PCI Biotech

Amphinex® – a new product for localised cancer treatment

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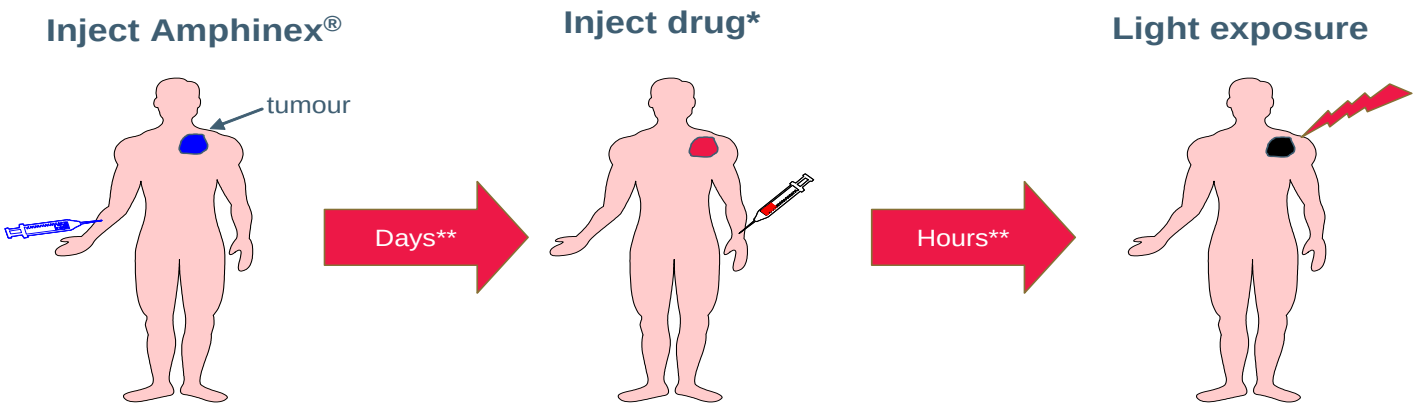
Photochemical Internalisation – a new technology for localised cancer treatment

- Light-induced enhancement of various drugs, using a unique and patented photosensitiser, Amphinex® to induce the enhancement.
- PCI Biotech is developing Amphinex® for local enhancement of marketed cancer drugs. Amphinex ® is being developed with the generic cytotoxic agents bleomycin for head & neck cancer and gemcitabine for bile duct cancer.
  - Started inclusion of patients in the ENHANCE study, the Phase II study in head & neck cancer patients
  - Preparing for a clinical proof of concept study in bile duct cancer, to start by end of 1H 2013
- Completed first clinical study with Amphinex® for enhancement of bleomycin. The results indicate that the treatment induce strong tumour response and is well tolerated.
- Promising results from preclinical program to investigate PCI used with vaccines. Preclinical program is ongoing to optimise a treatment regime, with the aim to develop a protocol for a clinical study that can start in 2013.

