Unlocking the potential of innovative medicines

PCI Biotech

Second Quarter and First Half 2013 Results

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Highlights 1H 2013

- Redesigned the ENHANCE study – a Phase II study in head & neck cancer patients
  - Treatment with intra-tumour illumination produced too strong local treatment effects
  - The study has been amended to include a light dose escalation run-in phase to optimise the intra-tumour treatment regimen and a proof-of-concept part to confirm safety and efficacy
  - Patient inclusion has been slower than anticipated
- Initiated a Phase I/II study in bile duct cancer (cholangiocarcinoma), with Amphinex enhancing the widely used marketed drug gemcitabine
  - An orphan indication with high unmet medical need and a good technical fit to PCI
- Increasing the focus on development of PCI as a technology platform for vaccination
  - *Ex vivo* and *in vivo* studies demonstrate the potential of PCI as a versatile vaccination platform for both therapeutic and prophylactic vaccination
- Strengthened the organisation with Business Development Executive
  - Gaël L'Hévéder appointed Head of Business Development

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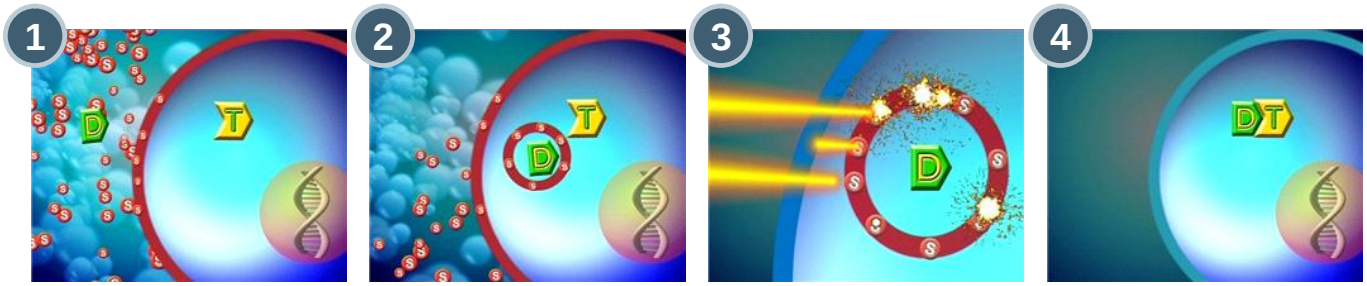
Unlocking the potential of innovative medicines

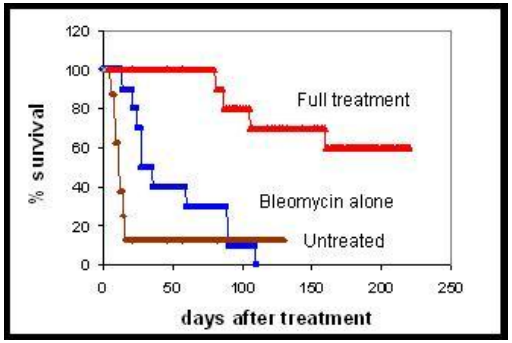
PCI Technology

PCI technology – significantly enhancing the local effect of cancer drugs

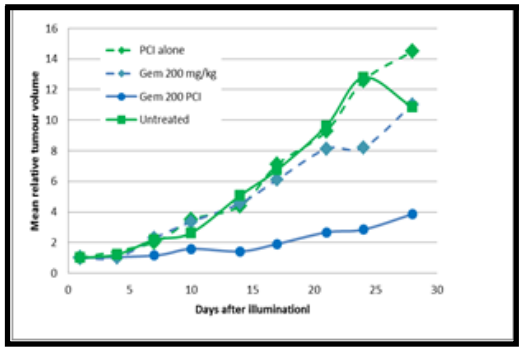
Enabling drugs to reach intracellular therapeutic targets



Positive *in vivo* results with several marketed cancer drugs



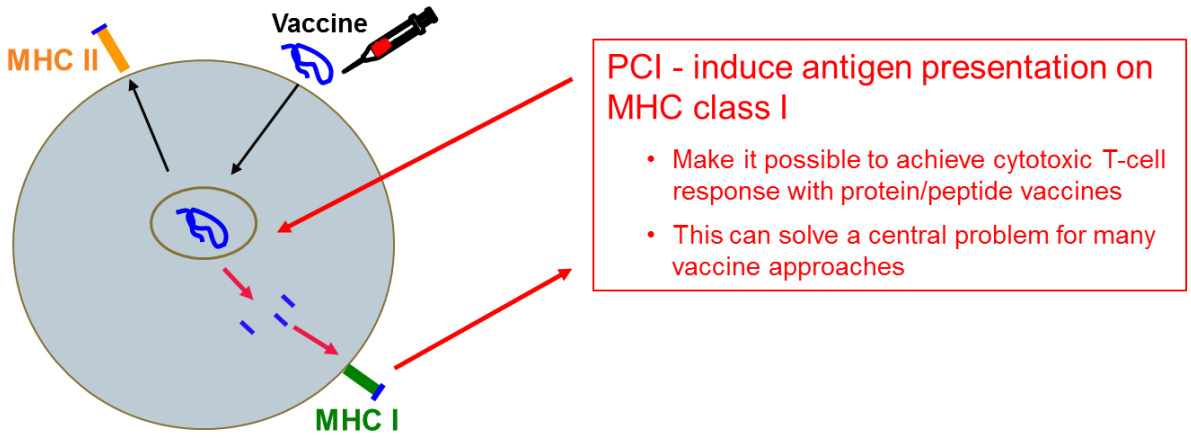
Significant enhancement of the local effect of bleomycin



Significant enhancement of the local effect of gemcitabine

PCI technology – significantly enhancing the Killer T-cell response in vaccination

