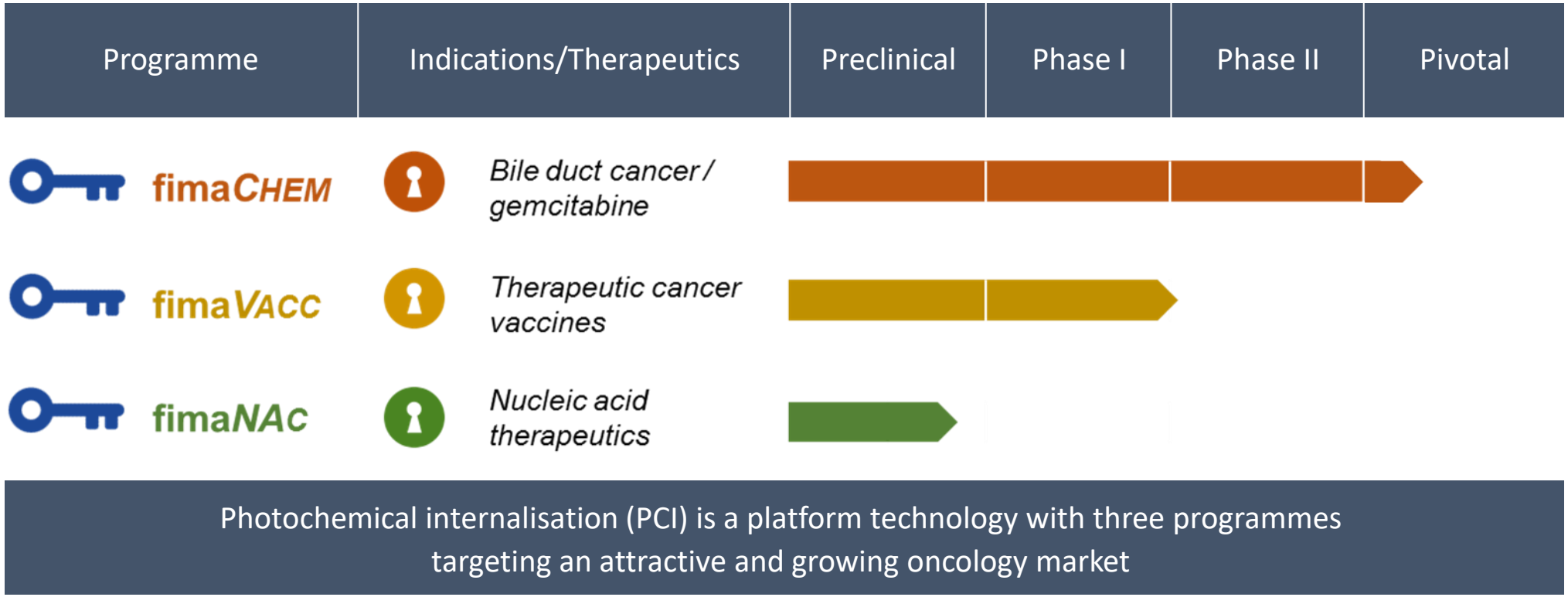
Q3 2021 HIGHLIGHTS

- **Corporate**

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

PCI Biotech – enabling intracellular delivery

- An oncology focused pipeline targeting significant unmet needs



Operational review - clinical

PCI Biotech

- Amphinex® as first line treatment for the orphan indication bile duct cancer*

Positive early clinical results

- Encouraging tumour response and survival data

Pathway to market settled by regulatory interactions

- Single pivotal study with potential accelerated approval based on interim analysis

