

PCI BIOTECH

Unlocking the potential of innovative medicines

Q3 2018 PRESENTATION

November 13, 2018

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PCI BIOTECH

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HIGHLIGHTS

► Third quarter 2018

fima *CHEM*

- Continued positive early signs of efficacy from Phase I
 - Preparations for the pivotal study progressing towards initiation in the first half of 2019
 - Presented Phase I dose-escalation results at the 2018 ESMO congress (subsequent event)
-

fima *VACC*

- Entered collaboration with a renowned international cancer immunology institute for analysis and characterisation of the clinical immune response
 - US patent granted for “band-aid-like” device for skin illumination/injection (subsequent event)
-

fima *NAC*

- Established new research collaboration with Bavarian Nordic, an immunotherapy-focused biotechnology company
-

Corporate

- Completed fully underwritten rights issue of NOK 360 million (subsequent event)
 - Further strengthened the clinical organisation (subsequent event)
-

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 Oslo University Hospital – the Radium Hospital

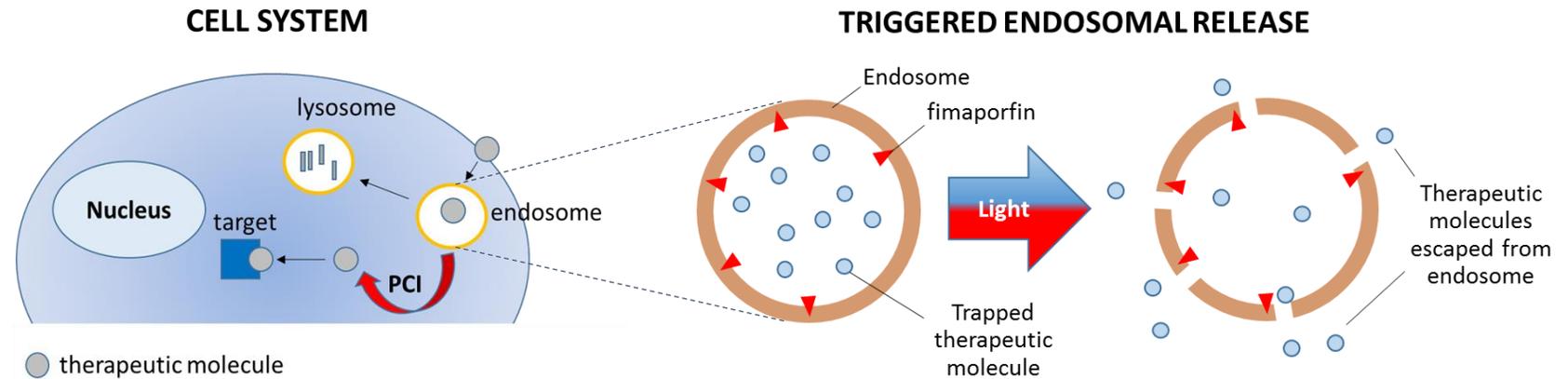
Programme	Indications / Therapeutics	Preclinical	Phase I	Phase II	Pivotal	Status
 fimaCHEM	 <i>Bile duct cancer / gemcitabine</i>					<ul style="list-style-type: none"> - Encouraging Phase I results for treatment in the orphan indication bile duct cancer - Expect to initiate pivotal study 1H 2019
 fimaVACC	 <i>Therapeutic cancer vaccines</i>					<ul style="list-style-type: none"> - Phase I study in healthy volunteers - Encouraging initial immune results - One research collaboration
 fimaNAC	 <i>Nucleic acid therapeutics</i>					<ul style="list-style-type: none"> - Six research collaborations

An oncology focused company with three well differentiated assets

PCI TECHNOLOGY

► Enabling drugs to reach intracellular therapeutic targets

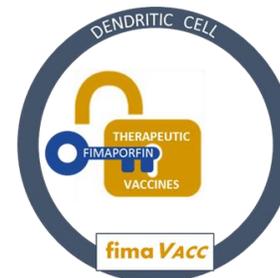
Mode of action



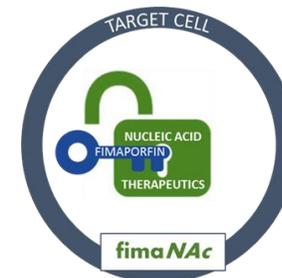
PCI – the solution to a key challenge for several modalities



