Press release

Cantargia AB
556791-6019
22 October 2021

Cantargia reports treatment of first patient in CESTAFOUR clinical trial

Cantargia AB today announced that the first patient has started treatment with nadunolimab (CAN04) and chemotherapy in the phase I/II clinical trial CESTAFOUR. This trial evaluates CAN04 in combination with standard of care chemotherapy in three different forms of cancer: biliary tract cancer (BTC), colorectal cancer (CRC) and non-small cell lung cancer (NSCLC) and is planned to include up to a total of 165 patients.

The interleukin-1 receptor accessory protein (IL1RAP)-binding antibody CAN04 is Cantargia's lead program and is investigated in multiple clinical trials. Approval was recently obtained to initiate the phase I/II clinical trial CESTAFOUR, which evaluates CAN04 in combination with chemotherapy in three forms cancer. The first patient has now started treatment in the CESTAFOUR trial.

In the most advanced clinical programs, CAN04 is evaluated in patients with NSCLC or pancreatic cancer in combination with chemotherapy. As these programs are advancing and have shown positive results, in parallel Cantargia intends to generate more knowledge around the applicability of these initial findings. The clinical development of CAN04 has therefore been broadened by initiating clinical trials in additional forms of cancer or with further chemotherapy regimens. This includes the CESTAFOUR study, where CAN04 is 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. Selection of these indications and combinations are supported by the substantial medical need as well as preclinical data which show that IL1RAP is expressed on these tumor types, and that CAN04 shows synergy with platinum-based chemotherapy or docetaxel.

The initial phase of CESTAFOUR, the dose escalation phase, will be performed in up to 15 patients for each combination. In this phase, the primary objective is to assess the safety and tolerability of the CAN04 combinations. In the phase II part, which will include approximately 40 patients for each of the three indications, the primary objective is to assess the antitumor efficacy. The study will be performed at approximately 20 clinical centers in Europe and the initial phase of the study will be conducted in France, Spain and the United Kingdom. Recruitment of patients to the three treatment arms of the initial dose escalation phase is expected to be finalized at different time points during H1 2022 and will be directly followed by the next phase. Additional trial details will be disclosed on clinicaltrials.gov.

"We are excited to have started treatment of patients in the CESTAFOUR trial. Based on the positive results combining nadunolimab and chemotherapy in previous studies, we see additional opportunities to add value to the program with the goal of providing new treatments to patients with cancer." 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 15.30 CET on 22 October 2021.

About Cantargia
Cantargia AB (publ), reg. no. 556791-6019, is a biotechnology company that develops antibody-based treatments for life-threatening diseases and has established a platform based on the protein IL1RAP, involved in a number of cancer forms and inflammatory diseases. The main project, the antibody nadunolimab (CAN04), is being studied clinically in combination 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 its target IL1RAP and functions by inducing ADCC and 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 multiple ongoing clinical trials. In the phase I/IIa-study CANFOUR, first line combination therapy is investigated with standard chemotherapies in patients with PDAC (gemcitabine/nab-paclitaxel) and patients with NSCLC (cisplatin/gemcitabine) (NCT03267316). Positive interim data for the combination therapies show durable responses or pseudoprogression in patients with PDAC, resulting in median iPFS of 7.8 months and median survival of 12.6 months. Stronger efficacy was also observed in NSCLC patients with median PFS of 7.2 months. A response rate of 53% was observed in non-squamous NSCLC patients, with even higher responses in patients previously treated with pembrolizumab. These results show stronger efficacy than expected from chemotherapy alone. CAN04 is investigated with chemotherapy also in the phase I study CAPAFOUR, with the FOLFIRINOX regimen for first line treatment of metastatic PDAC (NCT04990037), and in two further clinical studies, CESTAFOUR and TRIFOUR, in additional forms of cancer, including biliary tact cancer, colorectal cancer and triple negative breast cancer. CAN04 is also evaluated with the immune checkpoint inhibitor pembrolizumab, with or without chemotherapy, in the phase I study CIRIFOUR (NCT04452214).