RELEASE – a global pivotal registration intent study

- Recruitment ongoing at approx. 50 hospitals across three continents

*Cholangiocarcinoma; CCA

fimaCHEM

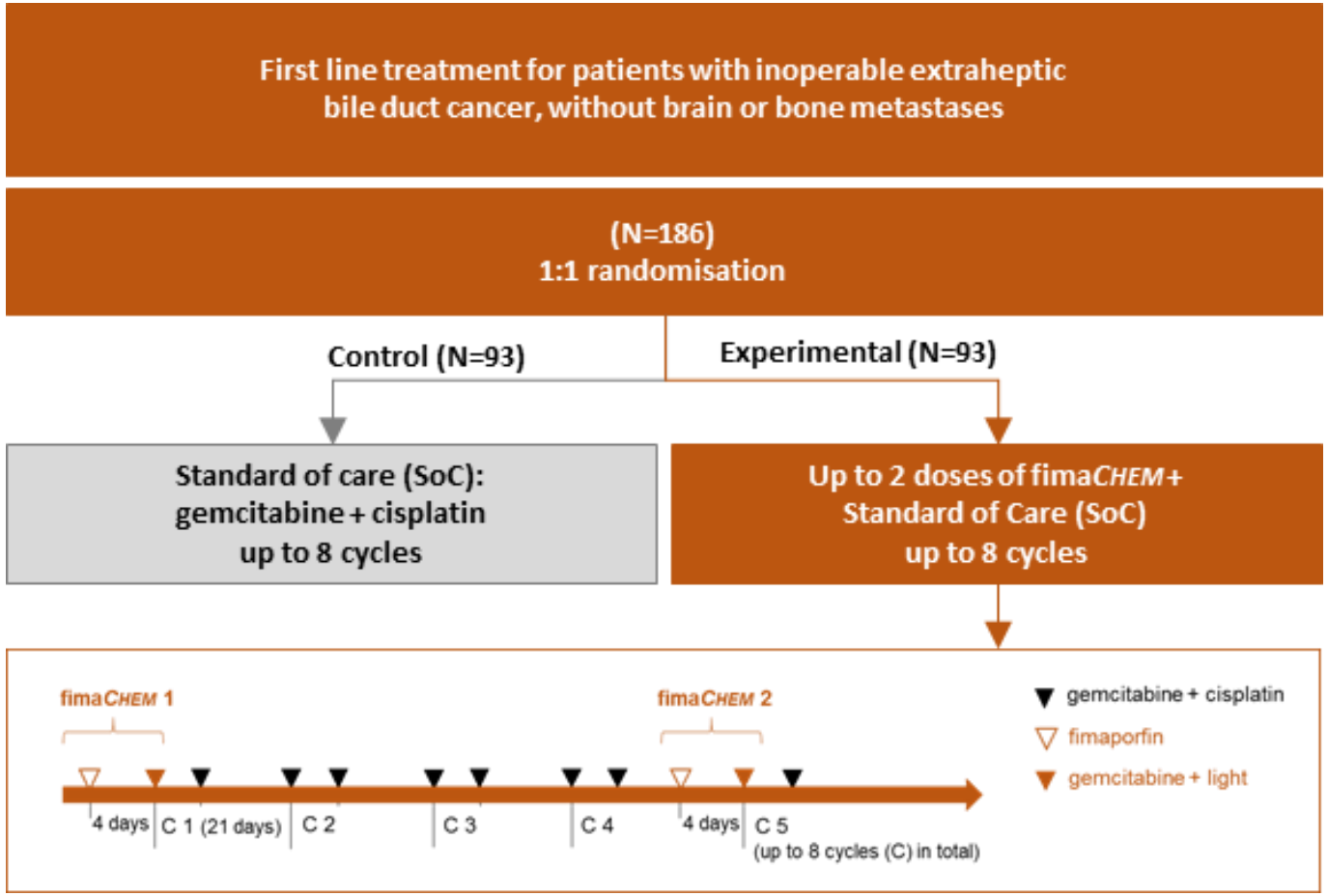
- Excellent fit with medical need and existing treatments

- **Efficacy:** mOS[1] of **22.8 months** at selected dose (cohort IV) in Phase I dose-escalation (vs. **11-12 months**[2] with standard of care for inoperable bile duct cancer treatments)
- **Easy to use:** Illumination through standard endoscopic methods compatible with endoscopic stenting for palliative biliary drainage
- **Positioning:** Enhances recommended first-line chemotherapy and boosts effect locally, where it is most needed (no direct competition)
- **Protection:** Orphan Drug designations in EU, US and South Korea offers market exclusivity, and use patent for treatment method approved in Europe (pending in other major markets)
- **Competition:** Precision/gene/small molecules in clinical development are mainly second line or towards targets mainly present in intrahepatic bile duct cancer, except acelarin, durvalumab & pembrolizumab
  - Recent positive read-out for durvalumab – efficacy results in relevant subgroups are not yet public
- **Premium price potential:** Mean annual price for OD in the US is $K150 (median $K109)[3]

1) Median overall survival 2) New England Journal of Medicine 2010;362:1273-8 3) EvaluatePharma® Orphan Drug Report 2019

Bile Duct Cancer – Release Study

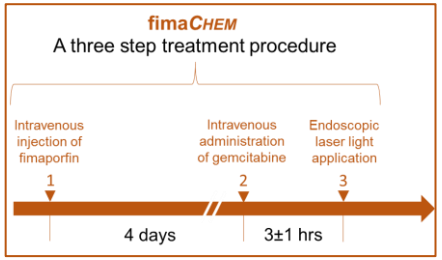
- Pivotal study with potential accelerated/conditional approval on interim analysis



- Rare disease
- Majority of cases are inoperable upon presentation
- Median overall survival of less than one year
- No approved treatment, limited development pipeline

- Approx. 50 clinical sites planned in EU, US and Asia
- 11 European countries, 2 Asian countries + USA