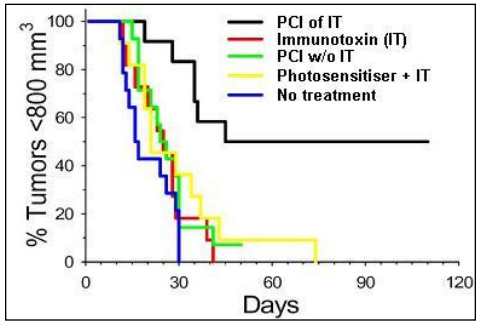
- PCI – induce antigen presentation on MHC class I
  - Make it possible to achieve Killer T-cell response with protein/peptide vaccines – a central problem for many vaccine approaches

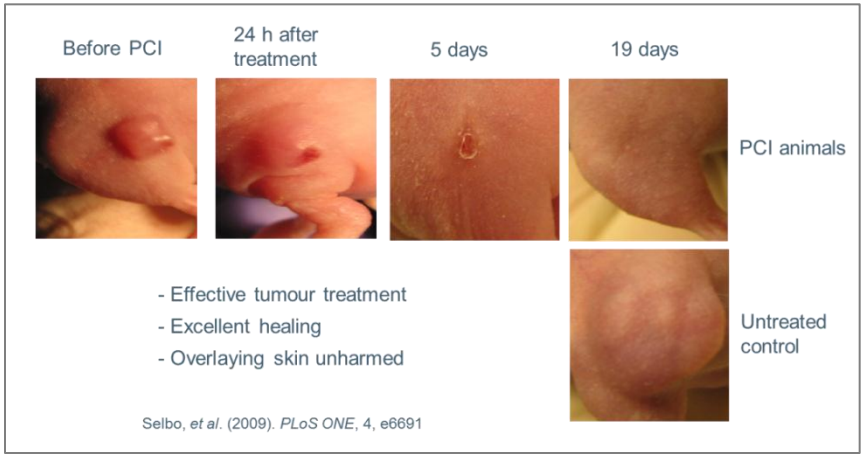


- In addition PCI can give a more unspecific ”adjuvant” immuno-stimulatory effect

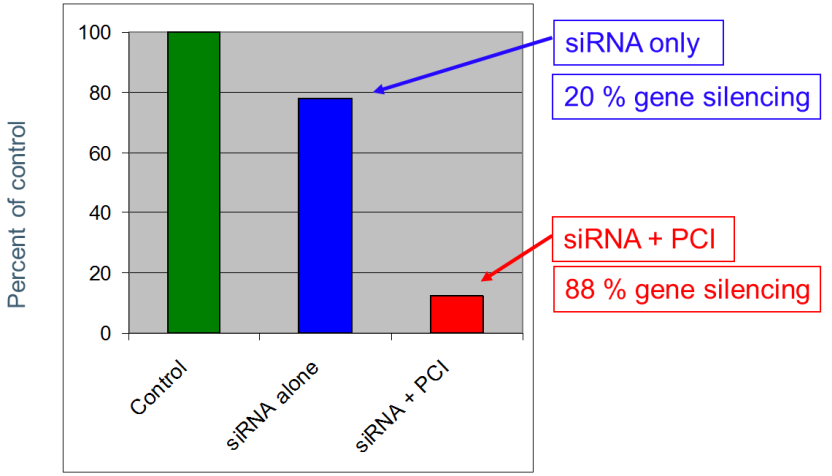
PCI technology – effective intracellular delivery of macromolecules

Amphinex and immunotoxin – in vivo data





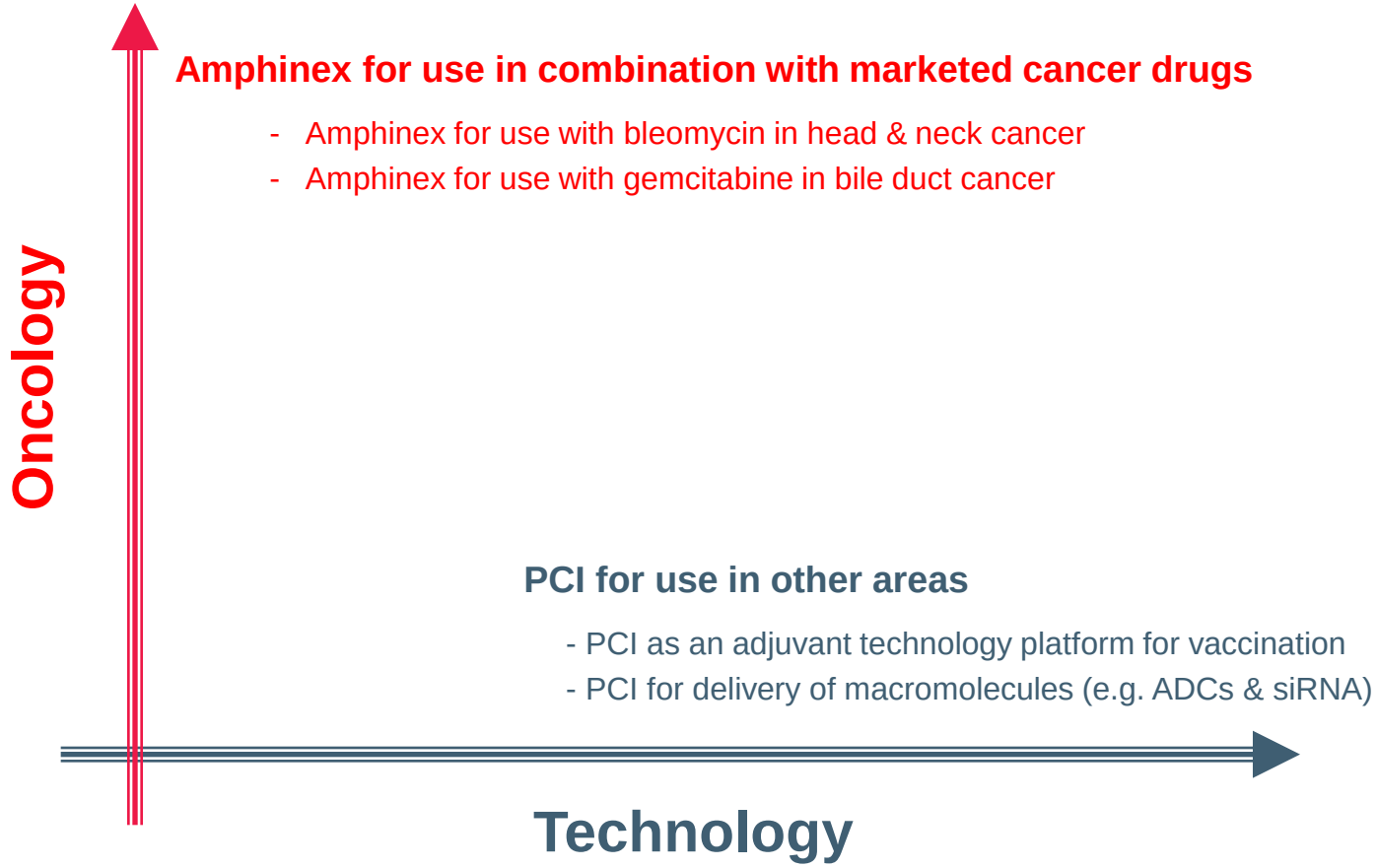
Enhancing siRNA's "gene silencing" effect



