Press release

Cantargia AB
556791-6019
29 September 2021

Cantargia receives regulatory approval to start TRIFOUR study in triple negative breast cancer

Cantargia AB today announced that the clinical trial application for the phase Ib/II clinical study TRIFOUR has received approval by the regulatory authority and ethics committee in Spain. This study broadens Cantargia's clinical program to include triple negative breast cancer (TNBC) and will investigate nadunolimab (CAN04) in combination with chemotherapy in up to approximately 120 patients with TNBC. The first patient is expected to be enrolled in November 2021.

The interleukin-1 receptor accessory protein (IL1RAP)-binding antibody CAN04 is Cantargia's most advanced candidate and is investigated in multiple clinical trials evaluating CAN04 in combination with different chemotherapy regimens, primarily in non-small cell lung cancer and pancreatic cancer. Cantargia is now broadening its clinical program for CAN04 with clinical studies in additional forms of cancer, including TNBC, which is the focus of the TRIFOUR study.

The Spanish regulatory authority, Agencia Española de Medicamentos y Productos Sanitarios, and the ethics committee, Comités de Ética de la Investigación con Medicamentos, have now approved the clinical trial application for the phase Ib/II clinical trial TRIFOUR, allowing Cantargia to advance the study and initiate patient recruitment. The study investigates CAN04 in combination with the chemotherapy regimen carboplatin/gemcitabine as first or second line treatment in patients with advanced TNBC and will be conducted at 24 clinical sites in Spain, in collaboration with the Spanish Breast Cancer Group, GEICAM.

In the initial stage, three dose levels of CAN04 will be evaluated in combination with carboplatin/gemcitabine in up to 18 patients. The primary objective will be to evaluate the safety and tolerability and to establish a recommended dose for the subsequent part. Biomarkers and early signs of efficacy will also be evaluated. 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 carboplatin/gemcitabine, compared to a control group receiving carboplatin/gemcitabine alone. Up to 98 patients will be included in the phase II part. Additional trial details will be disclosed on clinicaltrials.gov.

"In our efforts to provide new treatment alternatives to patients, we are very glad to have reached this important milestone. The medical need in TNBC is very high and we look forward to starting the trial." 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 16.30 CET on 29 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 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) https://clinicaltrials.gov/ct2/show/NCT03267316. Positive interim data for the combination therapies show durable responses or pseudoprogression in patients with PDAC, resulting in iPFS of 7.8 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. A phase I study, CAPAFOUR, was initiated in H1 2021 and investigates CAN04 in combination with the chemotherapy regimen FOLFIRINOX for first line treatment of metastatic PDAC (https://clinicaltrials.gov/ct2/show/NCT04990037). Another 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 with CAN04 are planned to initiate treatment of patients during 2021.