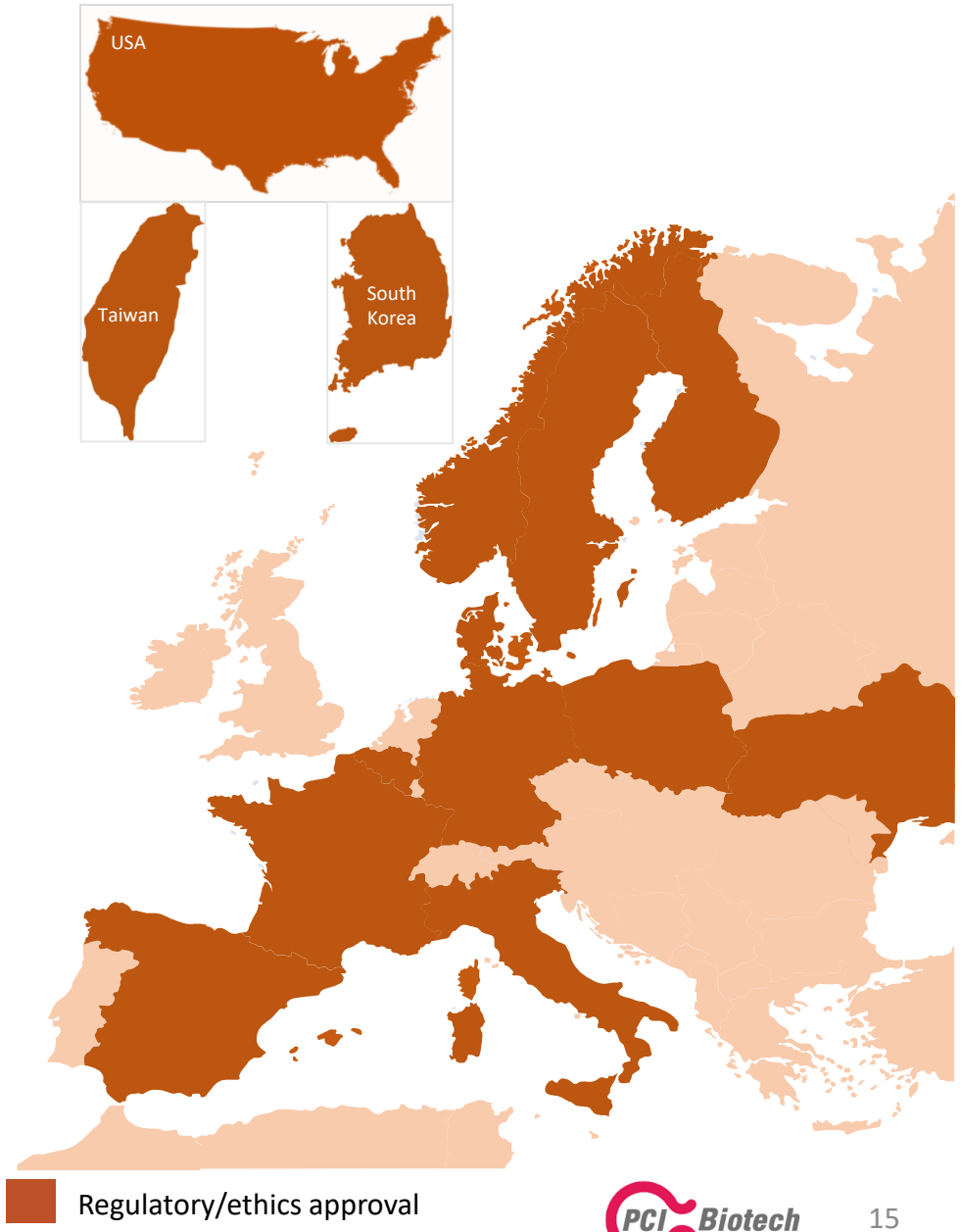
- **fimaCHEM** in addition to current Standard of Care



Bile Duct Cancer – Release Study

- Pivotal study status

  - 47 sites currently open for patient enrolment
    - 32 sites in Europe, 9 in Asia and 6 in the US
  - Several initiatives implemented with the aim to recoup the COVID-19 caused delay – the most important being increased number of sites and protocol amendment to expand eligible patient population
  - The initiatives provided increased screening and enrolment, but the level has been fluctuating during 2021
  - Five patients were enrolled in Q3, and three patients were enrolled in October, with total enrolment into the study: 30
  - Continued strong focus on enrolment of patients, with emphasis on regular trial management, including overall performance evaluation and site replacement – more than 10% of sites have been replaced so far in 2021



Bile Duct Cancer – Release Study

- Endpoints, milestones and timelines

Endpoints:

Interim analysis: Primary Endpoint: Objective Response Rate (ORR) Secondary endpoint: Overall Survival (OS)	• Orphan drug designation in EU, USA and South Korea – potential accelerated approval
Final analysis: Primary endpoint: Progression Free Survival (PFS) Secondary endpoint: Overall Survival (OS)	• Single randomised trial considered sufficient based on interaction with US and EU regulatory authorities

Milestones and timelines:

First patients enrolled in Europe in May 2019, in Asia in October 2020 and in the US in April 2021	• Enrolling patients on three continents
Seamless safety review by IDMC* when 8 patients have undergone two fima*CHEM* treatments	• IDMC safety review expected 2H 2021
Objective Response Rate (ORR) when 120 patients have been enrolled	• Interim analysis expected 2H 2023
Timing and format for study conclusion may be impacted by outcome of Interim analysis	• Final analysis expected approximately 2H 2024

*IDMC = Independent Data Monitoring Committee

Bile Duct Cancer – Release Study

- Patient retention

Background

- Ability to analyse the primary endpoint requires a specific number of events to occur in the trial
- Retention imbalance between arms could lead to bias and require additional statistical analyses by regulatory authorities

Challenges

- In open label studies, patients randomised to the control arm are more likely to leave the study
- Cancer patients are vulnerable to infections and may want to decrease risk for infection – especially during a pandemic
- Early signs in RELEASE suggest a lower retention rate of patients in the control arm

Strategies

- Working with clinical sites to strengthen the commitment of patients to the trial
- Support patients in all aspects of taking part in the study
- Evaluate the possibility to convert the randomised control arm to a hybrid control arm by adding external patients' data
- Evaluate options to decentralise the study, allowing treatment in nearer clinics and replacing site visits with home visits

Bile Duct Cancer – Release Study

- Patient recruitment

Background

- CCA is a rare disease and RELEASE targets a subpopulation of CCA patients
- The COVID-19 pandemic has affected both patients and clinicians – hesitation to come to hospitals; hospital shifting resources; increased workload on healthcare staff

Challenges

- Maintain momentum in a rare disease where sites expect to recruit only a few patients during the recruitment period
- The interdisciplinary coordination required is demanding in the complexity of a trial setting – especially in a pandemic
- Patients and investigators perceive odds of 50% to receive the investigational treatment low – patients may choose to pursue other investigational treatments, or receive the standard of care treatment closer to home