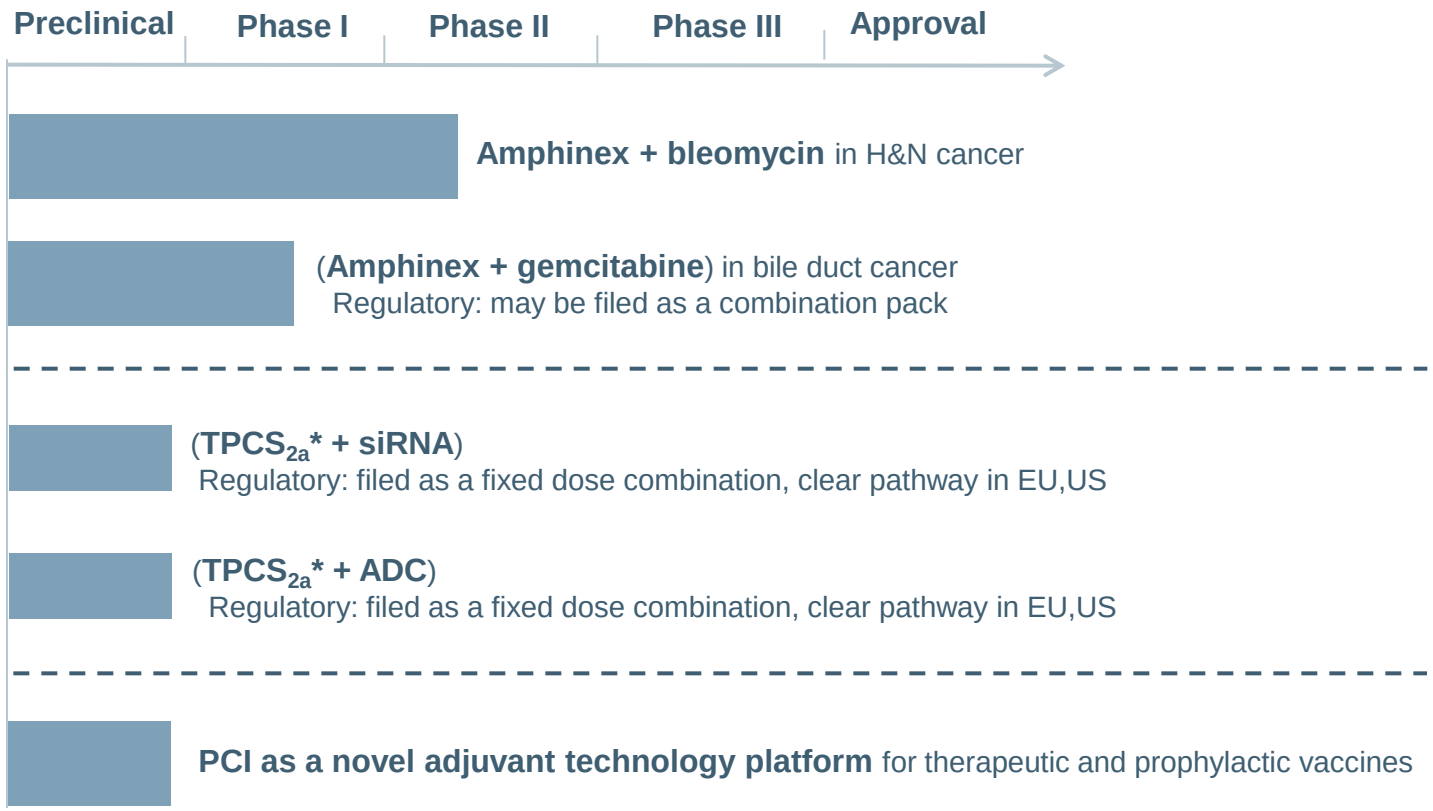
Bøe, S., Longva, A.S. and Hovig, E. (2007). *Oligonucleotides* 17, 166-73