PCI Biotech
– Focused on Localised Cancer Treatment

PCI Technology

Significantly enhancing the local effect of cancer drugs



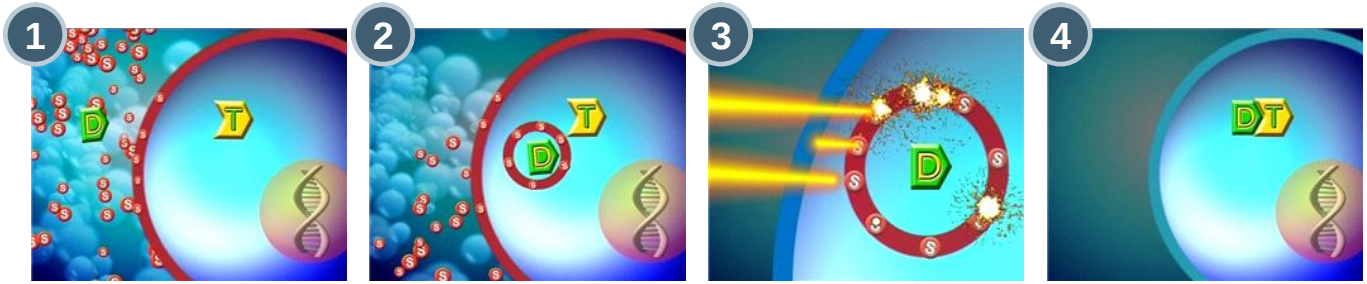
Amphinex® taken up by tumour cells

Drug taken up by tumour cells

Drug activated only in illuminated cells

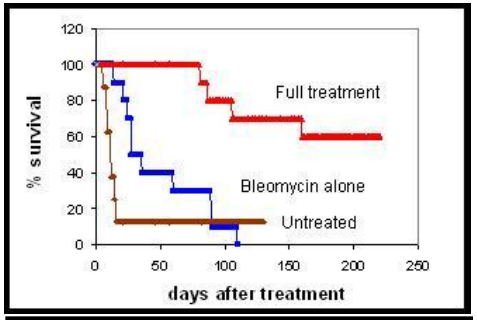
* PCI Biotech currently focus on generic drugs, such as bleomycin
** The optimal timing of injections and light exposure may vary with the drug to be delivered

Enabling drugs to reach intracellular therapeutic targets



Amphinex may enhance the localised effect of a wide range of different cancer drugs

- Positive *in vivo* results with several marketed cancer drugs
  - Enhancement of the local effect of bleomycin in several models
  - Significant enhancement of three widely used cancer drugs, including gemcitabine
- Effective delivery of macromolecules
  - Proven effective delivery of several types of macromolecules, including targeted immunotoxins



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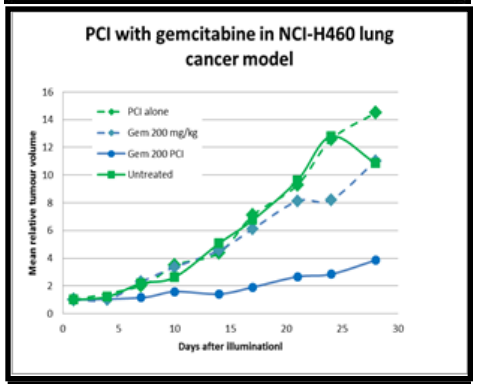

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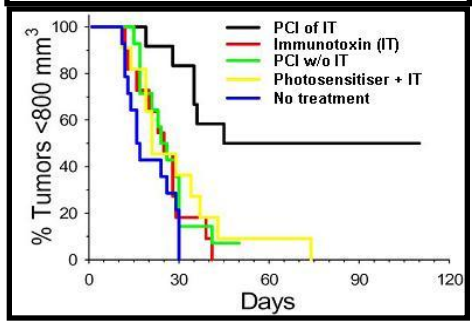

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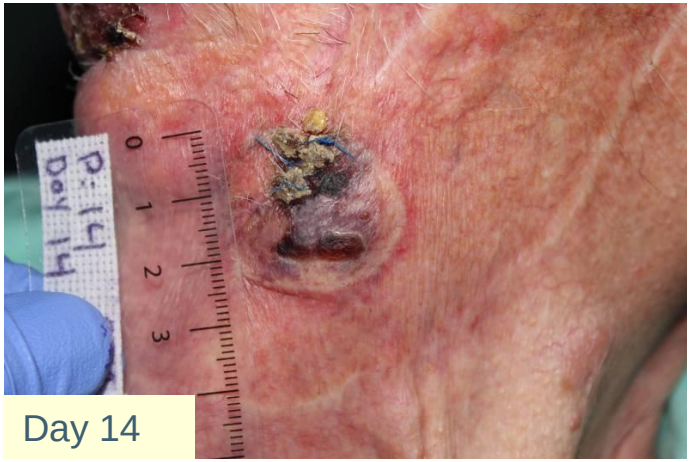
*Berg, K. *et al*. (2005) *Clin. Cancer Res*. 11, 8476
**Unpublished results
***Selbo, *et al*. (2009). *PLoS ONE*, 4, e6691