Strategies

- Optimising the eligibility criteria and study operational processes based on data and site/investigator feedback
- Frequent interaction with sites and investigators to facilitate focus and commitment to the trial
- Provide support to sites and patients in all aspects of taking part in the study
- Working with patient organisations and online initiatives to increase study awareness
- Conversion to a hybrid control arm, if feasible, is expected to mitigate the 1:1 randomisation issue

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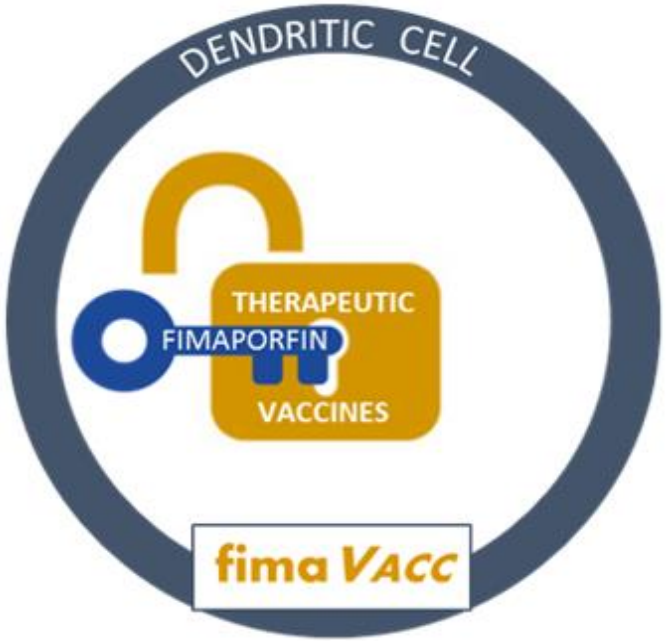
- Aiming to enhance the effect of immunotherapeutics



Compelling preclinical results

- Particularly strong CD8 T-cell immune responses

Successfully translated into humans

- Phase I study in healthy volunteers with peptide- and protein-based vaccines – results published

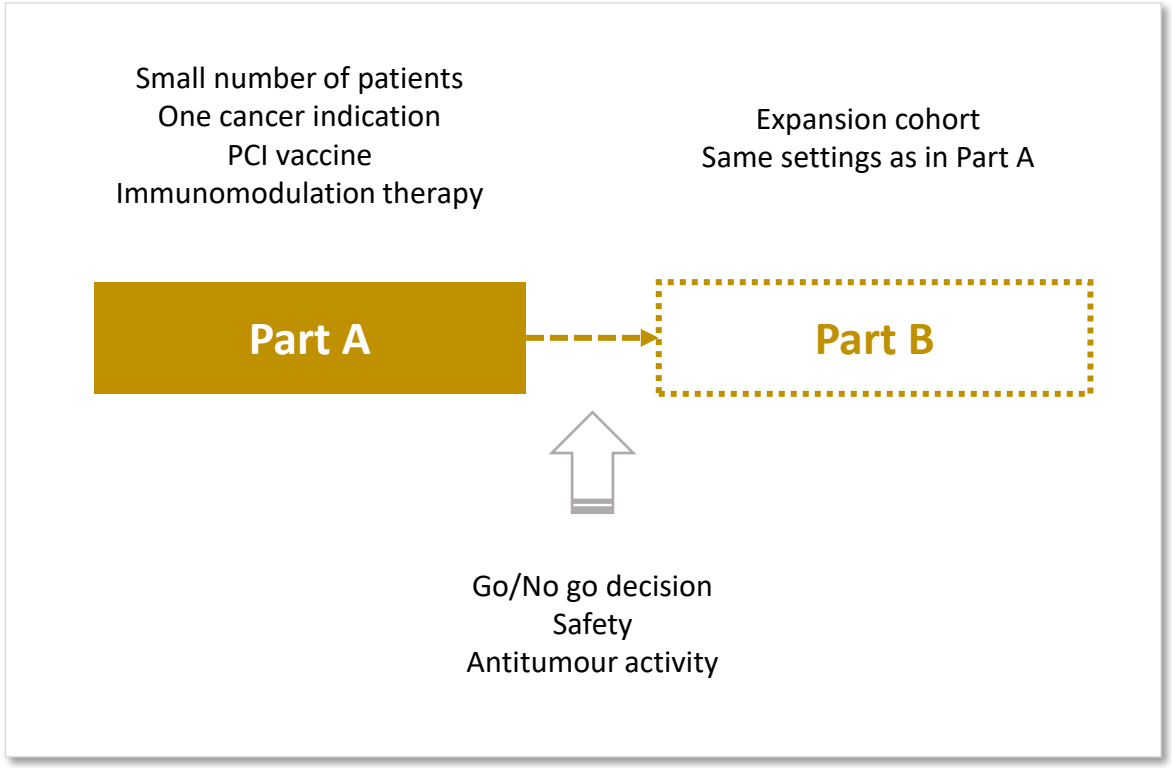
Versatile vaccination platform

- Can potentially be used with several modalities, including nucleic acid based technologies

PLANNED fimaVACC STUDY IN CANCER PATIENTS

- Strategy

- Start small and build upon the results
- Study in cancer patients with a goal to demonstrate anti-tumour activity
- One specific cancer type with perceived high likelihood of response and high unmet medical need
- Combine different therapeutic approaches to achieve maximal immunotherapy effect
- Work closely with international experts in the fields of the disease and immunotherapy