Strategy

Growth of PCI Biotech via 2 axes



A pipeline of potential partnering opportunities



* Active pharmaceutical ingredient in Amphinex

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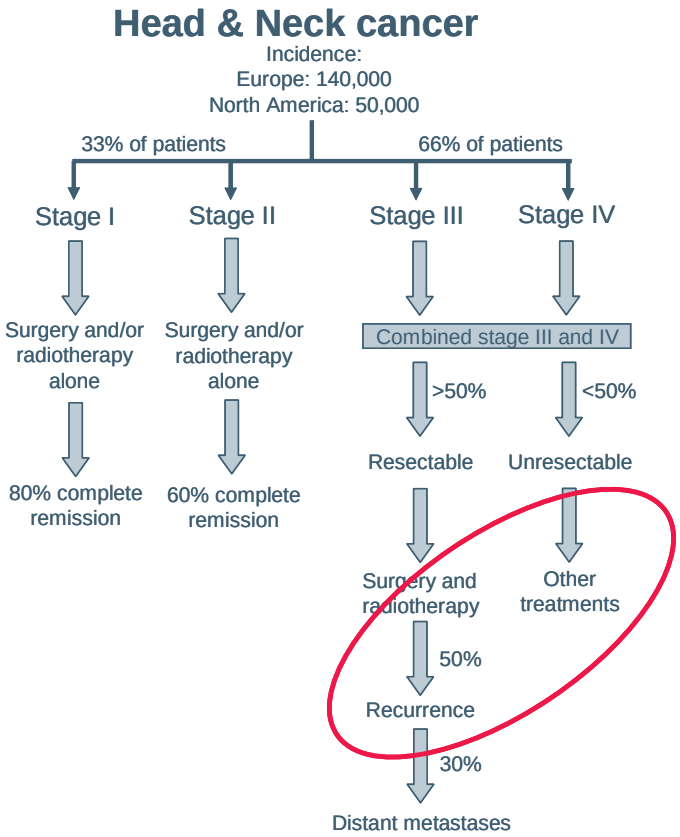
Unlocking the potential of innovative medicines

Head & neck cancer

Head & neck cancer – a disease in need of better localised treatment options

- Large patient population with high medical unmet need
  - Need of new treatments able to improve quality of life, reduce recurrence rates and prolong life
  - A field with lack of innovations
  - Appear to be few new products in development
- Current localised treatment options are often associated with functional and cosmetic impairments
  - Surgery
  - Radiotherapy
  - Significant activities to improve these technologies
- Recurrent disease mainly given palliative treatment
  - Quality of life is an important endpoint in this population
  - Palliative chemo/targeted combination therapy is often the only possible choice



Source: Datamonitor Stakeholder Opinions: Head and Neck Cancer (2004), GLOBOCAN (www-dep.iarc.fr, accessed March 2010)

Head & neck cancer – updated market assessment by Bridgehead International

- Market assessment performed in EU big 5 and US
  - 65,000 - 70,000 head & neck cancer patients in EU big 5, representing approximately 50% of all European H&N cancer patients
  - 45,000 - 50,000 head & neck cancer patients in US
  - Incidence has been flat since the 90's

- Key findings from Key Opinion Leader interviews:
  - Large patient population with need of new treatments able to reduce recurrence rates and prolong life
  - Quality of life and locoregional control considered more important than overall survival
  - Approximately 20% of head & neck cancer patients expected to be eligible for Amphinex
  - Cetuximab (Erbitux) is the most relevant medicinal price comparator
    - Total treatment cost of cetuximab costs is in the approximate range of $39-66k per patient
    - Total cetuximab sales in H&N cancer in EU is estimated to be in the $120-150M range
    - Justifiable price for Amphinex need to take into account cost of treatment procedure

Amphinex induced PCI of bleomycin in head & neck cancer – Phase II study

• Patient inclusion	2012 – 2014/15
• Target population	Recurrent head & neck squamous cell carcinoma, unsuitable for radiotherapy and surgery
• Type of study	Single arm, open label (run-in light dose escalation with interim PoC of intra-tumour treatment)
• Primary endpoint	Progression free survival at 6 months
• Number of patients	70-80 (+ up to 9 run-in patients)
• Where	Europe

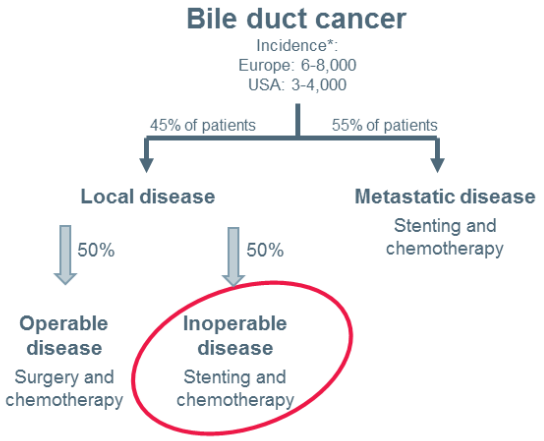
Amphinex induced PCI of bleomycin in head & neck cancer – Phase II study

- Patient inclusion for both surface and intra-tumour illumination was initiated 2Q 2012, but intra-tumour illumination was paused in 4Q on recommendation of the Independent Data Monitoring Board (IDMB)
  - Intra-tumour illumination produced stronger local treatment effects than expected and desired
- Amendment to optimise the intra-tumour treatment regimen
  - Light dose escalation 3+3 design starting at ⅙ of the previous light dose
  - Selected dose level will be confirmed for safety and efficacy in a total of 12 patients in an interim Proof-of-Concept part of the study
- Amendment is now approved by authorities and ethics committees in UK, NL and Germany, and the first sites reopened 2Q 2013
  - Patient inclusion has been slower than anticipated; one interstitial patient has been included thus far