Enabling approved drugs to fulfil unmet local treatment need



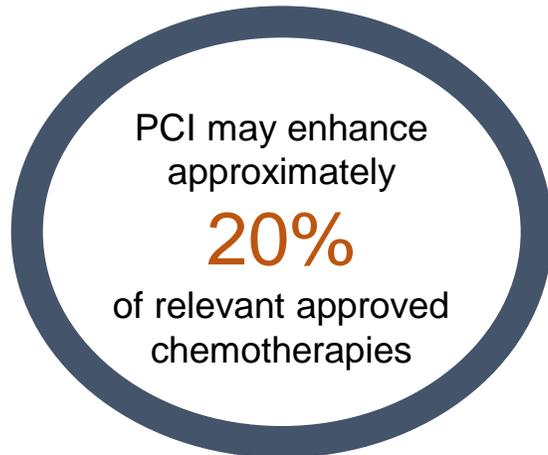
Enhancing cellular immune responses important for therapeutic effect



Providing a delivery solution for nucleic acid therapeutics

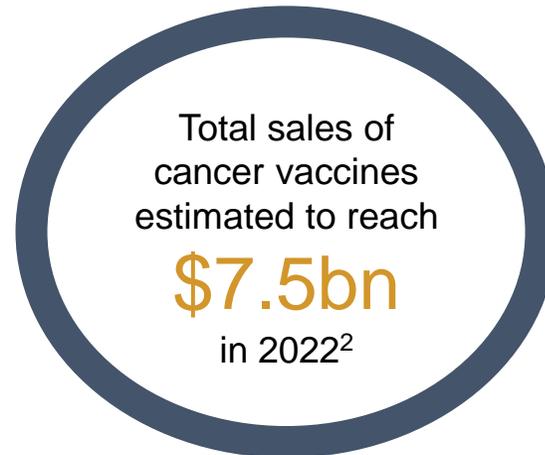
THREE WELL-DEFINED DEVELOPMENT PROGRAMMES

1 fimaCHEM



- ▶ First-in-man study published in Lancet Oncology¹
- ▶ Encouraging tumour responses and survival in Phase I in inoperable extrahepatic bile duct cancer
- ▶ Pivotal phase ready, with potential for approval based on interim read
- ▶ Orphan disease with high price potential

2 fimaVACC



- ▶ Expected market growth largely driven by therapeutic vaccine combinations with checkpoint inhibitors
- ▶ Strong preclinical data – ongoing clinical study with encouraging initial results
- ▶ Aim is to out-license the technology on non-/semi-exclusive basis – opportunity to develop own vaccination products

