KURZPROTOKOLL
PCI A203/18

Öffentlicher Titel	Phase II Studie zur Fimaporfin-induzierten photochemischen Internalisierung von Gemcitabin bei inoperablem Cholangiokarzinom
Wissenschaftl. Titel	A Multi-Centre, Randomised, Open-Label, Phase 2 Study to Assess the Safety, Tolerability and Efficacy of Fimaporfin-Induced Photochemical Internalisation of Gemcitabine Complemented by Gemcitabine/Cisplatin Chemotherapy Versus Gemcitabine/Cisplatin Alone in Patients With Inoperable Cholangiocarcinoma
Kurztitel	PCI A203/18
Studienart	multizentrisch, prospektiv, Therapiestudie, randomisiert, offen/unverblindet, Pharma-Studie, zweiarmig
Studienphase	Phase II
Erkrankung	Verdauung: Gallengangs-/Gallenblasenkrebs (maligne biliäre Tumoren): Erstlinie
Einschlusskriterien	- Capable of understanding the written informed consent, provides signed and witnessed written informed consent, and agrees to comply with protocol requirements; - Male or female patient >=18 years of age; - Histopathologically/cytologically (C5) verified adenocarcinoma consistent with CCA; - Cholangiocarcinoma must be considered inoperable with respect to radical resection; - At least 1 lesion (measurable and/or non-measurable but evaluable) that can be accurately assessed at baseline and is suitable for repeated evaluation. - If metastatic, metastases must be limited to the liver parenchyma only and/or restricted only to the local lymph nodes with peritoneal engagement locally within close proximity to the hepatoduodenal ligament; - Biliary lesion causing bile obstruction that requires stenting and is accessible for PCI light treatment; - Adequate biliary drainage (either at least 50% of the liver volume, or at least 2 sectors), with no evidence of active uncontrolled infection (patients on antibiotics are eligible); - Eastern Cooperative Oncology Group (ECOG) performance status of 0 or 1; - Estimated life expectancy of at least 12 weeks.
Ausschlusskriterien	- Previously received any prior anti-tumour (either local or systemic) treatment for CCA; - Severe visceral disease other than CCA; - Primary sclerosing cholangitis; - Porphyria or hypersensitivity to porphyrins; - An active second primary cancer, defined as one with a disease-free interval of <5 years before screening, with the exception of adequately treated basal cell carcinoma, squamous cell carcinoma or other non-melanomatous skin cancer, in-situ carcinoma of the uterine cervix, or prostate cancer that is controlled by hormone therapy (patients may continue hormone therapy while on study); - Unable to undergo contrast-enhanced CT or MRI; - Currently participating in in any other interventional clinical trial; - Planned surgery, endoscopic examination, or dental treatment in the first 30 days after PCI treatment; - Co-existing ophthalmic disease likely to require slit-lamp examination within the first 90 days after PCI treatment; - Clinically significant and uncontrolled cardiac disease including unstable angina, acute myocardial infarction within 6 months prior to baseline, congestive heart failure, and arrhythmia requiring therapy, with the exception of extra systoles or minor conduction abnormalities and controlled and well treated chronic atrial fibrillation;

- Known allergy or sensitivity to photosensitisers, (the active substance and/or any of the excipients); or chronic use of other photosensitising therapies (Section 5.5.3);
- Known hypersensitivity to or contraindication to the use of gemcitabine (the active substance and/or any of the excipients);
- Known hypersensitivity, or contraindication to the use of cisplatin (the active substance and/or any of the excipients);
- Ataxia telangiectasia;
- Upon the Investigator's discretion, evidence of any other medical conditions (such as psychiatric illness, physical examination or laboratory findings) that may interfere with the planned PCI treatment, affect patient compliance or place the patient at high risk from treatment-related complications;
- Significant hearing impairment;
- Plans to have, or has recently had, vaccination with a live vaccine, including for yellow fever;
- Concurrently receiving treatment with phenytoin;
- Male patients unwilling to use highly effective contraception or female patients of childbearing potential unwilling to use a highly effective form of contraception such as the following: Hormonal contraceptives (oral, injectable, or patches), Intrauterine devices (hormonal-eluting or not), Bilateral tubal ligation, Male sterilisation or Double-barrier (condoms with spermicide). Patients must continue the use of contraception during PCI treatment and subsequent chemotherapy, and for at least 6 months thereafter.
- Breastfeeding women or women with a positive pregnancy test at baseline;
- Inadequate bone marrow function as evidenced by one of the following: Absolute neutrophil count (ANC) <1.5 x 109/L, Platelet count <100 x 109/L or Haemoglobin <6 mmol/L (transfusion allowed);
- Inadequate liver function despite satisfactory endoscopic or percutaneous biliary tree stenting, defined as:
- 1. Serum (total) bilirubin persisting at >2.5 x the upper limit of normal (ULN) for the institution.
- 2. Aspartate aminotransferase (AST) or alanine aminotransferase (ALT) >3.0 x ULN (>5 x ULN if liver metastases are present)
- 3. Alkaline phosphatase (ALP) levels >5.0 x ULN;
- Inadequate renal function, defined as creatinine clearance <60 mL/min or <45 mL/min as determined by local practice for patients on fractionated platinum-based chemotherapy.

Alter 18 Jahre und älter

Prüfzentren

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Sponsor	PCI Biotech
Registrierung in anderen Studienregistern	EudraCT 2018-002647-29 ClinicalTrials.gov NCT04099888 (primäres Register)