Press release

Cantargia AB
556791-6019
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Cantargia completes patient recruitment to the phase IIa pancreatic cancer extension cohort in the CANFOUR study

Cantargia AB today announced that all planned 40 patients with advanced pancreatic cancer (PDAC) have started therapy in the phase IIa extension cohort in the CANFOUR study. Preliminary data from these patients confirm a good safety profile of nadunolimab (CAN04) combined with gemcitabine/nab-paclitaxel. Presentation of safety and efficacy data for the extension cohort is planned for the first half of 2022. Adding this group to the primary group previously analyzed, more than 70 patients with PDAC have now received CAN04 combined with chemotherapy. Preparations are ongoing for a randomized clinical study in PDAC, including interactions with major regulatory authorities.

The interleukin-1 receptor accessory protein (IL1RAP)-binding antibody CAN04 is Cantargia's most advanced program and is investigated in multiple clinical trials evaluating combination with various chemotherapy regimens in non-small cell lung cancer (NSCLC), PDAC and other forms of cancer. CANFOUR, a phase I/IIa clinical study, investigates CAN04 with gemcitabine and cisplatin as first line combination or on progression after pembrolizumab in NSCLC patients, or with gemcitabine and nab-paclitaxel as first line combination in patients with advanced PDAC (https://clinicaltrials.gov/ct2/show/NCT03267316).

In October 2020, Cantargia completed recruitment of the primary cohort of PDAC patients in the CANFOUR phase IIa study. Positive interim data presented on the 33 patients in May 2021 showed good safety, durable responses, as well as long progression-free survival and median survival for the combination therapy. To increase the patient database and obtain additional information on the combination between CAN04 and gemcitabine/nab-paclitaxel, an expansion cohort was included in the study design and the first patient recruited in February 2021. Different dose levels and a modified dosing regimen were investigated in these patients to obtain more information regarding efficacy and safety.

The extension cohort has now been fully recruited, with all planned 40 patients enrolled, and preliminary data confirm the favorable safety profile of the combination therapy. Both short-term and long-term efficacy parameters are currently being generated and a detailed presentation of these, as well as safety data, are planned to be presented in the first half of 2022.

"In a short period of time, we have recruited all patients in this important part of the CANFOUR trial. We are thereby on track to advance nadunolimab development towards the goal of providing new treatment options to patients with life-threatening diseases", 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 13:00 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.