3 fimaNAC

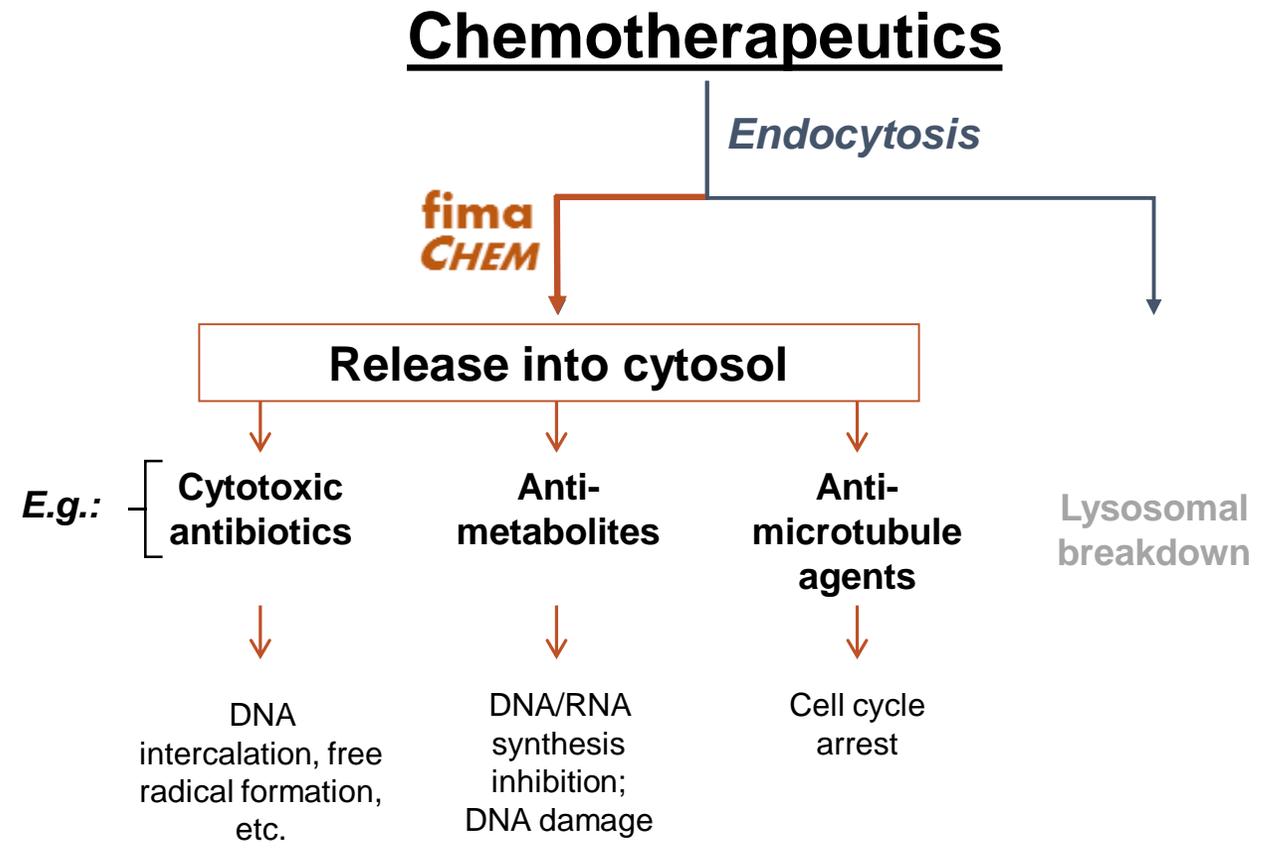
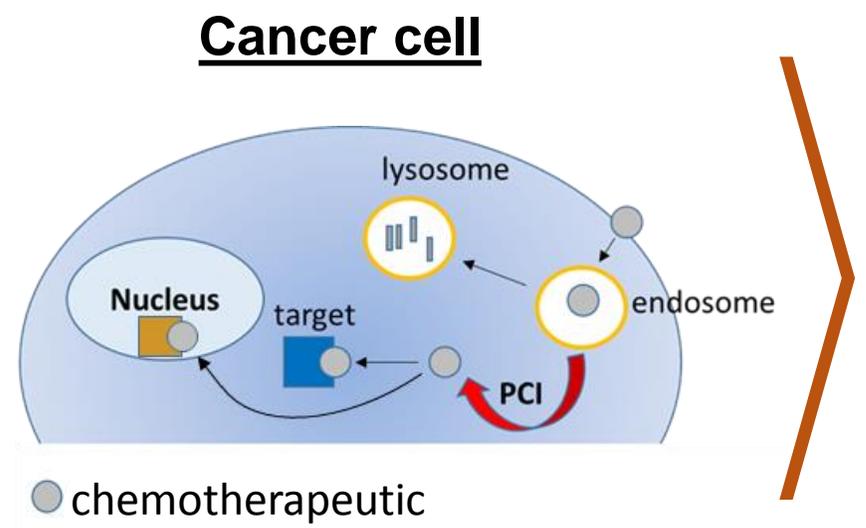


- ▶ Estimated sales of \$18bn in 2030³ (RNAi alone)
- ▶ Strong preclinical data with several RNAi's
- ▶ Collaborative approach – six collaborations with key players established
- ▶ Aim is to out-license the technology on non-/semi-exclusive basis

1) Lancet Oncology (2016) 17(9): p1217–1229
2) GBI Research (2016) Global Cancer Vaccines Market to 2022
3) Research and Markets (2015) RNAi therapeutics market

PCI TECHNOLOGY

► **fimaCHEM** – mode of action



BILE DUCT CANCER

▶ Excellent fit between medical need and **fimaCHEM**

- ▶ Orphan indication, yearly incidence rate of 1-2 per 100,000 in the western world – higher in Asia
- ▶ Five-year survival rate of less than 5% and almost 0% when inoperable
- ▶ Average survival inoperable: ≈12 months
- ▶ Current management
 - Surgery
 - Only potentially curative treatment
 - Less than 1/3 are resectable at presentation
 - Stenting
 - **Endoscopic** stenting for palliative biliary drainage
 - Chemotherapy
 - No approved chemotherapy
 - Recommended: **gemcitabine** and cisplatin