PCI 652 Laser – designed for PCI treatment

- Prototyped, produced, and received CE marking for the PCI 652 nm medical laser
- PCI Biotech approved as manufacturer and supplier of the laser
- Designed for PCI treatment with Amphinex®
- One channel (5W) for superficial and 6 channels (0.5W) for interstitial light application
- Is used in the Phase II study of Amphinex® in combination with bleomycin in head and neck cancer and in the clinical Proof of Concept study in bile duct cancer

Amphinex induced PCI of bleomycin – may provide excellent cosmetic outcome

Baseline



Day 14

Day 28


Day 90

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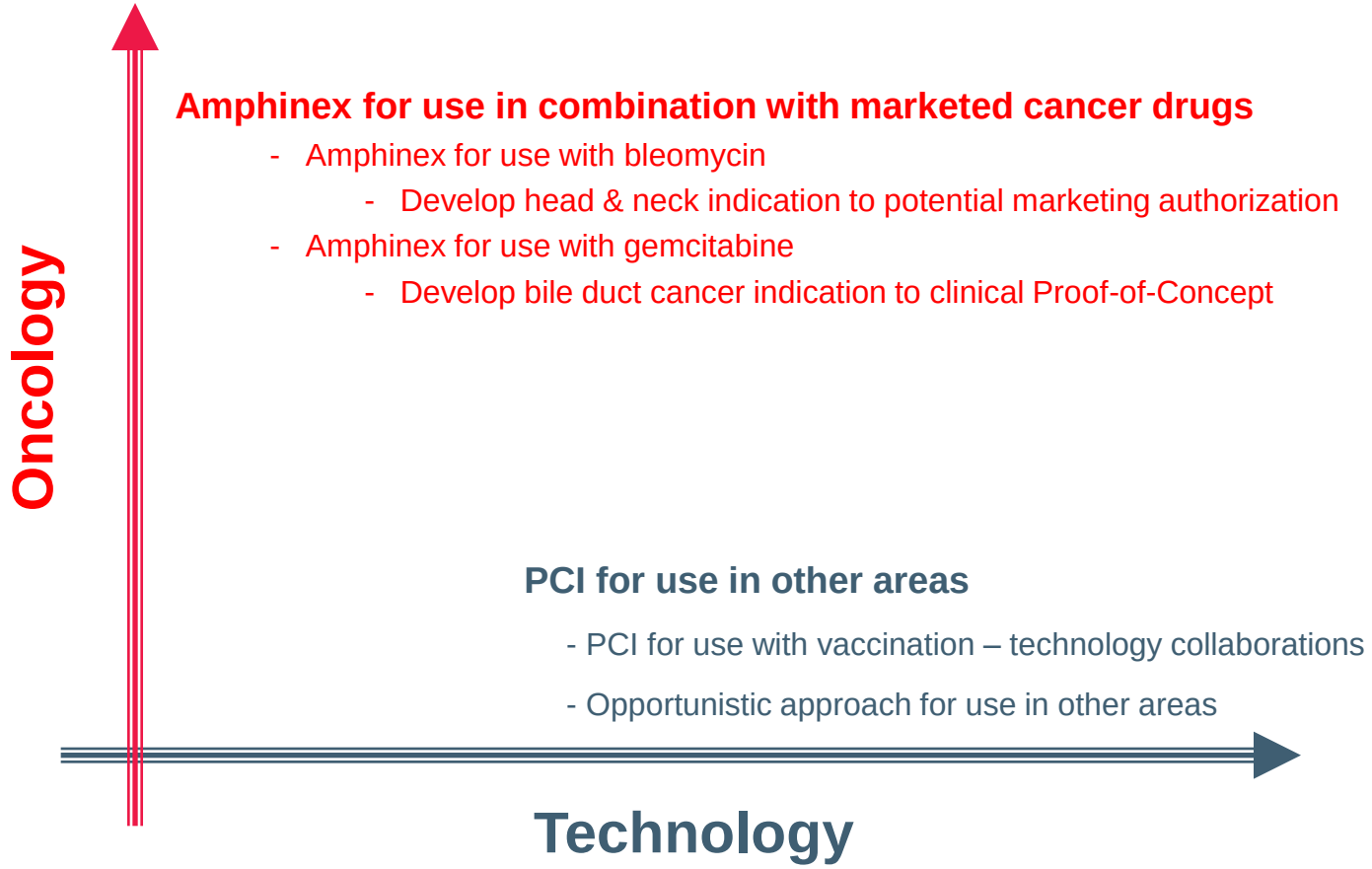
Strategy