PLANNED fimaVACC STUDY IN CANCER PATIENTS

- Improving the response to immune checkpoint inhibition

Study treatment

- Combination with relevant immunomodulation therapy for effective immunotherapy
- Fimaporfin, a mix of relevant peptide antigens, and a synergistic adjuvant will be included
- Intradermal and intratumoural administration are considered

Study population

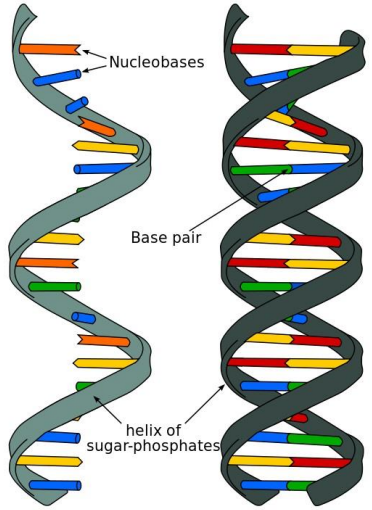
- Patients with recurrent or metastatic solid tumours who progressed on 1st line immune checkpoint inhibition (ICI) therapy
- Aim is to convert cold tumours into hot tumours and thereby achieve long-term response to ICI therapy in more patients

Study design, operations & status

- A 2 stage study is planned, starting with a small cohort of patients to assess safety and hint of antitumour activity, and expanding the study upon good results
- The study is planned to start in Europe and expand to US upon good results – timelines TBA
- Ongoing activities focusing on preparation of the study protocol, CMC and operational activities, and establishing a forum of clinical investigators to support the preparations and conduct of the study

Operational review - preclinical

Nucleic Acid Delivery with PCI



- Nucleic acids – a rapidly growing area with potential for the treatment and prophylaxis for many diseases, and with approvals in e.g.:
  - Covid-19 – mRNA prophylactic vaccines
  - Treatment of SMA (high price levels)
    - Spinraza – oligonucleotide for treatment of spinal muscular atrophy (SMA)
    - Zolgensma - gene therapy (virus based) for treatment of SMA – approved for use in Norway
- Delivery to the target tissues still represents a major barrier
  - Lipid nanoparticles work well for prophylactic intramuscular vaccination approaches
  - Technologies for liver delivery are available
  - Effective delivery systems remain to be established for most other tissues
  - The optimal delivery solution will probably vary between different tissues
- PCI can enhance and direct nucleic acid delivery to target sites that can be illuminated, on the body surface or inside the body (e.g. tumours via an optical fibre)

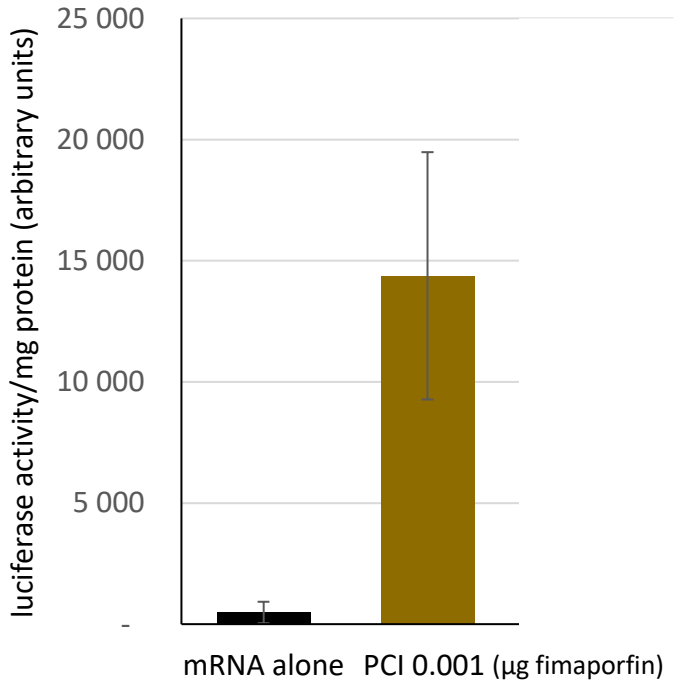
PCI Strongly Improves Delivery of Naked mRNA to Skin

PCI can enhance functional naked mRNA delivery to skin (intradermal inj.) about 30 times

IVIS imaging after i.d. inj. of luciferase mRNA and subsequent i.v. inj. of the substrate luciferin

Control PCI

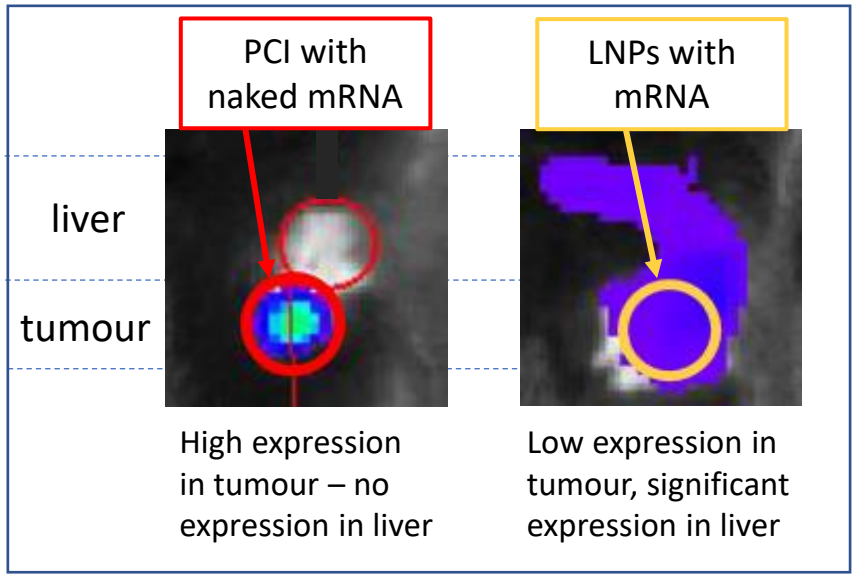
Enzymatic luciferase activity in skin samples after i.d. inj. of luciferase mRNA