Enhancing the active and recommended chemotherapy

- Combination therapy with gemcitabine and cisplatin is recommended
- Gemcitabine is significantly enhanced by **fimaCHEM**
- Enhancing systemic therapy locally

Easy illumination through standard endoscopic methods

- Patients are treated with endoscopic methods (ERCP) for diagnosis and stenting
- Optic fibre and illumination easily included in the ERCP procedure

Boosting chemotherapy effect where it is most needed

- Tumours tend to block the bile duct
- Liver function is often affected
- Biliary drainage is key for patient treatment and survival

Inducing immunogenic tumour cell death

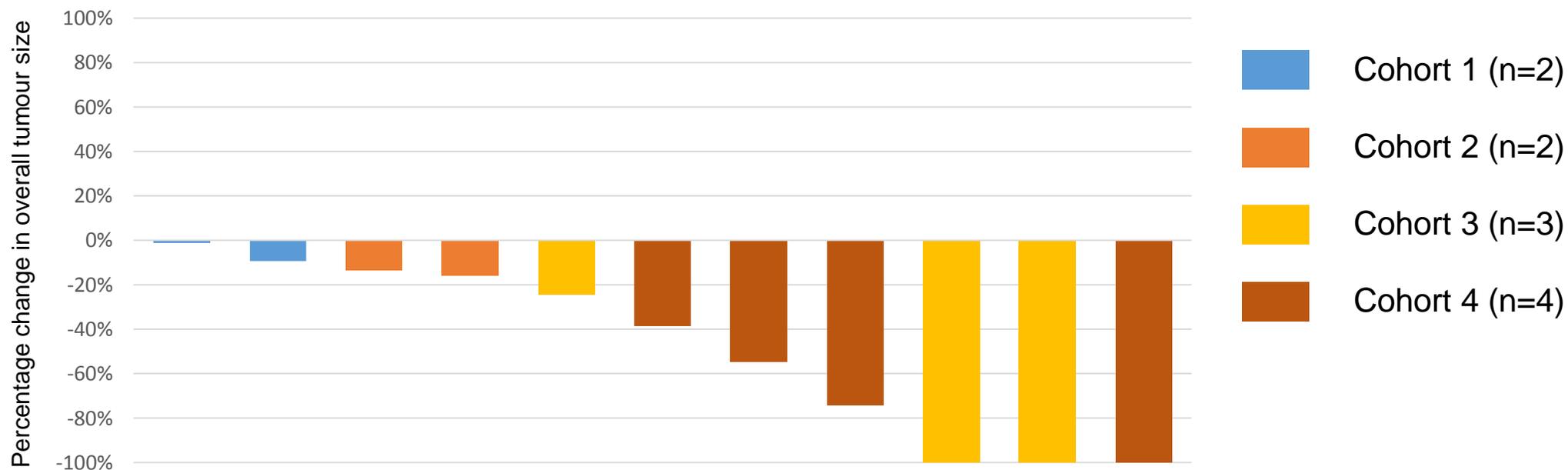
- Preclinical and clinical data supports the notion of potential abscopal effects with **fimaCHEM**
- May be ideal for combination with checkpoint inhibitors

BILE DUCT CANCER – CLINICAL PHASE I/II STUDY

► Encouraging early signs of efficacy in Phase I

- Interim average overall survival (OS) of all 16 patients in Phase I is 18.9 months per October 2018, with 19% of the patients still being alive. Median OS ended at 14.4 months.

