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No assurance can be given that such expectations will prove to have been correct. PCI Biotech disclaims any obligation to update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.
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 Norwegian Radium Hospital
► Clinical programmes
  - **fimaChem** – fimaporfin (Amphinex®) for the orphan indication inoperable bile duct cancer, Phase I completed
  - **fimaVacc** – Vaccination technology that provides strongly enhanced cellular immune responses, Phase I ongoing
► Pre-clinical programme
  - **fimaNac** – Efficient intracellular delivery of nucleic acid therapeutics, with four active research collaborations

**PCI – the solution to a key challenge for several modalities**

- **fimaChem**
  - Enabling approved drugs to fulfil unmet local treatment need

- **fimaVacc**
  - Enhancing cellular immune responses important for therapeutic effect

- **fimaNac**
  - Providing a delivery solution for nucleic acid therapeutics
PCI TECHNOLOGY

Enabling drugs to reach intracellular therapeutic targets

CELL SYSTEM

- lysosome
- nucleus
- endosome

therapeutic molecule
- Small molecules (chemotherapeutics – fimChem)
- Antigens (peptides/proteins – fimVac)
- Oligonucleotides (mRNA, RNAi - fimNAc)

TRIGGERED ENDOSONAL RELEASE

- Endosome
- fimaporfin
- Trapped therapeutic molecule

Red or blue light activation of fimaporfin

Therapeutic molecules escaped from endosome

PCI Biotech
CHEMOTHERAPEUTICS

► A cornerstone in current cancer therapy

Chemotherapeutics will remain a CORNERSTONE in cancer treatment for the foreseeable future.

PCI may enhance approximately 20% of relevant approved chemotherapies.

Niche indications may allow for ORPHAN DRUG applications.

► fimaChem may enable approved drugs to fulfil unmet local treatment needs
► First-in-man study published in Lancet Oncology*, with independent expert commentary
► Completed Phase I in bile duct cancer with promising early signs of efficacy
► Opportunity for development in further niche indications

*Lancet Oncology (2016) 17(9): p1217–1229
PCI TECHNOLOGY

► fimaCHEM – mode of action

Cancer cell

Chemotherapeutics

Endocytosis

Lysosomal Breakdown

Release into cytosol

E.g.
- Cytotoxic antibiotics
- Anti-metabolites
- Anti-microtubule agents

DNA intercalation; free radical formation; etc.

DNA /RNA synthesis inhibition; DNA damage

Cell cycle arrest

chemotherapeutic
Often referred to as cholangiocarcinoma

The cancer cells originates from the cells inside the bile duct (called cholangiocytes)

Cholangiocarcinoma includes:

- Intrahepatic tumours (10%*)
- Perihilar tumours (60-70%*)
- Distal tumours (20-30%*)
- Different incidence, pathobiology and management

* Bile duct cancer, Am Cancer Soc, 10/30/2013
Bile Duct Cancer

- The unmet need

- Rare disease, yearly incidence rate of 1-2 per 100,000 in the western world – higher incidences in Asia
- Five-year survival rate of less than 5%, and almost 0% when inoperable – average approx. 12 months survival

- Current management
  - Surgery
    - Only potentially curative treatment
    - Less than ⅓ are resectable at presentation
  - Stenting
    - Endoscopic stenting for palliative biliary drainage
  - Chemotherapy
    - No approved chemotherapy
    - Recommended chemotherapy: gemcitabine and cisplatin

**Excellent technology fit with PCI**

Targeted illumination is done using standard endoscopic procedure

The active chemotherapy gemcitabine is significantly enhanced by **fimaCHEM**
Bile Duct Cancer

► A sizeable orphan market potential

► Immediate target market is as first line treatment
  ▪ Incidence is close to 15,000 across Europe and the US
  ▪ Immediate target is inoperable patients with primary hilar disease
  ▪ Approximately 3,000 assumed to be eligible for fimaCHEM
  ▪ Possible upside in distal and more advanced metastatic disease
  ▪ Higher incidences in Asia

► Attractive price potential
  ▪ Lack of approved medicinal treatment options
  ▪ Diseases with <10,000 in US support annual pricing >$100,000¹

► Potential significant majority share of the market
  ▪ Anticipated benefits
    – No competing marketable treatment alternatives
    – Greater efficacy due to local chemotherapy boost
    – Easy light access through established standard procedures