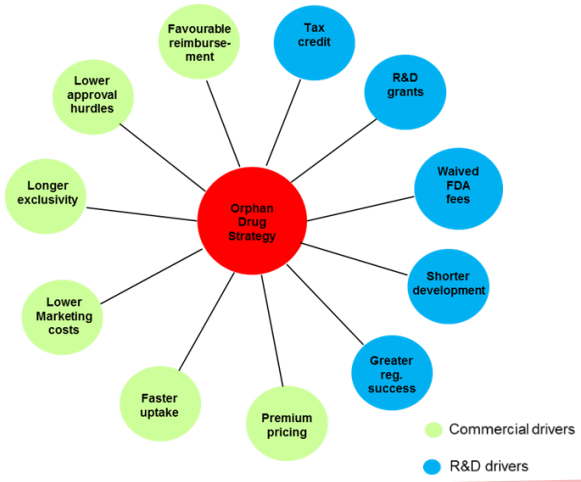
Bile duct cancer

Bile duct cancer – an orphan indication for development with Amphinex

- Patient population with high medical unmet need
  - Resection is only potential cure, but majority of patients are inoperable
  - Incidence and mortality rates are increasing worldwide
  - Remarkable resistance to common chemotherapy
- Could PCI play a role in treatment of bile duct cancer?
  - Medical need for better local treatment methods
  - Easy access with light through routine endoscopic methods
  - Gemcitabine is significantly enhanced by PCI
- Orphan indications represents a distinct market opportunity
  - A range of development and market incentives
  - About one third of orphan drugs have sales > $1b
  - Orphan market totalled $50b in 2011 (~6% of pharma sales)



*Source; Khan et al, Lancet 2005; 366:1303
Gatta et al, Eur J Cancer 2011; 47:2493



Amphinex induced PCI of gemcitabine in bile duct cancer – Phase I/II study

- Patient inclusion — First sites opened 2Q 2013; estimated finish late 2014 / early 2015
- Target population — Patients with inoperable bile duct caner
- Study design — Open-label, multi-center Phase I/II study in up to 45 patients to assess the safety and efficacy of Amphinex induced PCI of gemcitabine, followed by systemic cisplatin/gemcitabine

  Phase I: A dose escalation study to assess the tolerance of local bile duct treatment

  Phase II: randomized double-arm Phase II study

  - PCI arm: stenting followed by Amphinex induced PCI of gemcitabine, followed by gemcitabine/cisplatin chemo
  - Control arm: stenting alone followed by gemcitabine/cisplatin chemo
  - Randomization ratio 2.5;1 in favor of the PCI arm

Amphinex induced PCI of gemcitabine in bile duct cancer – Phase I/II study

- Endpoints in Phase II — Primary endpoint – progression free survival
  Secondary endpoints include overall survival
- Number of patients — Phase I: up to 12 patients. Patient inclusion approx. 6 months
  Phase II: up to 35 patients. Patient inclusion approx. 10 months
- Follow up in Phase II — 15 months
- Where — Phase I: 4-5 European hospitals
  Phase II: Approx. 10 European hospitals
- Status — All approvals granted and first sites opened late Q2 2013
  Three out of the five planned sites for Phase 1 are actively screening

Vaccines

PCI – an innovative and versatile adjuvant vaccination platform

- PCI vaccination technology
  - An innovative adjuvant platform able to stimulate Killer T-cell responses by enhancing the antigen presentation on MHC class 1, especially important in therapeutic vaccination
  - A versatile adjuvant platform that works in combination with various types of antigens in both *in vivo* and *ex vivo* vaccination settings

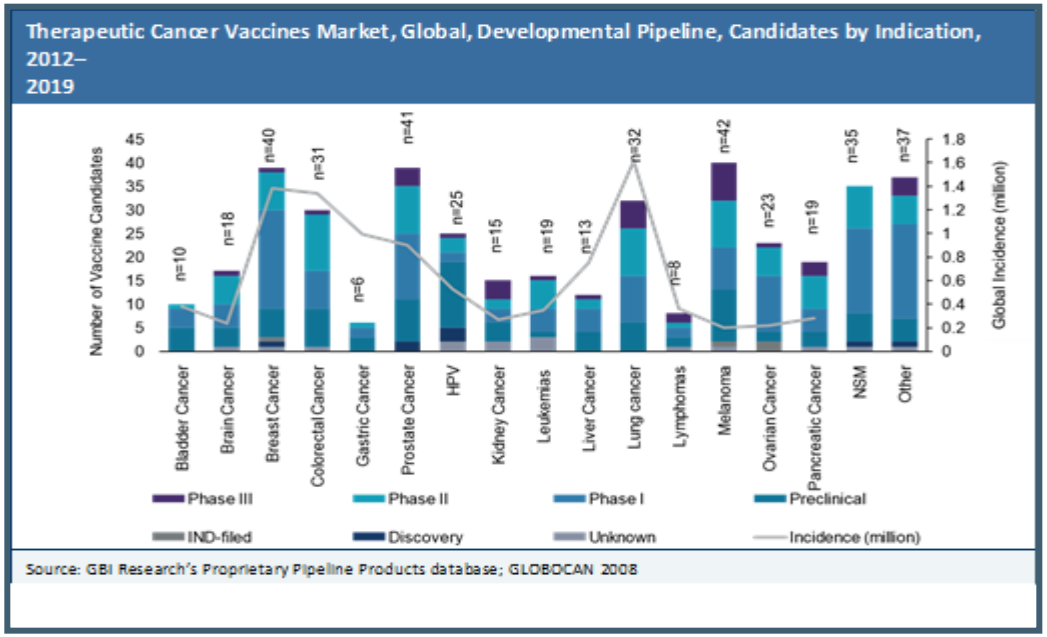
- Prophylactic vaccines
  - Prevent disease from developing
    - Typically infections

- Therapeutic vaccines
  - Treat already established disease
    - Cancer
    - Virus infections (Hepatitis, HIV)
  - Intense research in the cancer area, but so far only one approved therapeutic cancer vaccine

Cancer therapeutic vaccines – Industry Pipeline

Therapeutic vaccination against cancer – a potentially effective and powerful approach

- **Powerful**: attacks cancer systemically
- **Specific**: attacks only cancer cells expressing tumour antigens – hence fewer side effects
- **Durability of action**: chemotherapy has a limited action in time but vaccines continue to protect by teaching the immune system
- **Indications**: potentially all cancers



