KURZPROTOKOLL
Predict (AIO-PAK-0216)

Öffentlicher Titel	Prädiktive Rolle der Gemcitabin-Erstlinientherapie auf den Erfolg der Zweitlinientherapie mit NAL-IRI bei fortgeschrittenem Bauchspeicheldrüsenkrebs
Wissenschaftl. Titel	Zweitlinientherapie mit Nal-IRI nach Versagen von Gemcitabin/Nab-Paclitaxel bei fortgeschrittenem Bauchspeicheldrüsenkrebs – Prädiktive Rolle der Erstlinientherapie
Kurztitel	Predict (AIO-PAK-0216)
Studienart	multizentrisch, Therapiestudie, offen/unverblindet, einarmig, Pharma-Studie
Studienphase	Phase III
Erkrankung	Verdauung: Bauchspeicheldrüsenkrebs (Pankreaskarzinom): Zweitlinie oder höher
Einschlusskriterien	- Written informed consent including participation in translational research and any locally-required authorization (EU Data Privacy Directive in the EU) obtained from the subject prior to performing any protocol-related procedures, including screening evaluations - Clinical indication for a 2nd-line systemic therapy according to current standard-of-care - Age >= 18 years at time of study entry - Patients with histologically or cytologically confirmed pancreatic ductal adenocarcinoma - Imaging of evaluable lesions (either sonography, X-ray, CT scans, MRI): only in case of treatment failure because of progress - ECOG performance status 0-2 - One line of systemic gemcitabine/Nab-paclitaxel -based therapy for advanced disease (irrespective of prior adjuvant therapy) OR - Previous adjuvant gemcitabine/Nab-paclitaxel-based chemotherapy with documented progression less than 6 months after termination - Documentation of prior therapy (duration, maximum toxicity, reason for discontinuation) - Adequate blood count, liver-enzymes, and renal function: - (1) neutrophil count > 1.5 x 10^6/mL - (2) Platelet count >= 100 x 10^9/L (>=100,000 per mm^3) - (3) AST (SGOT)/ALT (SGPT) <= 5 x institutional upper limit of normal - (4) bilirubin <=1.5 ULN (<3 x ULN in patients with confirmed mechanical cholestasis) - (5) Creatinine Clearance CLcr >= 30 mL/min - Subject is willing and able to comply with the protocol for the duration of the study including undergoing treatment and scheduled visits and examinations including follow up
Ausschlusskriterien	- Medical criteria: - (1) Any condition or comorbidity that, in the opinion of the investigator, would interfere with evaluation of study treatment or interpretation of patient safety or study results, including but not limited to: - a) Active uncontrolled infection, chronic infectious diseases, immune deficiency syndromes - b) Premalignant hematologic disorders, e.g. myelodysplastic syndrome - c) Clinically significant cardiovascular disease in (incl. myocardial infarction, unstable angina, symptomatic congestive heart failure, serious uncontrolled cardiac arrhythmia) 6 months before enrollment

- d) Prior (<3 years) or concurrent malignancy (other than biliary-tract cancer) which either progresses or requires active treatment. Exceptions are: basal cell cancer of the skin, pre-invasive cancer of the cervix, T1a or T1b prostate carcinoma, or superficial urinary bladder tumor [Ta, Tis and T1].
- e) Pre-existing lung disease of clinical significance or with impact on performance status
- f) History or clinical evidence of CNS metastases
- Exceptions are: Subjects who have completed local therapy and who meet both of the following criteria:
- aa) are asymptomatic and
- bb) have no requirement for steroids 6 weeks prior to start of study treament. Screening with CNS imaging (CT or MRI) is required only if clinically indicated or if the subject has a history of CNS metastases
- g) Allogeneic transplantation requiring immunosuppressive therapy or other major immunosuppressive therapy
- h) Severe non-healing wounds, ulcers or bone fractions
- i) Evidence of bleeding diathesis or coagulopathy
- j) Major surgical procedures, except open biopsy, or significant traumatic injury within 28 days prior to star of study treatment, or anticipation of the need for major surgical procedure during the course of the study except for surgery of central intravenous line placement for chemotherapy administration
- k) Known Gilbert-Meulengracht syndrome
- l) Known chronic hypoacusis, tinnitus or vertigo
- m) Bone marrow depression (e.g., after radiation therapy)
- n) Pernicious anemia and other megaloblastic anemias secondary to vitamin B12 deficiency
- o) Severe impairment of hepatic function
- p) Diarrhea
- Drug related criteria:
- (1) Medication that is known to interfere with any of the agents applied in the trial
- (2) Known dihydropyrimidine dehydrogenase (DPD) deficiency
- (3) History of hypersensitivity to any of the study drugs or any of the constituents of the products
- (4) Any other efficacious cancer treatment except protocol specified treatment at study start
- Safety criteria:
- (1) Female subjects who are pregnant, breast-feeding or male or female patients of reproductive potential who are not employing an effective method of birth control (failure rate of less than 1% per year). [Acceptable methods of contraception are: implants, injectable contraceptives, combined oral contraceptives, intrauterine pessars (only hormonal devices), sexual abstinence or vasectomy of the partner]. Women of childbearing potential must have a negative pregnancy test (urine or serum -HCG acc. to SOC) at Screening
- Methodological criteria:
- (1) Any experimental pretreatment for advanced disease

	- (2) Participation in another clinical study with an investigational product during the last 30 days before inclusion or 7 half-lifes of previously used trial medication, whichever is longer, with the following exception: Any clinical study with the IMPs Nab-paclitaxel + gemcitabine and under the condition that the potential study subject was only exposed to Nab-paclitaxel + gemcitabine doublet chemotherapy during the course of the previous study is exempt. The previous Nab-paclitaxel + gemcitabine treatment must be consistent with current treatment approaches for first-line therapy with regard to dosing and scheduling. The following non-comprehensive list of clinical trials may serve as a guidance: ALPACA (EudraCT number: 2014-004086-24); GrantPax (EudraCT Number: 2015-002890-40), NEONAX (EudraCT number: 2013-005559-34), NEOLAP (EudraCT number: 2013-004796-12). - (3) Previous enrollment in the present study (does not include screening failure) - Regulatory and ethical criteria: - (1) Patient who might be dependent on the sponsor, site or the investigator - (2) Patients who are unable to consent because they do not understand the nature, significance and implications of the clinical trial and therefore cannot form a rational intention in the light of the facts [§ 40 Abs. 1 S. 3 Nr. 3a AMG]
Alter	18 Jahre und älter
Sponsor	AIO-Studien GmbH
Förderer	Baxalta
Registrierung in anderen Studienregistern	EudraCT 2016-005147-17