Press release

Cantargia AB
556791-6019
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Cantargia advances development of nadunolimab in triple negative breast cancer through submission of clinical protocol for TRIFOUR study

Cantargia AB today announced the submission of the clinical trial application for TRIFOUR, a phase Ib/II trial investigating nadunolimab (CAN04) combined with gemcitabine and carboplatin for treatment of triple negative breast cancer (TNBC). After an initial safety lead in, the study will include a randomized phase II part. This trial will be performed in Spain in collaboration with the Spanish Breast Cancer Group, GEICAM. Up to 120 patients may be included and the first patient is estimated to be enrolled in November 2021.

The antibody CAN04, binding to interleukin-1 receptor accessory protein (IL1RAP), is Cantargia's most advanced program and is investigated in multiple clinical trials. CANFOUR, a phase I/IIa trial, investigates CAN04 first line combination with gemcitabine and nab-paclitaxel in patients with advanced pancreatic cancer (PDAC), as well as with gemcitabine and cisplatin in non-small cell lung cancer (NSCLC), https://clinicaltrials.gov/ct2/show/NCT03267316. In CAPAFOUR, a phase Ib trial, CAN04 in combination with FOLFIRINOX is evaluated for first line treatment of metastatic PDAC. CESTAFOUR, a phase I/II trial, will also investigate CAN04 with chemotherapy in three forms of solid tumors; biliary tract cancer, colorectal cancer and NSCLC. Additionally, CAN04 is investigated in the phase Ib trial CIRIFOUR, in combination with the checkpoint inhibitor pembrolizumab, in four solid tumor indications, https://clinicaltrials.gov/ct2/show/NCT04452214.

The clinical trial application for a fifth study, called TRIFOUR, has now been submitted to the regulatory authorities in Spain. This study will be conducted in collaboration with GEICAM and the submission follows the previously communicated letter of intent with GEICAM. TRIFOUR is a phase Ib/II trial designed to evaluate CAN04 in combination with gemcitabine and carboplatin as first or second line treatment in patients with advanced TNBC. TNBC is an aggressive and difficult to treat form of breast cancer that expresses IL1RAP at higher levels than other forms of breast cancer.

The primary objective in the initial stage is to evaluate the safety and tolerability of CAN04 in combination with this chemotherapy regimen. Biomarkers and early signs of efficacy will also be evaluated at this stage. If prespecified milestones are reached in the initial open label part, the trial will be expanded into a randomized phase II part, to investigate the efficacy of CAN04 combination with gemcitabine and carboplatin, compared to a control group receiving gemcitabine and carboplatin alone. The trial is estimated to include up to 120 patients at approximately 24 sites in Spain. The first patient is expected to be enrolled in the study in November 2021. Additional trial details will be disclosed on clinicaltrials.gov during Q3 2021.

"The development of nadunolimab is advancing with this study investigating nadunolimab in triple negative breast cancer. It is a disease of high relevance for our therapeutic approach and this study is the first controlled trial we perform to verify the positive effects observed in other inflammatory-driven cancer forms.", 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 09.00 CET on 1 July 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 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. 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.