Press release

Cantargia AB
556791-6019
19 August 2021

Cantargia expands CIRIFOUR trial after successful completion of recruitment in the pembrolizumab combination arm

Cantargia AB today announced that the last patient in the initial treatment arm of the phase Ib clinical study CIRIFOUR has started treatment. A total of 15 patients have so far been recruited to this study, which evaluates nadunolimab (CAN04) in combination with Keytruda® (pembrolizumab), and preliminary data indicate a good safety profile. The CIRIFOUR study protocol will now be expanded to include the next combination therapy arm where CAN04 is evaluated with pembrolizumab and platinum-based chemotherapy in patients with non-small cell lung cancer (NSCLC).

The interleukin-1 receptor accessory protein (IL1RAP)-binding antibody CAN04 is Cantargia's most advanced program and is investigated in multiple clinical trials evaluating CAN04 in combination with different chemotherapy regimens in NSCLC, pancreatic cancer and other forms of cancer. CIRIFOUR is a phase Ib study conducted in the US with the aim to assess CAN04 in combination with the checkpoint inhibitor pembrolizumab in patients with NSCLC, head and neck cancer, bladder cancer or malignant melanoma, who progressed on previous therapy with immune checkpoint inhibition.

The patient recruitment to the initial treatment arm of CIRIFOUR has now been finalized and a total of 15 patients have started treatment. These include 7 NSCLC patients, 7 head and neck cancer patients and 1 malignant melanoma patient. The primary objective of this study is to assess the safety and tolerability of CAN04 in combination with pembrolizumab and to establish a recommended dose of CAN04 in this combination. Secondary objectives include assessment of clinical activity and biomarkers. The preliminary results show that the combination is well-tolerated and are planned to be reported in Q4 2021.

Pembrolizumab is frequently utilized for first line combination with the platinum-based chemotherapy regime carboplatin/pemetrexed for treatment of non-squamous NSCLC. As both clinical and preclinical data indicate the ability of CAN04 to potentiate platinum-based chemotherapy, the data obtained in the CIRIFOUR study form the basis for further evaluation of CAN04 in combination with pembrolizumab and platinum doublets. Therefore, the CIRIFOUR study will now be expanded to include an additional arm to study safety, biomarkers and efficacy of such a combination in first line non-squamous NSCLC patients. The treatment of the first patient in this new arm is expected to start in Q4 2021 and the plan is to recruit up to 30 patients.

"We are pleased to have reached the milestone of full recruitment in the first trial investigating CAN04 combination therapy with pembrolizumab and are excited to take the next step by adding CAN04 to the widely used combination of pembrolizumab and carboplatin/pemetrexed", said Göran Forsberg, CEO of Cantargia.

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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 11.30 CET on 19 August 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 in combination with an immune checkpoint inhibitor and was started H2 2020 (https://clinicaltrials.gov/ct2/show/NCT04452214). Additional clinical combination studies are planned to start during 2021.