265 vaccines in development

Top 5 indications:

- Breast
- Colorectal
- Lung
- Prostate
- Melanoma

Effective adjuvant technologies are key to the success of therapeutic cancer vaccination

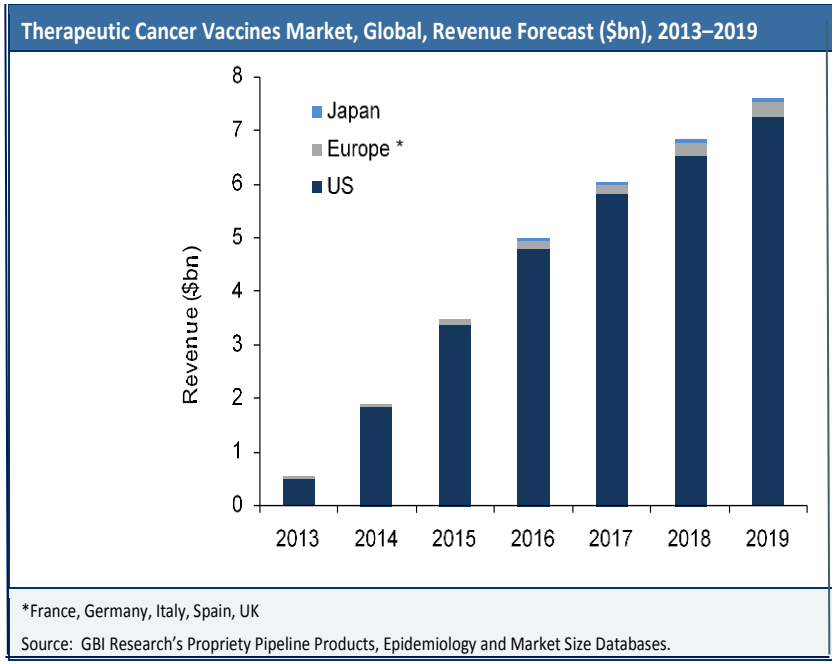
Cancer therapeutic vaccines – Forecast 2013-2019

Marketed therapeutic cancer vaccine

- There is currently only one marketed therapeutic cancer vaccine, Provenge – for the treatment of metastatic prostate cancer – with annual global sales of approx. $200 million

Market potential of therapeutic cancer vaccines

- Therapeutic cancer vaccine market could grow to a value of $7.6 billion by 2019[1]

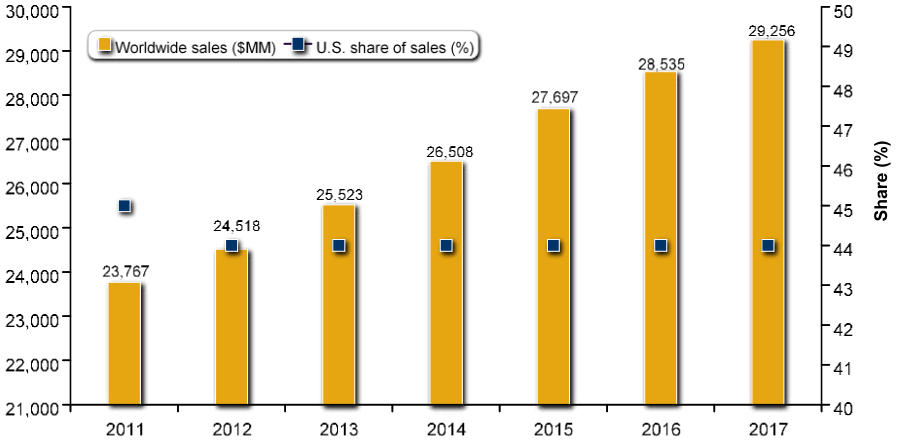


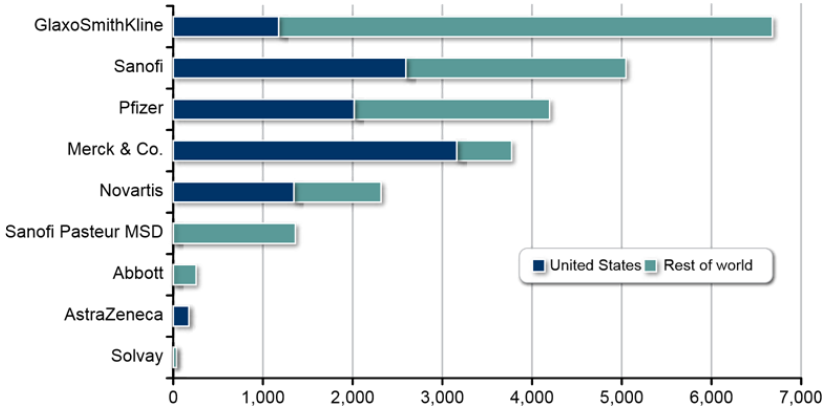
All the characteristics of an innovative emerging market:

- Forecast based on approval of up to 12 vaccines by 2019
- >90% sales, US only
- High rate of growth
- Rich pipeline
- Lots of biotech including start-ups
- Active licensing and M&A
- **PCI is well positioned to capture part of that growth**

[1] GBI Research, March 2013

Anti-infective prophylactic and therapeutic vaccines – forecast 2011-2017





It is a maturing market:

- Much larger than cancer vaccines
- Slower growth, 3.5% per annum
- Much less driven by innovation
- Concentrated players
- Few new products launches (HPV)
- Share of US decreasing to less than half by 2017
- **PCI could be of interest to large vaccines developers looking for innovation: concentrated group gives competition to acquire new technologies**