¹ LifeSciCapital, OD Market Sector Analysis 2016
**Bile Duct Cancer**

- A proven technology with excellent fit to standard procedures

**fimaCHEM**

A three step treatment procedure

1. Intravenous injection of fimaporfin
2. Intravenous administration of gemcitabine
3. Endoscopic laser light application

1. 4 days
2. 3±1 hrs

**Potential for retreatment with fimaCHEM at set intervals**

- Up to 8 cycles
- fimaporfin + gemcitabine
- gemcitabine + cisplatin
- gemcitabine + cisplatin
- gemcitabine + cisplatin
- 4 days, 7-21 days, 21 days, 21 days
**Bile Duct Cancer – Clinical Phase I/II Study**

► Early promising signs of durable response in Phase I

► 6 months radiology data from all dose cohorts – local read

<table>
<thead>
<tr>
<th>RECIST*</th>
<th>PD</th>
<th>SD</th>
<th>PR</th>
<th>CR</th>
<th>NA**</th>
</tr>
</thead>
<tbody>
<tr>
<td>Cohort IV***</td>
<td>1</td>
<td></td>
<td>2</td>
<td>1</td>
<td>2</td>
</tr>
<tr>
<td>Cohort III</td>
<td></td>
<td>1</td>
<td>1</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>Cohort II</td>
<td></td>
<td>1</td>
<td></td>
<td>2</td>
<td></td>
</tr>
<tr>
<td>Cohort I</td>
<td>1</td>
<td>1</td>
<td></td>
<td></td>
<td>1</td>
</tr>
</tbody>
</table>

**PD**: Progressive disease (>20% growth)
**SD**: Stable Disease
**PR**: Partial Response (>30% shrinkage)
**CR**: Complete Response (no visible tumour)

* Response Evaluation Criteria In Solid Tumours (rules defining when cancer patients improve, stay the same or worsen during treatments)
** Not measurable / Not radiologically evaluable
*** Cohort IV expanded; Four radiologically evaluable patients at 6 months

- The last patient in the Phase I study received **fimaChem** treatment March 2016
- Subjects are in the study for 6 months after PCI treatment and thereafter followed for survival only
- Average overall survival by end March 2017 was 14.5 months, with 25% of patients still being alive
- Commissioned central independent radiological expert RECIST evaluation of Cohort III & IV, as this is an expected regulatory requirement
**Bile Duct Cancer – Clinical Phase I/II Study**

► Six month radiology data – central read confirms promising early tumour response

► **Cohort III & IV – RECIST classification of patients**

<table>
<thead>
<tr>
<th>RECIST</th>
<th>PD</th>
<th>SD</th>
<th>PR</th>
<th>CR</th>
<th>NA*</th>
</tr>
</thead>
<tbody>
<tr>
<td>Central read</td>
<td>2**</td>
<td>1</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
</tbody>
</table>

* Not measurable / Not radiologically evaluable
** Progressive disease due to appearance of new lesions

► **Cohort III & IV – response at single lesion level**

<table>
<thead>
<tr>
<th>Measurable lesions</th>
<th>Lesion shrinkage</th>
<th>Stable lesion</th>
<th>Lesion growth</th>
</tr>
</thead>
<tbody>
<tr>
<td>19</td>
<td>17</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>(total number of targets selected across the two independent readers)</td>
<td>(lesion not detectable)</td>
<td>(&lt;20% reduction &amp; &lt;10% increase)</td>
<td>(&gt;10% mass increase)</td>
</tr>
<tr>
<td>12</td>
<td>5</td>
<td>1</td>
<td>1</td>
</tr>
<tr>
<td>(&gt;20% mass reduction)</td>
<td>(&lt;20% reduction &amp; &lt;10% increase)</td>
<td></td>
<td></td>
</tr>
</tbody>
</table>

**Phase I results presented as late-breaking news at United European Gastroenterology Week**
Bile Duct Cancer

Status and strategy going forward

► Phase I completed with good tolerability and very promising early signs of efficacy
  ▪ No serious unexpected safety findings and no apparent increase in adverse reactions with increasing doses
  ▪ Very promising early signs of efficacy – significant tumour shrinkage observed radiologically
  ▪ Results verified at central evaluation by study-independent external radiological experts in RECIST
  ▪ Encouraging emerging survival data
  ▪ A Phase I extension is about to be initiated, to determine safety of repeated treatments

► Orphan designation
  ▪ Granted Orphan Drug Designation in EU
  ▪ Open IND in US – Orphan Drug application submitted