Growth of PCI Biotech via 2 axes

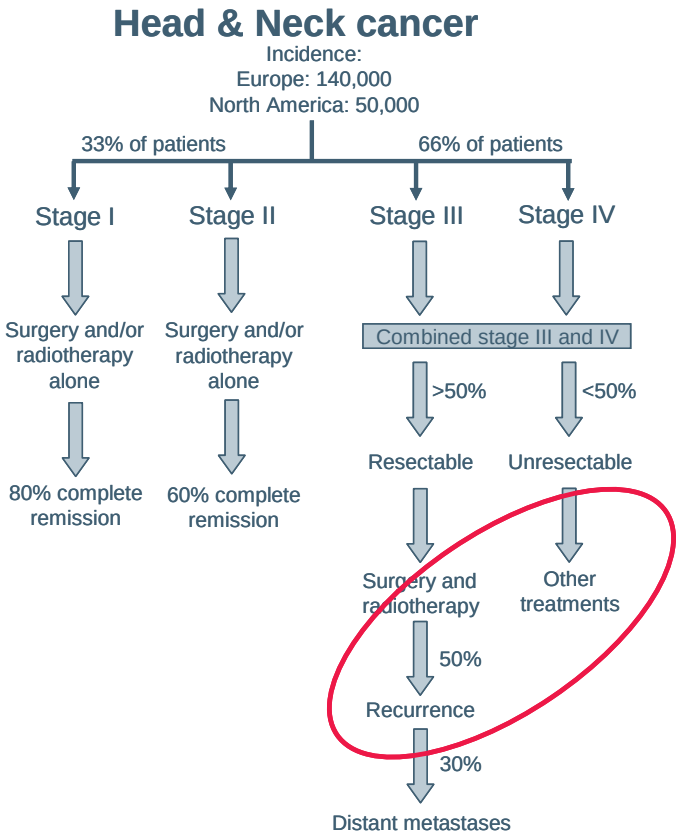


Amphinex

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 new innovations
- Current localised treatment options are often associated with functional and cosmetic impairments
  - Surgery
  - Radiotherapy
- 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 – market assessment by Bridgehead International

- Market assessment performed in France, Germany, Italy, UK 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

- 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
  - Cetuximab (Erbitux) most relevant price comparator
  - Approximately 20% of head & neck cancer patients eligible for Amphinex