Best Overall Response* (all radiologically evaluable patients)



* Cohort 1 & 2: local read; Cohort 3 & 4: central read

BILE DUCT CANCER – CLINICAL PHASE I STUDY

► Cohort IV is selected dose for pivotal study – limited but encouraging data (Oct 2018)

Parameters	Cohort IV (N=6) (0.25mg/kg)	Phase I – full study (N=16) (0.06-0.25mg/kg)
1) Average number gemcitabine/cisplatin cycles	6.0 (range: 0 - 8)	6.4 (range: 0 - 8)
2) Patients w/ radiologically measurable lesions	5/6 (83%)	12/16 (75%)
3) Average overall tumour size	5.2 cm (range: 2.1 - 7.8 cm)	4.1 cm (range: 1.5 - 7.8 cm)
4) Objective Response Rate (ORR)	3/5 patients (60%) (2 PR; 1 CR)	4/12 patients (33%) (2 PR; 2 CR)
5) Interim average Duration of Response (DoR)	≥15.4 months (range: 8.0 – 20.2 months)	≥12.4 months (range: 6.5 – 20.2 months)
6) Overall Survival (OS)	median OS: 21.7 months interim avg OS: 19.8 months (33% alive)	median OS: 14.4 months interim avg OS: 18,9 months (19% alive)

The table contains key background and measured endpoints for the Phase I dose-escalation study. The background parameters (1-3) were essentially similar for Cohort IV and the full Phase I study. The data is limited, but the measured endpoints (4-6) show a clear trend towards improved outcome in Cohort IV compared to the full study and is also encouraging when seen in relation to the most appropriate published comparator data (see quarterly report for more details).

BILE DUCT CANCER

▶ Status and strategy going forward

▶ Orphan designation

- Granted in both the US and EU, recognising the medical need and potential therapeutic benefits

▶ Phase I dose-escalation completed with good tolerability and promising early signs of efficacy

- Tumour shrinkage in almost all radiologically evaluable patients
- Encouraging overall survival data at the selected dose level

▶ Fastest way to market determined through regulatory interactions with authorities

- Single randomised pivotal study with potential for accelerated / conditional approval based on interim analysis

▶ Preparations for pivotal phase progressing towards initiation in first half 2019

- Plan is to use currently available extension study safety data for initiation of the pivotal study with up to two treatments
- Extensive feasibility study has provided a solid foundation for the selection of high quality sites with large catchment areas
- Strengthened the clinical organisation by appointing Karin Staudacher, M.Sc. as Clinical Project Director

BILE DUCT CANCER – PIVOTAL STUDY

► Randomised study with interim analysis for potential accelerated/conditional approval

- Randomised pivotal study in newly diagnosed patients with inoperable extrahepatic bile duct cancer +/- liver metastases
- Study design based on thorough discussions with the EMA^a and the US FDA^b
- Will involve approx. 40 key hospital sites across Europe and USA
- Approx. 36 months to interim and 50 to final analysis
- Randomisation (1:1) of 186 patients to treatment with either fimaCHEM + SoC^c or SoC only
- Primary endpoint: Progression Free Survival (PFS), with Overall Survival (OS) as key secondary
- Interim analysis primary endpoints: PFS followed by Objective Response Rate (ORR)
- Regular IDMC^d review, but no formal futility stop

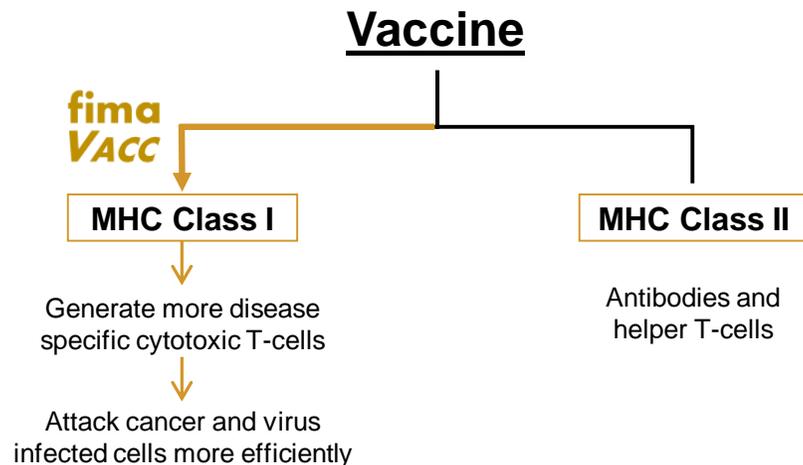
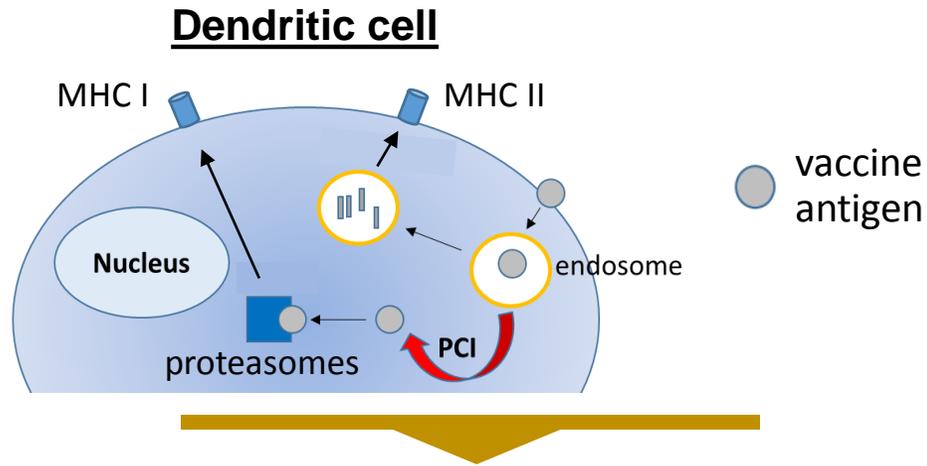
Pivotal trial progress reporting:

