Press release

Cantargia AB
556791-6019
10 September 2021

Cantargia receives regulatory approval to start CESTAFOUR clinical study with nadunolimab in combination with chemotherapy

Cantargia AB today announced approval to start the phase I/II clinical study CESTAFOUR by the regulatory authority and ethics committee in France. This study broadens the clinical development for nadunolimab (CAN04) to include biliary tract cancer (BTC), colorectal cancer (CRC) and late-stage non-small lung cancer (NSCLC) and will evaluate CAN04 in combination with standard of care chemotherapy. The study will be conducted at approximately 20 clinical centers in Europe and will include up to a total of 165 patients. The first patient is estimated to be enrolled in September/October 2021.

Cantargia's most advanced candidate, the interleukin-1 receptor accessory protein (IL1RAP)-binding antibody CAN04, is investigated in multiple clinical trials in combination with various chemotherapy regimens, primarily in NSCLC and pancreatic cancer. With the aim to broaden the clinical development of CAN04, Cantargia recently submitted a clinical trial application to start a new phase I/II clinical study, CESTAFOUR, which will evaluate CAN04 in additional forms of cancer, such as BTC, CRC and late-stage NSCLC, in combination with standard of care chemotherapy.

The French regulatory authority, Agence nationale de sécurité du médicament et des produits de santé (ANSM), and ethics committee, Comité de protection des personnes, have now approved the CESTAFOUR study. In CESTAFOUR, CAN04 will be evaluated as first line therapy of advanced BTC in combination with gemcitabine and cisplatin, third line therapy of CRC in combination with FOLFOX, and second or third line therapy of NSCLC in combination with docetaxel. The selected chemotherapy combinations are supported by preclinical data, showing that CAN04 enhances antitumor activity of platinum-based chemotherapy or docetaxel.

In the initial dose escalation phase of CESTAFOUR, performed in approximately 15 patients for each indication/combination, the primary objective is to assess the safety and tolerability of the CAN04 combinations, and to establish a recommended dose of CAN04 for the subsequent part. In the phase II part, the primary objective is to assess the antitumor efficacy and will include approximately 40 patients for each of the three indications. The phase I part of the study will be performed in France, Spain and the United Kingdom, and the first patient is estimated to be enrolled in September/October 2021. Additional trial details will be disclosed on clinicaltrials.gov.

"CESTAFOUR is a very important trial, designed to broaden the use of nadunolimab for patient groups with very high medical need. The regulatory approval is therefore a highly important milestone and we look forward to start treating patients", 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 13.30 CET on 10 September 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 through 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 three ongoing 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 IL-6 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, CAPAFOUR, was initiated in H1 2021 and will investigate CAN04 in combination with the chemotherapy regimen FOLFIRINOX for first line treatment of metastatic PDAC (https://clinicaltrials.gov/ct2/show/NCT04990037). A phase I study, CIRIFOUR, is also currently investigating CAN04 combined with an immune checkpoint inhibitor, with or without chemotherapy, and was started H2 2020 (https://clinicaltrials.gov/ct2/show/NCT04452214). Additional clinical combination studies are planned to start during 2021.