KURZPROTOKOLL
CANFOUR

Öffentlicher Titel	First-in-Human-Studie zu CAN04 bei fortgeschrittenen oder rezivierten/refraktären soliden Tumoren
Wissenschaftl. Titel	An open label, dose escalation followed by dose expansion, safety and tolerability trial of CAN04, a fully humanized monoclonal antibody against IL1RAP, in subjects with solid malignant tumors
Kurztitel	CANFOUR
Studienart	multizentrisch, prospektiv, Therapiestudie, offen/unverblindet, mehrarmig
Studienphase	Phase I/II
Erkrankung	Lunge: Lungenkrebs: Nicht kleinzelliges Lungenkarzinom (NSCLC) - Zweitlinie oder höher Geschlechtsorgane: Brustkrebs: Zweitlinie oder höher Verdauung: Darmkrebs (Kolorektales Karzinom): Zweitlinie oder höher Verdauung: Bauchspeicheldrüsenkrebs (Pankreaskarzinom): Zweitlinie oder höher
Einschlusskriterien	- Age >= 18 year - Measurable disease in accordance to immune related Response Criteria (irRC) by computed tomography (CT) or magnetic resonance imaging (MRI) scan, no more than 6 weeks prior to screening - At least 4 weeks since the last dose of chemotherapy, radiation therapy, immunotherapy, or surgery; at least 6 weeks for therapy which is known to have delayed toxicity; at least 4 weeks since treatment with biologic/targeted therapies. - Eastern Cooperative Oncology Group (ECOG) performance status <=1. - Histologically or cytologically confirmed, unresectable, locally advanced or metastatic NSCLC, PDAC, CRC or TNBC tumor, relapsed or refractory to standard therapy or for which there is no standard therapy (applicable for Part I only) - Histologically or cytologically confirmed, unresectable, locally advanced, or metastatic squamous or non-squamous NSCLC or PDAC, relapsed or refractory to standard of care therapy or for whom there is no standard therapy (applicable for Part II, monotherapy arms only) - Histologically or cytologically confirmed diagnosis of unresectable stage IIIB or stage IV squamous or non-squamous NSCLC (applicable Part II, Combination - NSCLC arm only) - Newly diagnosed, treatment nave, histologically confirmed, unresectable, locally advanced or metastatic (stage III or stage IV) PDAC (applicable Part II, Combination - PDAC arm only)
Ausschlusskriterien	- Subjects receiving live vaccination, etanercept or other TNF-alpha inhibitors or any other investigational agents during or just prior to (within 28 days of first study drug administration) participation in this study - Clinical evidence of an active second malignancy - Subjects with a life expectancy <12 weeks - Uncontrolled or significant cardiovascular disease defined as New York Heart Association Classification III, or IV - Immunocompromised subject currently receiving systemic therapy - Other medical conditions that in the opinion of the investigator disqualify the subject for inclusion - Applicable Part II, Combination - NSCLC arm only: - 1. Prior lines of treatment with anti-cancer medication other than pembrolizumab administered as 1st line - 2. Known tumor EGFR mutation, unless contraindication to EGFR-directed therapy - 3. Known tumor ALK rearrangements, unless contraindication to ALK-directed therapy or ALK-directed therapy not available

Alter	18 Jahre und älter
Sponsor	Cantargia AB
Registrierung in anderen Studienregistern	ClinicalTrials.gov NCT03267316 EudraCT 2017-001111-36