- Key milestones for will be communicated in press releases
 - Start of study (first patient dosed); IDMC^d recommendations; clinical results presentations, filing, etc.
- Progress will be updated in quarterly reports
 - Number of country approvals
 - Number of sites open for enrolment

^a EMA: European Medicines Agency; ^b FDA: Food and Drug Administration; ^c SoC: standard of care treatment (gemcitabine + cisplatin);
^d IDMC: Independent Data Monitoring Committee

PCI TECHNOLOGY

▶ **fima VACC** – aiming to enhance immunogenicity of vaccines for immunotherapy field



Strong potential

- ▶ 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
 - Prophylactic & therapeutic vaccination
- ▶ Excellent stability
 - Few logistical challenges (stable at room temperature in solution and can be autoclaved)
- ▶ Important recent IP generation

PROGRESSING CLINICAL TRANSLATION

► Phase I study in healthy volunteers

- Overall objective:
 - Determine the safety, tolerability and immune response of **fima VACC**
- Study consists of three parts:
 1. Tolerability
 2. **fima VACC** vaccination
 3. Optimisation of the **fima VACC** regimen
- Status:
 - More than 90 subjects have so far been treated
 - Part 1 is completed
 - Part 2 is completed
 - Initial data suggest enhancement of antigen specific T-cell response at tolerable doses, with earlier responses and higher response rates
 - Near-term focus on characterisation of the immune response
 - Analyses are done in collaboration with Laboratory of Experimental Cancer Immunology and Therapy, Department of Medical Oncology at Leiden University Medical Center under the leadership of Prof. Sjoerd van der Burg
 - Part 3 TBD
 - Expected study completion: 2H 2018

Vaccination features: **fima VACC**

<i>Enhanced T-cell responses</i>	<input checked="" type="checkbox"/>
<i>High T-cell response rates</i>	<input checked="" type="checkbox"/>
<i>Early T-cell responses</i>	<input checked="" type="checkbox"/>