► Regulatory interactions with EU and US authorities, to determine fastest way to market
  ▪ Promising signs of efficacy in a life threatening orphan indication without approved treatment alternatives
  ▪ May allow for marketing authorisation based on restricted data, e.g. a pivotal Phase II study
IMMUNOTHERAPY
▶ A new hope for millions of patients

- Total estimated immunotherapy sales of $35bn in 2023*
- More than 100 projects in development**
- Combinations with THERAPEUTIC VACCINES may enhance CPI*** response rates

► fimaVacc enhances cellular immune responses important for therapeutic effects
► Ongoing Phase I study in healthy volunteers for clinical validation
► Aim is to out-license the technology on non-/semi-exclusive basis
► Opportunity to develop own therapeutic vaccination products

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* Citi Research “Immunotherapy – the beginning of the end for cancer”. Baum, May 2013
** Clinicaltrials.gov. Therapeutic cancer vaccines, PCIB analysis, August 2016
*** CPI: Checkpoint inhibitors
Dendritic cell

Vaccine

Endocytosis

MHC Class II

Antibodies and helper T-cells

MHC Class I

Generate more disease specific cytotoxic T-cells

Attack cancer and virus-infected cells more efficiently

PCI TECHNOLOGY

► fimaVacc – mode of action

Vaccination antigen

proteasomes

endoosome

nucleus

MHC I

MHC II

PCI Biotech
fima VACC STRONGLY ENHANCES VACCINATION EFFECTS

- Impressive effects with clinically relevant HPV therapeutic vaccine in mice

Cytotoxic (CD8) T-cells

- Most important immune cells to fight tumours
- Difficult to induce with vaccination
- fima VACC strongly enhances the ability of vaccines to induce CD8 T-cells:
  - >20 and >40 times enhancement seen in spleen and blood cells, respectively
  - Generation of immunological memory
THERAPEUTIC VACCINATION IN TUMOUR MODEL

- *fima Vacc* induces cytotoxic T-cells that infiltrate tumours

Therapeutic *fima Vacc* vaccination with OVA in animal tumour model (B16-OVA melanoma/OT-1)

![Graph showing tumour volume at different time points after inoculation](image)

**Tumour volume at different time points after inoculation**

*mean values; n=5/group*

- Without vaccination
- Vaccination with tumour cell antigen
- PCI* vaccination with tumour cell antigen

**Tumour infiltration of CD8+ T-cells**

*PCI = *fima Vacc*
THERAPEUTIC VACCINATION WITH fima VACC

► Opportunity to play a key role in second generation immunotherapy

► Unique mode of action
  – induction of antigen specific cytotoxic T-cells by MHC class I antigen presentation in dendritic cells

► Ease of use
  – fimaporfin mixed with vaccine
  – intradermal vaccination

► Broad applicability
  – peptide and protein antigens
  – particulate antigen formulations
  – prophylactic & therapeutic vaccination

► Excellent stability and cost effective synthesis

► Phase I study in healthy volunteers ongoing
  – first results read-out 2Q 2017

Patented disposable “band-aid-like” device for user-friendly illumination of the vaccination site
NUCLEIC ACID THERAPEUTICS
► A treatment modality with huge potential

Estimated sales of USD 18bn in 2030* (RNAi alone)
mRNA is a hot new field with HIGH DEAL ACTIVITY
Main HURDLE IS DELIVERY into cells

► fimaNAC may provide a delivery solution for many nucleic acid therapy applications
► Opportunistic collaborative approach
► Aim is to out-license the technology on non-/semi-exclusive basis

* Research and Markets “RNAi therapeutics market”. Dec 2015
PCI TECHNOLOGY

fimaNAC – mode of action

Target cell

Nucleic Acid Therapeutics

Endocytosis

Release into cytosol

Lysosomal Breakdown

- siRNA
- miRNA
- mRNA
- DNA
- CRISPR

Knockdown of gene expression
Therapeutic protein production
Repair of genetic defects
**ENHANCING mRNA DELIVERY**