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

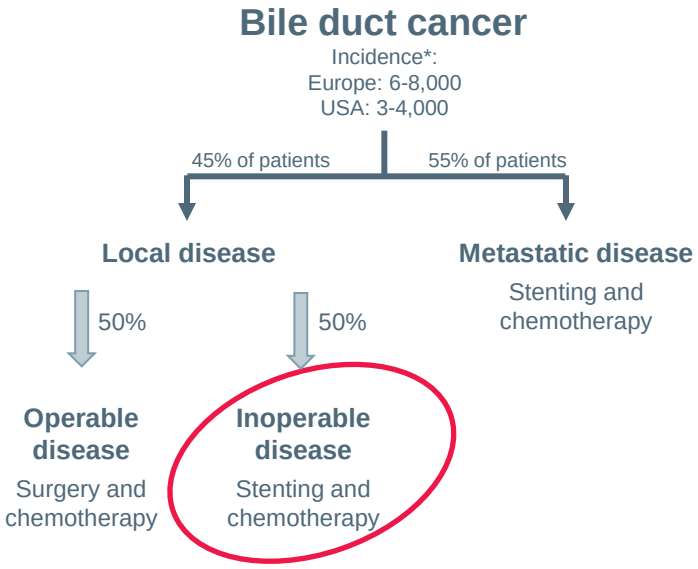
- Patient inclusion — Q2 2012 – 2013
- Target population — Recurrent head & neck squamous cell carcinoma without distant metastases, unsuitable for radiotherapy and surgery
- Type of study — Single arm, open label
- Primary endpoint — Progression free survival at 6 months
- Number of patients — 70-80
- Where — Europe

Amphinex

Bile duct cancer

Bile duct cancer– selected as second indication for the development of Amphinex

- Patient population with high medical unmet need
  - Tumour resection is currently the only potential cure
  - Majority of patients are inoperable at presentation
  - Incidence and mortality rates are increasing worldwide
  - Remarkable resistance to common chemotherapy
  - Need of new treatments able to prolong and improve quality of life



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

- Could PCI play a role in treatment of bile duct cancer?
  - Medical need for better local treatment methods
  - Easy access with light through the endoscopic methods routinely in use
  - Gemcitabine is one of the drugs that in preclinical studies are significantly enhanced by PCI, and is one of the most studied and used chemotherapies in bile duct cancer

Amphinex induced PCI of gemcitabine in bile duct cancer – Proof of Concept study

- Patient inclusion — Start by end of 1H 2013; finish 2014
- 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 treatment of gemcitabine, followed by gemcitabine/cicplatin chemo
  - Control arm: stenting alone followed by gemcitabine/cicplatin chemo
  - Randomization ratio 2.5;1 in favor of the PCI arm

Amphinex induced PCI of gemcitabine in bile duct cancer – Proof of Concept 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

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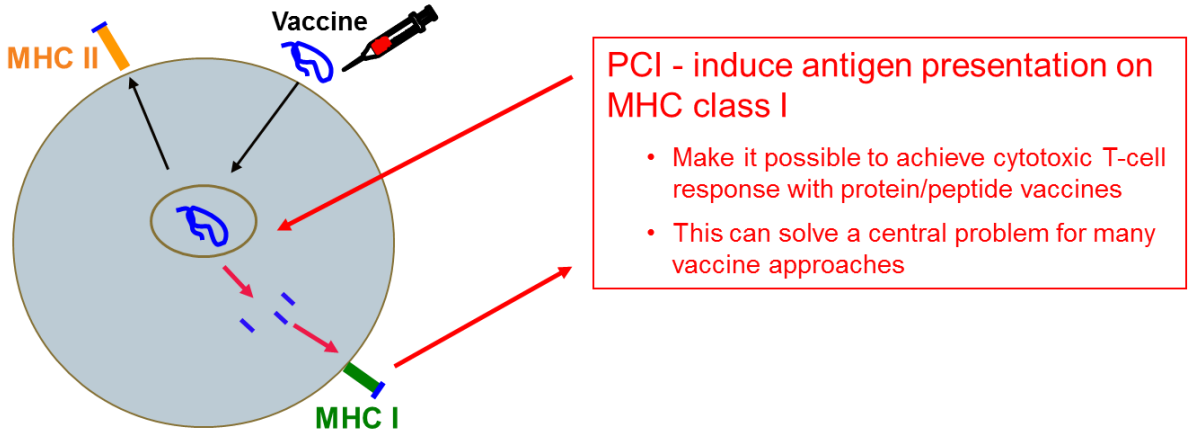
Vaccines