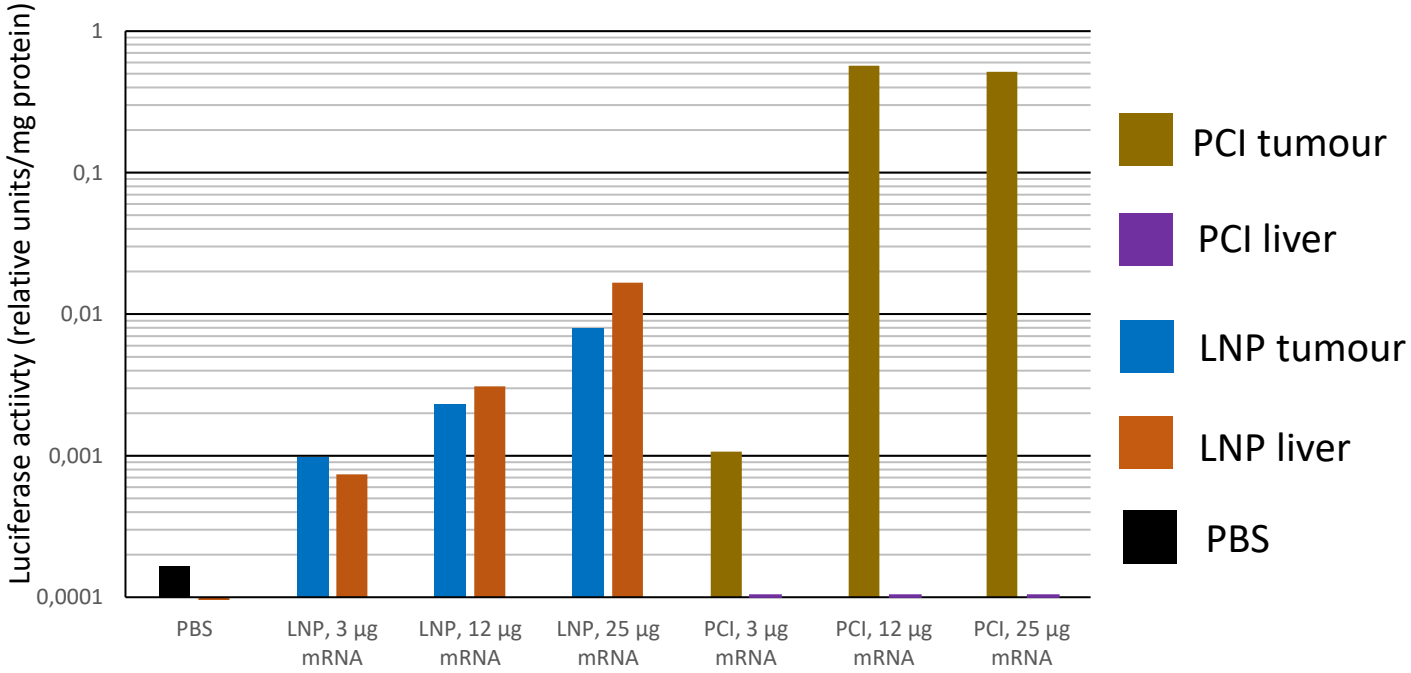
PCI vs. LNPs for mRNA Delivery to Tumours

- PCI enhances delivery and prevents undesirable off-target effects

IVIS imaging after intratumoural inj. of luciferase mRNA and subsequent i.v. inj. of the substrate luciferin