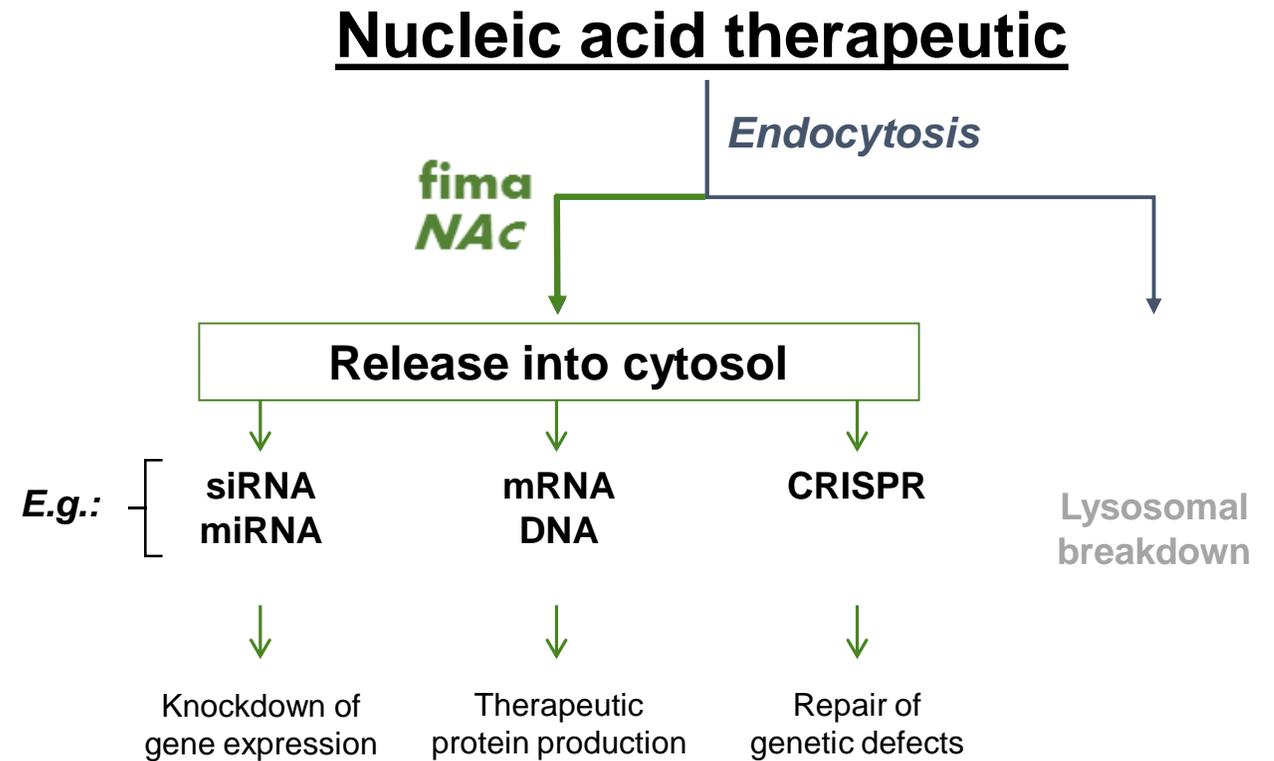
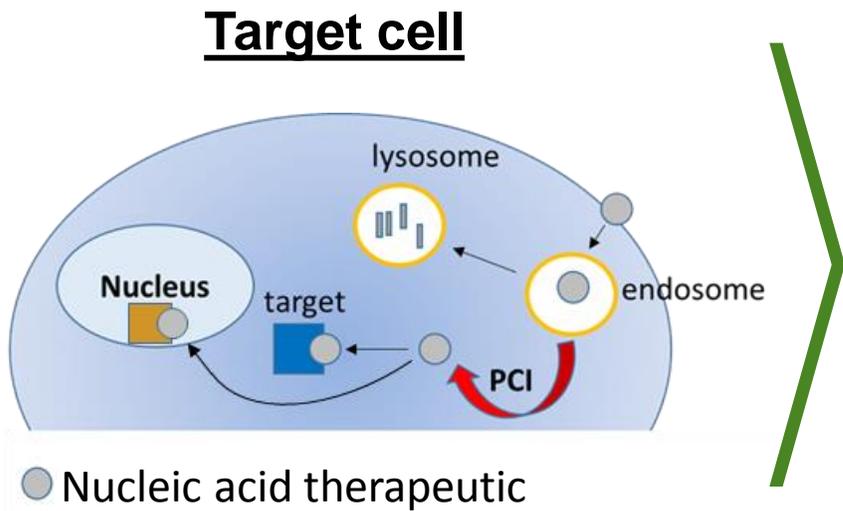


Patented disposable “band-aid-like” device for user-friendly illumination of the vaccination site*