Recent vaccines-related transactions

Company	Partner	Deal	indication	Technology	Date
Takeda	Inviragen	$35M upfront, $215M clinical and commercial milestones	Infectious diseases, dengue	vaccines	May 2013
GSK	Okairos	$325M	Infectious diseases	Adenovirus vector (*works by stimulating responses from CD8+ T cells which are not reached by existing vaccines*)	May 2013
Novavax	Isconova	$29.6M all stock bid	Pandemic flu and other infectious disease indications	Immune modulation adjuvant platform	June 2013

Immune system – arms of defence

Immune system – two important arms of defence:

Defence arm 1: Detect and destroy infectious agents present in blood stream or on body surfaces *(mainly relevant for prophylactic vaccination)*

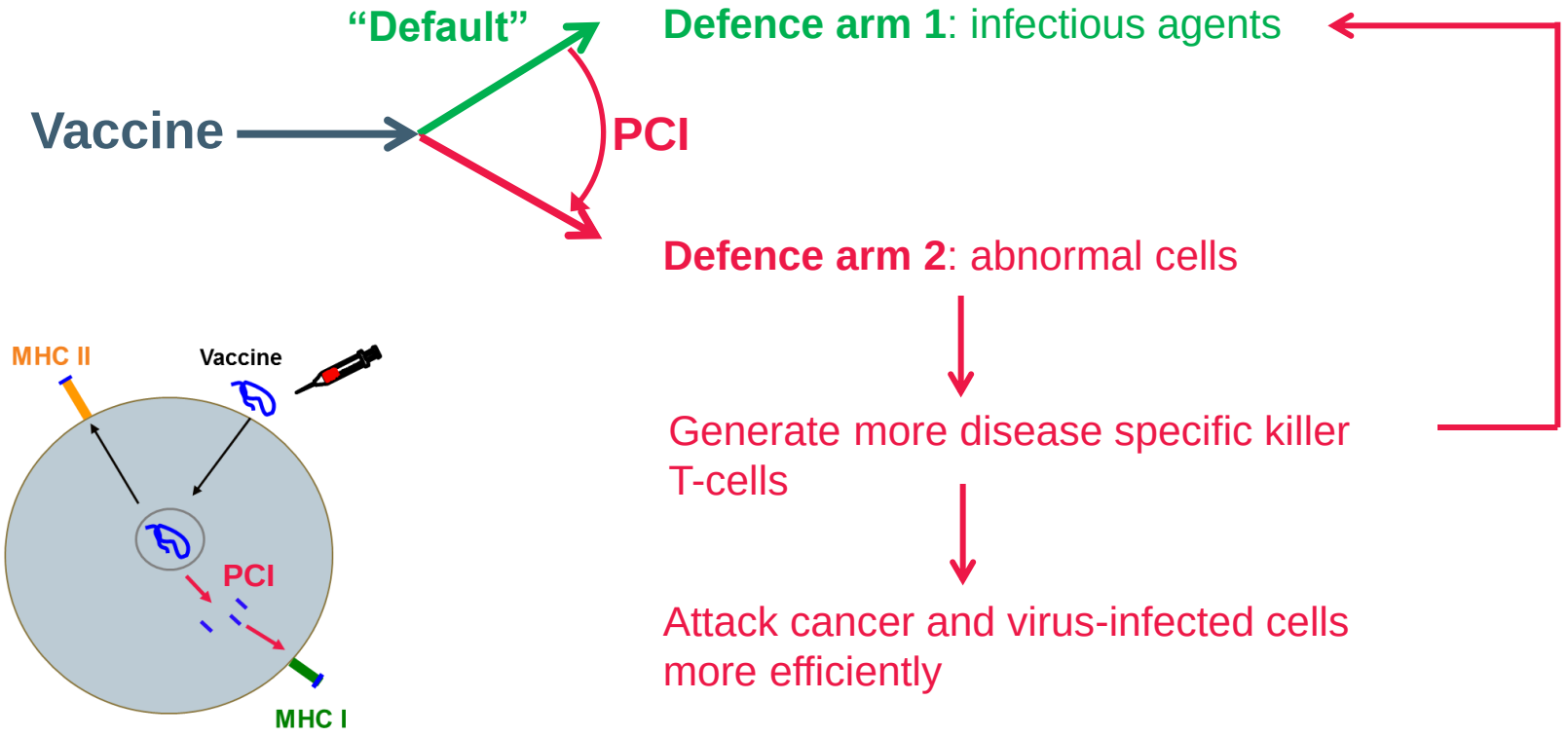
- Bacteria, virus, parasites

Defence arm 2: Detect and destroy abnormal or infected cells in the body *(mainly relevant for therapeutic vaccination)*

- Cancer cells
- Virus infected cells
- Kill the body's own cells
  - Is performed by special immune cells called **killer T-cells**
  - Must be tightly controlled and regulated process
  - Killer T-cells must receive the right signals to be activated
  - **PCI can help to achieve this**

- Stimulating defence arm 1 by vaccination is much easier than stimulating arm 2

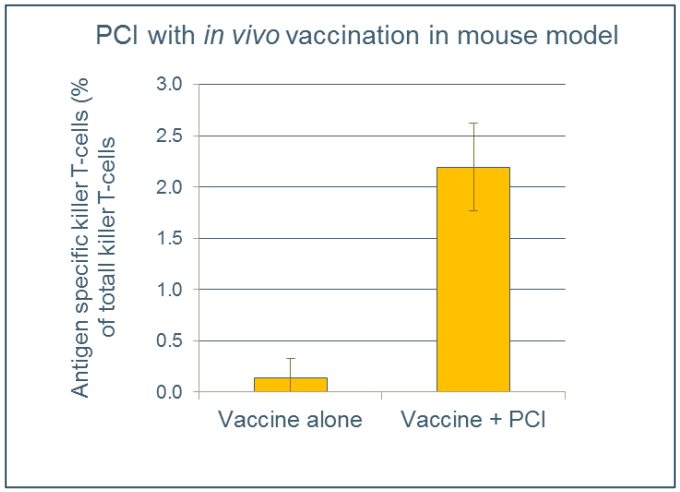
PCI for vaccination – enhancing killer T-cell response