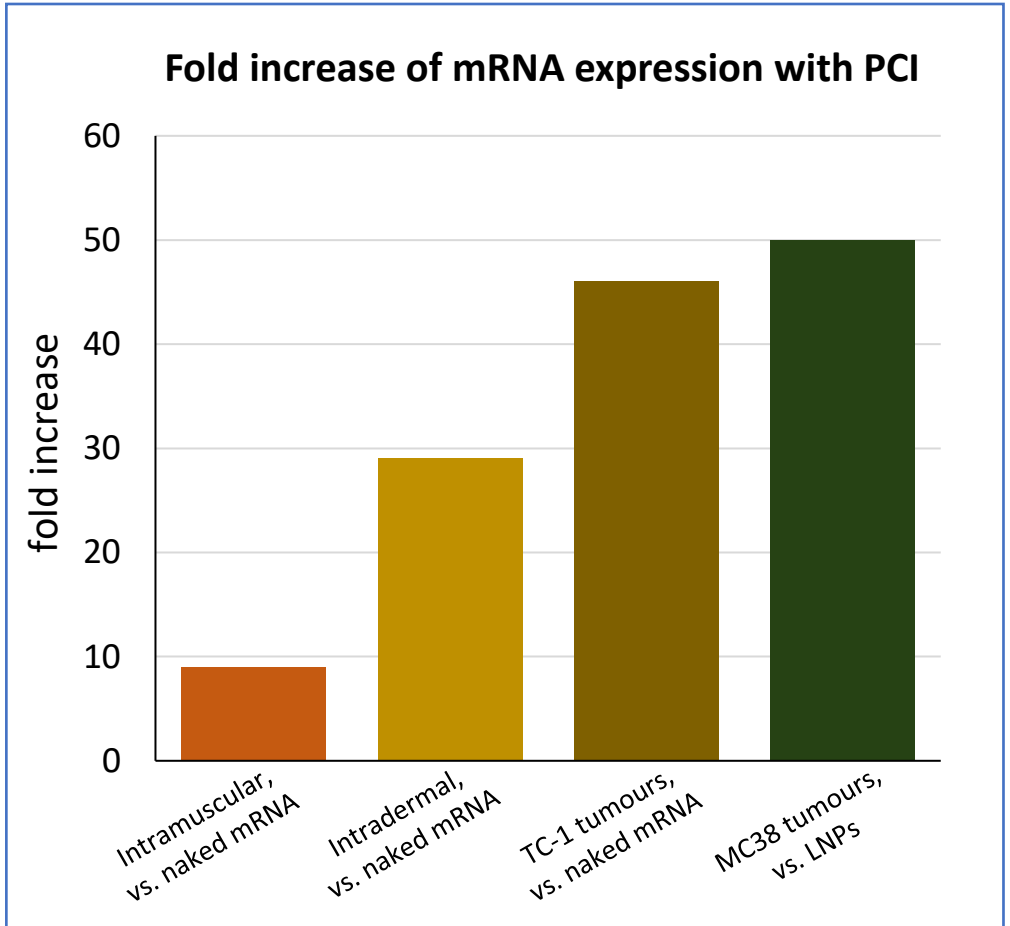
Luciferase expression in MC38 tumours and liver after intratumoural delivery of luciferase mRNA by LNPs or PCI. Median values.



- Off-target delivery can give serious safety problems in patients
- With PCI-mediated delivery of naked mRNA, expression in the tumour is higher than with LNPs, and confined to tumour
- LNPs seem to leak out of the tumour, leading to unwanted expression in the liver, at equal expression levels as in tumour

Naked mRNA Delivery with PCI – Different Applications

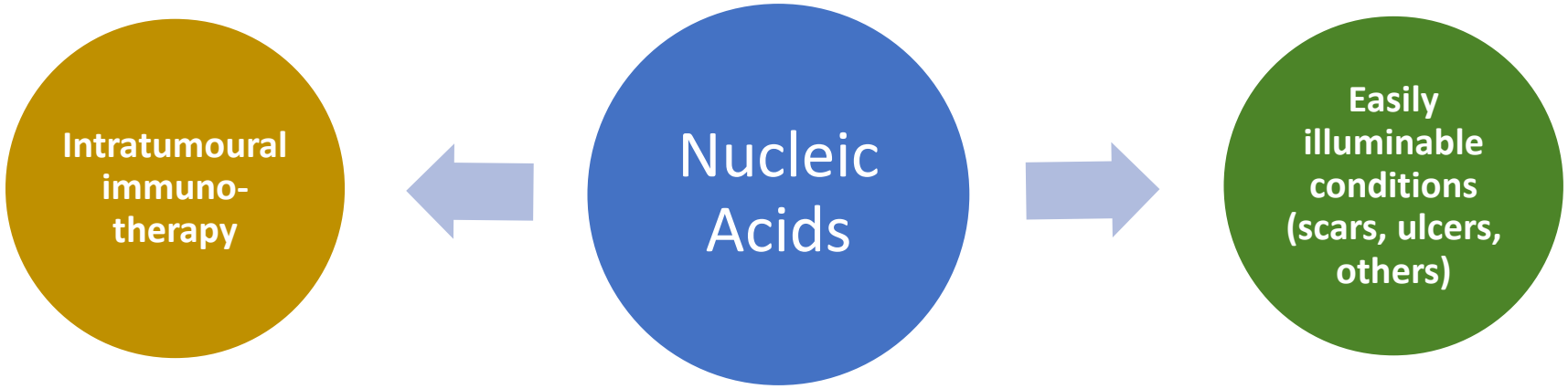
- Best effect seen for intratumoural delivery



Substantially enhanced delivery to tumour, muscle and skin

- Local delivery technology
  - mRNAs and fimaporfin can be mixed and administered as one injection, with illumination in the same procedure
  - mRNA expression spatially restricted to illuminated area
- Many applications where a local effect is desired
  - Skin, tumours, muscles, eye, joints, lymph nodes
- Substantial enhancement in tumour, skin and muscle
- Internal research is actively centred towards the most attractive applications

PCI for Nucleic Acid Delivery – Top Priorities



- Good technological fit – a lot of interesting options
- PCI delivery works well in animals
- Treatment of tumours can be performed at several sites in the body
- Treatment of one tumour can give systemic effects
- On-going collaboration: eTheRNA

- Good technological fit – a lot of interesting options
- PCI delivery works well in animals
- Easy illumination access
- Many relevant diseases
- On-going collaboration: OliX Pharmaceuticals

Development of PCI for Nucleic Acid Delivery

RNA intratumoural immunotherapy

- Pro-actively develop technology and seek further partnerships for intratumoural immunotherapy, based on current data
- Already collaboration with a leading company in this area (eTheRNA)
- Also possibilities for own products

Easily illuminable conditions

- Actively approach companies based on current data
- Very interesting collaboration with OliX
- Develop technology further internally and with collaborators