PCI for vaccination – enhancing cytotoxic T-cell response

- PCI - induce antigen presentation on MHC class I
  - Make it possible to achieve cytotoxic T-cell response with protein/peptide vaccines
  - Can solve a central problem for many vaccine approaches:
    - Therapeutic vaccines
      - Cancer
      - Chronic viral diseases
    - Some prophylactic vaccines



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

PCI to enhance vaccines

- Therapeutic vaccines – an area with increased focus world wide
  - Rapid marked growth expected within therapeutic vaccines – first product on the market in 2010 and many products under development
- PCI to enhance ex-vivo vaccines – preclinical program ongoing at University Hospital Zurich, CH
  - Will be completed by end of 1H 2013.
  - If positive results => Further development by partners
- PCI to enhance in-vivo vaccines – preclinical program ongoing at University Hospital Zurich, CH
  - Optimised treatment regime to be developed during 2013, with the aim to start a clinical study in 2013.
  - If positive results => Further development by partners

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Summary

PCI Biotech – well positioned for attractive development opportunities

Amphinex with bleomycin	• Phase I/II study successfully completed – well tolerated & strong tumour response • Phase II study in head & neck cancer started – further expansion of sites in Europe
Amphinex with gemcitabine	• Bile duct cancer and gemcitabine selected as next clinical indication • Clinical proof of concept study planned to start by end of 1H 2013
Vaccination	• Proof of principle for *ex vivo* PCI enhancement of vaccination • Further pre-clinical work initiated, with plan to start clinical study in 2013
Other	• PCI 652 medical laser designed and approved for PCI treatment

2012	2013	2014
Amphinex Phase I/II extension study completed	Complete inclusion of Phase II head & neck cancer study	Complete inclusion of PoC study in bile duct cancer
Amphinex head & neck cancer Phase II study initiated	Complete pre-clinical vaccination project	Final results of Phase II head & neck cancer study
PCI vaccination – proof of principle studies completed	Start clinical vaccination study	Amphinex partnering
	Start PoC study in bile duct cancer	

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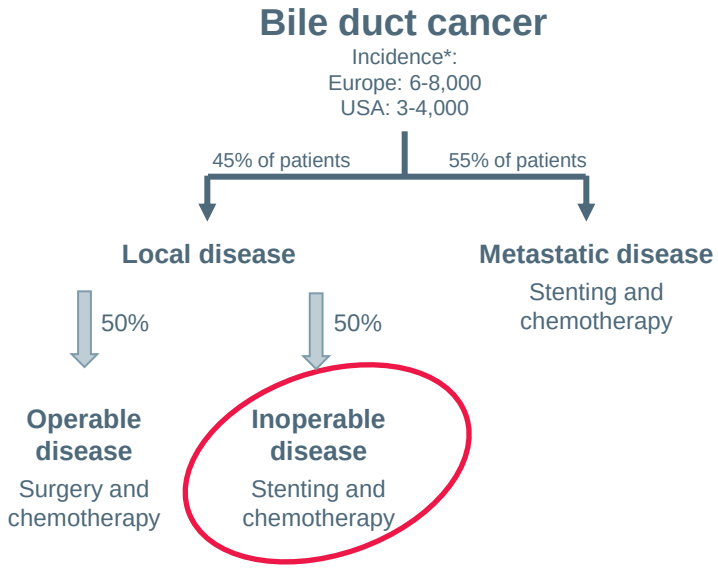
Bile duct cancer
Incidence*:
Europe: 6-8,000
USA: 3-4,000
45% of patients
55% of patients
Local disease
Metastatic disease
Stenting and chemotherapy
50%
50%
Operable disease
Surgery and chemotherapy
Inoperable disease
Stenting and chemotherapy