- Strongly increased GFP synthesis with increasing light doses

**fimaNAC** with polyethylenimine (PEI) vehicle

<table>
<thead>
<tr>
<th>Time</th>
<th>PEI w/o fimaNAC</th>
<th>PEI w/ fimaNAC</th>
</tr>
</thead>
<tbody>
<tr>
<td>0 s</td>
<td>1.4%</td>
<td></td>
</tr>
<tr>
<td>30 s</td>
<td>1.2%</td>
<td></td>
</tr>
<tr>
<td>60 s</td>
<td>8.9%</td>
<td></td>
</tr>
<tr>
<td>120 s</td>
<td>45.6%</td>
<td></td>
</tr>
<tr>
<td>240 s</td>
<td>92.4%</td>
<td></td>
</tr>
<tr>
<td>360 s</td>
<td>90.2%</td>
<td></td>
</tr>
</tbody>
</table>

Control: PEI w/o fimaNAC w/ fimaNAC

Cell survival

- 7% positive
- 75% positive

Control

fimaNAC
VERSATILITY OF *fimaNAC*

Delivery of many types of nucleic acid with many different vehicles *in vitro*

- Main bottleneck in the field is delivery
- *fimaNAC* can deliver many types of nucleic acids
- Enhancement by *fimaNAC* is best under conditions favourable for vehicle safety
  - Low ratio of vehicle to nucleic acid
  - Low concentration of vehicle/nucleic acid complex
- Especially advantageous *in vivo*
  - Difficult to achieve a high concentration of vehicle/nucleic acid complex in target cells
  - Toxicity may limit the amount of vehicle used

<table>
<thead>
<tr>
<th>Type of nucleic acid</th>
<th>Delivery vehicle</th>
</tr>
</thead>
<tbody>
<tr>
<td>Plasmids</td>
<td>PEI, cationic peptides, cationic lipids, polylysine ++ Targeting to EGF-R, transferrin-R</td>
</tr>
<tr>
<td>siRNA</td>
<td>PEI, cationic peptides, dendrimers, lipofectamine, DOTAP, nanogels, chitosan ++</td>
</tr>
<tr>
<td>PNA (peptide nucleic acids)</td>
<td>None, cationic amino acids attached</td>
</tr>
<tr>
<td>mRNA</td>
<td>PEI, Protamine</td>
</tr>
<tr>
<td>Adenoviral vectors</td>
<td>None, cationic polymers</td>
</tr>
<tr>
<td>AAV vector</td>
<td>None</td>
</tr>
</tbody>
</table>

Opportunistic approach – pursuing collaboration and partnering opportunities
RESEARCH COLLABORATIONS

Four active collaborations within nucleic acid therapeutics

RXi Pharmaceuticals
- Initiated 2Q 2015
- Listed on Nasdaq
- Innovative therapeutic siRNA
- Clinical programmes in dermatology and ophthalmology
- New focus on immuno-oncology after MirImmune acquisition

Top-10 large pharma
- Initiated 3Q 2015
- A global leader in nucleic acid therapeutics
- Collaborative research funded by partner
- Evaluate synergistic effects between companies’ technologies

BioNTech
- Initiated 3Q 2016
- German biotechnology company developing individualised cancer immunotherapies
- Clinical programmes in melanoma, head & neck, breast, ovarian and pancreatic cancer

eTheRNA
- Initiated 4Q 2016
- Belgian immunotherapy company
- Proprietary TriMix platform programming dendritic cells with synthetic mRNA
- Clinical programmes in melanoma and triple negative breast cancer

Research collaborations aim to evaluate synergies between the fima platform and partner technologies, with the potential for further partnerships
**DEVELOPMENT PIPELINE**

- Unlocking the true potential of innovative medicines

<table>
<thead>
<tr>
<th>Programme</th>
<th>Therapeutic agents</th>
<th>Preclinical</th>
<th>Phase I</th>
<th>Phase II</th>
<th>Status</th>
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</thead>
<tbody>
<tr>
<td><strong>fima</strong> <strong>CHEM</strong></td>
<td>Chemotherapeutics</td>
<td></td>
<td></td>
<td></td>
<td>Phase I in the orphan indication bile duct cancer completed with promising early signs of efficacy</td>
</tr>
<tr>
<td><strong>fima</strong> <strong>VACC</strong></td>
<td>Therapeutic cancer vaccines</td>
<td></td>
<td></td>
<td></td>
<td>Phase I study ongoing One active R&amp;D collaboration</td>
</tr>
<tr>
<td><strong>fima</strong> <strong>NAC</strong></td>
<td>Nucleic acid therapeutics</td>
<td></td>
<td></td>
<td></td>
<td>Four active R&amp;D collaborations</td>
</tr>
</tbody>
</table>

*An oncology focused company with three well differentiated assets*
PCI BIOTECH

Unlocking the potential of innovative medicines

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