FINANCE

- Key financial figures

  - CF impacted by timing difference of received annual SkatteFUNN grant (Q3 21 vs Q4 20)
  - Cash position with an expected financial runway into Q4 2022 at current cost base

(figures in NOK 1,000)	Q3 2021	Q3 2020	YTD 2021	YTD 2020	FY 2020
Other income (public grants)	1 187	1 963	5 085	5 801	7 368
Operating results	-22 503	-22 534	-62 757	-60 760	-82 121
Net financial result	*1 080*	*1 329*	*-586*	*14 985*	*9 881*
Net profit/loss	-21 423	-21 204	-63 343	-45 775	-72 239

(figures in NOK 1,000)	Q3 2021	Q3 2020	YTD 2021	YTD 2020	FY 2020
Cash & cash equivalents	135 513	210 233	135 513	210 233	187 967
Cash flow from operating activities	-13 141	-22 443	-50 984	-61 372	-77 391

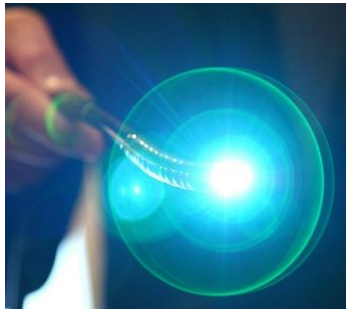
PROGRESSING THE PCI-TECHNOLOGY PIPELINE

- Strengthened the organisation with recruitment of three key senior employees

fimaCHEM

Progressing development in bile duct cancer towards marketing authorisation application

- RELEASE study with interim read for potential accelerated approval ongoing across three continents
- Implemented improved trial design and several initiatives to optimise execution during the pandemic
- Proactively pursuing strategies to address recruitment and retention challenges
- IDMC safety review of two treatments expected 2H 2021
- Interim analysis for potential accelerated approval expected 2H 2023



fimaVACC

Programme progressing towards initiation of a Phase II clinical proof of concept study

- Phase I results published in high-impact immunology journal: Frontiers in Immunology
- Clinical proof of concept study aiming to improve the response to immune checkpoint inhibitors
- Versatile vaccination technology available for partnering and licensing

fimaNAC

Providing an intracellular delivery solution for nucleic acid therapeutics

- Presented encouraging mRNA data and established a new extensive research collaboration in RNAi
- Actively centre internal research efforts towards the most attractive applications

INVESTMENT HIGHLIGHTS

Broad platform technology	PCI is a platform technology with three programmes targeting an attractive and growing oncology market, with a clear path to a high unmet need orphan oncology market for the lead candidate
Advanced lead product candidate	**fima CHEM** – Amphinex® is an orphan designated (EU, US, South Korea) first-in-class product candidate in pivotal development for treatment of extrahepatic bile duct cancer – a disease without approved drugs
Encouraging clinical results	Positive early signs of tumour response in a first-in-man study published in Lancet Oncology, and in a Phase I study specifically targeting bile duct cancer – encouraging survival data
Defined development strategy	Development strategy for lead candidate established based on thorough regulatory discussions with FDA and EMA – a single randomised pivotal study with accelerated/conditional approval potential
Pipeline opportunities	**fima VACC** – a clinical stage vaccination technology with encouraging cellular immune responses **fima NAC** – a preclinical gene therapy delivery solution with established key player collaborations
Experienced leadership	Management team, Board of Directors and advisors with extensive pharmaceutical industry experience across a range of medical development and commercial areas

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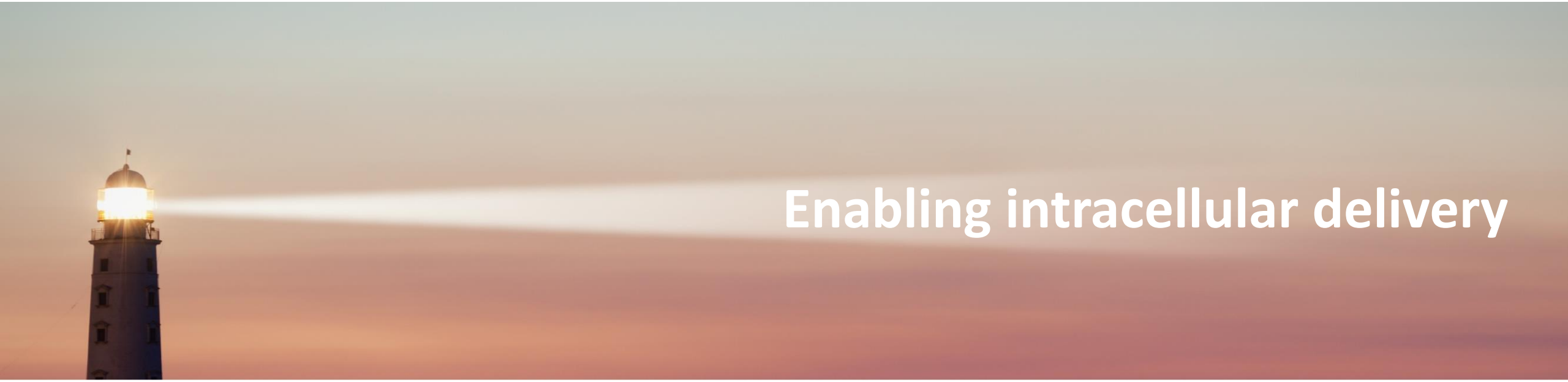

For enquiries:

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