* Patent granted in the US in Oct 2018

PCI TECHNOLOGY

► **fimaNAC** – mode of action



RESEARCH COLLABORATIONS

► Six active collaborations within nucleic acid therapeutics and vaccination

<div style="background-color: #4CAF50; color: white; padding: 10px; writing-mode: vertical-rl; transform: rotate(180deg); font-weight: bold; font-size: 1.2em;">fima NAc</div>		<ul style="list-style-type: none"> - Collaboration initiated 2Q 2015 - Listed on Nasdaq, developing innovative therapeutic siRNA - Collaboration expanded to immuno-oncology following RXi's MirImmune acquisition
	<p>Top-10 large pharma</p>	<ul style="list-style-type: none"> - Collaboration initiated 3Q 2015 - A global leader in nucleic acid therapeutics - Collaboration expanded to include <i>in vivo</i> studies and duration to end 2018
		<ul style="list-style-type: none"> - Collaboration initiated 3Q 2016 - German biotech company developing individualised cancer immunotherapies - Clinical programmes in melanoma, head & neck, breast, ovarian and pancreatic cancer
		<ul style="list-style-type: none"> - Collaboration initiated 4Q 2016 - Belgian biotech with proprietary TriMix platform programming dendritic cells - Clinical programmes in melanoma and triple negative breast cancer
		<ul style="list-style-type: none"> - Collaboration initiated 2Q 2018 - A listed Canadian clinical stage immunotherapy biotech - Multiple clinical-stage programmes in cancer and infectious diseases
		<ul style="list-style-type: none"> - Collaboration initiated 3Q 2018 - A listed Danish clinical stage immunotherapy biotech - Multiple clinical-stage programmes in cancer and infectious diseases
<div style="background-color: #FF9800; color: white; padding: 10px; writing-mode: vertical-rl; transform: rotate(180deg); font-weight: bold; font-size: 1.2em;">fima VACC</div>		<ul style="list-style-type: none"> - Collaboration initiated 1Q 2016 - Norwegian immunotherapy company - Therapeutic cancer vaccine against human telomerase

FINANCE

▶ Fully underwritten rights issue of NOK 360 million completed in October 2018

▶ Important milestone for the **fimaCHEM** development programme

- expected to fund pivotal study beyond interim read-out for potential accelerated approval

▶ The rights issue

- supported by major shareholders and 87% subscription
- net proceeds estimated to NOK 328 million
- part of proceeds placed in Euro as a hedge of the pivotal trial currency risk

FINANCE

► Use of Proceeds

Estimated uses per programme 2019-2022 (NOK million)				
fima CHEM	fima VACC	fima NAc	General corporate purposes	Total
270-290	22-25	3-5	15-20	310-340*
<ul style="list-style-type: none"> Expected to cover financing beyond interim read of pivotal study for potential accelerated approval Additional funding requirement to final analysis is estimated to NOK 80-90 million 	<ul style="list-style-type: none"> Commercial optimisation and partnering activities 	<ul style="list-style-type: none"> Collaborative strategy, with focus on business development activities and alliance management 		

* Estimated figures are subject to several risk and uncertainty factors (foreign exchange rate, public grants, patient inclusion rate, number- and location of sites etc). Transaction costs not included.

FINANCE

▶ Key financial figures

- ▶ Public grants (Other income) in line with last year
- ▶ Operating result YTD impacted by increased clinical activity for **fimaCHEM** and **fimaVacc**

(in NOK 1,000)	Q3 2018	Q3 2017	YTD 2018	YTD 2017
Other income	2,238	2,350	6,613	7,183
Operating results	-8,386	-10,456	-30,241	-27,507

(in NOK 1,000)	Q3 2018	Q3 2017	YTD 2018	YTD 2017
Cash flow operating activities	-7,819	-8,842	-30,551	-27,569

(in NOK 1,000)	30.09 2018	31.12 2017
Cash	20,536*	50,789

* Prior to NOK 360 million in gross proceeds from the rights issue completed in October 2018

KEY NEAR-TERM MILESTONES

- 1H 2018 ✓ **Corporate** Transfer of listing from Oslo Axess to Oslo Børs
- 2H 2018 ✓ **Corporate** Financing for pivotal **fimaCHEM** study
- 2H 2018 ✓ **fimaCHEM** Design of pivotal study finalised
- 2H 2018 ➤ **fimaCHEM** Safety of repeated treatment
- 2H 2018 ➤ **fimaVACC** Phase I in healthy volunteers completed
- 1H 2019 ➤ **fimaCHEM** Initiation of pivotal bile duct cancer study

INVESTMENT HIGHLIGHTS

Market

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 product candidate

Lead product

Amphinex[®] is a **pivotal phase ready orphan designated (EU & US) first-in-class** photochemical internalisation product for treatment of bile duct cancer – a **disease without approved drugs**

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**

Pipeline

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**

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**

Leadership

Management team, Board of Directors and advisors with **extensive pharmaceutical industry experience** across a range of medical development and commercial areas

FOR ENQUIRIES

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