Press release

Cantargia AB
556791-6019
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Cantargia receives regulatory approval to start clinical trial investigating nadunolimab and FOLFIRINOX in pancreatic cancer

Cantargia AB today announce that the clinical trial application to investigate the antibody nadunolimab (CAN04) in combination with the FOLFIRINOX chemotherapy regimen for first line treatment of metastatic pancreatic cancer (PDAC), has been approved by the regulatory authority and the central ethics committee in France. The current estimate is to enroll the first patient in June 2021.

The approvals by the Agence nationale de sécurité du médicament et des produits de santé, ANSM, and the central ethics committee, follow the previously communicated application of this CAN04 study on Mar 10, 2021. The study will be performed in France and Spain. The review is still ongoing in Spain.

The interleukin-1 receptor accessory protein (IL1RAP)-binding antibody CAN04 is Cantargia's most advanced program. CAN04 is currently investigated in an open label phase I/IIa clinical trial, CANFOUR, examining first line combination with gemcitabine and nab-paclitaxel in patients with advanced PDAC, as well as with gemcitabine and cisplatin in non-small cell lung cancer (NSCLC) (https://clinicaltrials.gov/ct2/show/NCT03267316).
An additional trial, CIRIFOUR, investigates CAN04 in combination with pembrolizumab in four different solid tumor indications (https://clinicaltrials.gov/ct2/show/NCT04452214).

This third clinical study, named CAPAFOUR, aims to investigate CAN04 in combination with one of the two most commonly used first line chemotherapy regimens in metastatic PDAC, FOLFIRINOX. In the initial part of the study, a safety lead-in phase using an adaptive design of different dose levels of CAN04, in combination with the FOLFIRINOX regimen, will be investigated. The trial will then be expanded at one dose level in approximately 15 patients. CAPAFOUR is planned to include approximately 30 patients, and the first patient is expected to be enrolled in June 2021. The primary endpoint is safety, and important secondary endpoints include effects on biomarkers and antitumor activity. The study has been designed based on previous results from CAN04 combined with chemotherapy. Biopsies are planned pre-dose and during therapy to learn more about potential effects in the tumor microenvironment. One specific aspect relates to the granulocyte growth factor, G-CSF, which will be prophylactically used to counteract neutropenia. Additional trial details will be disclosed on clinicaltrials.gov during Q2 2021.

"We are excited to start the CAPAFOUR trial investigating nadunolimab with chemotherapy. Based on positive clinical results using nadunolimab in pancreatic cancer and synergies in preclinical models using components of the FOLFIRINOX regimen, this milestone is an important step forward", said Göran Forsberg, CEO of Cantargia.

For further information, please contact
Göran Forsberg, CEO
Telephone: +46 (0)46-275 62 60
E-mail: goran.forsberg@cantargia.com

This is information that Cantargia AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 10.00 CET on 8 June 2021.

About Cantargia
Cantargia AB (publ), reg. no. 556791-6019, is a biotechnology company that develops antibody-based treatments for life-threatening diseases. The basis for this is the protein IL1RAP that is involved in a number of diseases and where Cantargia has established a platform. The main project, the antibody CAN04, is being studied clinically as combination therapy with chemotherapy or immune therapy with a primary focus on non-small cell lung cancer and pancreatic cancer. Positive interim data from the combination with chemotherapy indicate stronger efficacy than would be expected from chemotherapy alone. Cantargia's second project, the antibody CAN10, addresses treatment of serious autoimmune/inflammatory diseases, with initial focus on systemic sclerosis and myocarditis.

Cantargia is listed on Nasdaq Stockholm (ticker: CANTA). More information about Cantargia is available at www.cantargia.com.

About nadunolimab (CAN04)

The antibody CAN04 binds strongly to the target IL1RAP and functions both though ADCC as well as blocking IL-1α and IL-1β signaling. Thereby, CAN04 can counteract the contribution of the IL-1 system to the immune suppressive tumor microenvironment and development of resistance to chemotherapy. CAN04 is investigated in two clinical trials. In the first phase I/IIa-study, CANFOUR, first line combination therapy is investigated using two different standard chemotherapies in patients with NSCLC (gemcitabine/cisplatin) and patients with PDAC (gemcitabine/nab-paclitaxel), as well as monotherapy in late stage patients (https://clinicaltrials.gov/ct2/show/NCT03267316). Phase I monotherapy data from 22 patients were presented at ASCO 2019 and showed good safety with infusion-related reaction being the most common side effect. In addition, the biomarkers IL6 and CRP decreased during treatment. Positive interim data from the combination therapies show durable responses or pseudoprogression in patients with PDAC, resulting in iPFS of 7.8 months, and also a higher response rate of patients with NSCLC, compared to chemotherapy alone. A phase I study, CIRIFOUR, investigating CAN04 in combination with an immune checkpoint inhibitor, started H2 2020 (https://clinicaltrials.gov/ct2/show/NCT04452214). Additional clinical combination studies are planned to start during 2021.