PCI – a simple and effective procedure for both modes of therapeutic vaccination

In vivo vaccination

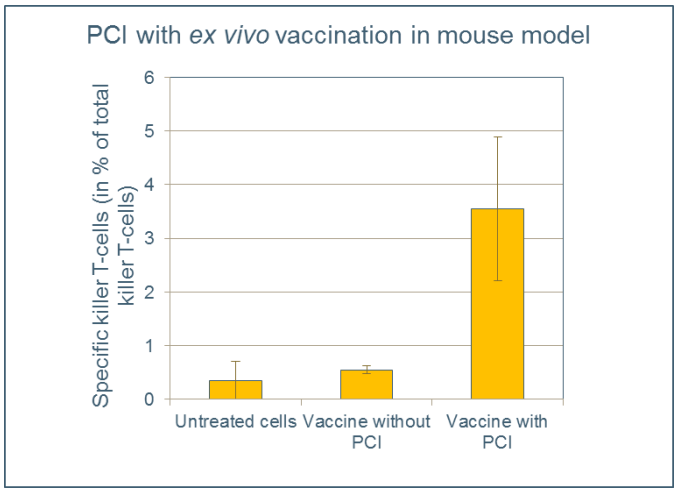
- Inject vaccine (+ adjuvant) into patient, e.g. in or under the skin
- PCI: add photosensitiser and illuminate
  - > *PCI enhancement of vaccination up to 40 times has been seen*
  - > *Optimisation of* in vivo *PCI vaccination method ongoing*



(collaboration with NTNU & University Hospital Zurich)

Ex vivo vaccination

- Remove immune cells from patient
- Give vaccine + adjuvant treatment to the cells in laboratory; PCI: performed on cells in laboratory
- Return the treated cells to the patient
  - > *PCI enhancement of vaccination up to 16 times has been seen*
  - > *Optimisation of* ex vivo *PCI vaccination method ongoing*



(collaboration with NRH & University Hospital Zurich)

PCI for vaccination – mode of action & summary

- The overall concept is to modulate the activity of the antigen processing machinery to enhance and direct the presentation of antigens to the immune system
- In many vaccination approaches it is highly desired to stimulate Killer T-cells to recognize and destroy diseased cells (e.g. tumour or virus infected cells).
- This effect is dependent on proper presentation of antigen on MHC I molecules on the surface of antigen presenting cells; the action of PCI is to enhance such presentation
- PCI has the potential to be used in combination with a wide variety of antigens with different physical characteristics: peptides, proteins, and various forms of particulate antigen formulations.
- The PCI adjuvant platform can be applied to antigens from infectious pathogens as well as tumour antigens for cancer vaccines

PCI for vaccination – an exciting opportunity

- Effective adjuvant technologies are key to the success of therapeutic vaccination
  - Vaccination companies are seeking improved adjuvant technologies for their vaccine technologies
  - The novel mode of action may allow the use of PCI as a new adjuvant system for vaccinations where existing adjuvant systems don't work
- Improved adjuvant technologies are important also for prophylactic vaccines
- PCI represents a simple and innovative adjuvant platform that may be licensed on a non-exclusive basis in an innovative emerging market in need of novel solutions

Plans:

➢ *Build a robust PCI vaccination IP estate*	*Continuous*
➢ *Further strengthen our promising preclinical data* ➢ *Optimise conditions for PCI vaccination* ➢ *Generate results in relevant tumour models*	*2H 2013*
➢ *Ramp up communication and partnering activities*	*2H 2013 - 1H 2014*

Financial results

Financial key figures 2013 and 2012

P&L (TNOK)	Q2 2013	Q2 2012	1H 2013	1H 2012	2012
Grants	1 688	1 896	3 078	3 805	6 765
Research and development costs	6 551	5 925	14 523	13 497	31 263
General and administrative costs	1 027	262	1 689	793	2 856
Total operating costs	7 578	6 187	16 212	14 290	34 119
Operating results	-5 890	-4 291	-13 134	-10 485	-27 354
Profit before tax	**-5 412**	**-3 763**	**-12 236**	**-9 272**	**-25 259**
Cash flow (TNOK)					
Net cash flow from operations	-6 735	-4 391	-13 453	-9 212	-22 032
Net cash flow from investments					
Net cash flow from financials					
Net cash flow	**- 6 735**	**-4 391**	**-13 475**	**-9 212**	**-22 032**

Financial key figures 2013 and 2012

Balance (TNOK)	30.06.2013	30.06.2012	31.12.2012
Fixed assets	21	0	0
Short term receivables	4 813	5 892	5 118
Cash & cash equivalents	**59 608**	**85 903**	**73 083**
Equity	58 445	84 031	69 706
Long term debt	0	0	0
Short term debt	5997	7 764	8 495

Summary

PCI Biotech – summary

Head & neck cancer

- ENHANCE – a Phase II study in head & neck cancer, started in 2012
  - Intra-tumour illumination produced too strong local treatment effects
  - Study is redesigned to optimise intra-tumour treatment
  - Light dose escalation with intra-tumour treatment proof of concept included

Bile duct cancer

- Orphan indication in combination with the widely used cytotoxic gemcitabine
- Initiated a clinical Phase I/II study

Vaccination

- Proof of principle for PCI enhancement of vaccination achieved
- Establishing a robust PCI vaccination IP estate
- Strengthening preclinical data and optimising treatment conditions
- Ramping up communication and partner discussions

2013	2014
Intra-tumour dose escalation in head & neck cancer	Complete intra-tumour PoC in head & neck cancer
Start Phase I/II study in bile duct cancer	Complete Phase I part of study in bile duct cancer
Complete pre-clinical vaccination project	Amphinex and/or vaccination partnering

Enquiries

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