Press release

Cantargia AB
556791-6019
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Cantargia advance development of antibody CAN04 by a new clinical trial in triple negative breast cancer

Cantargia AB today announced signing a Letter of Intent with the Spanish Breast Cancer Group (GEICAM) to perform a new clinical trial investigating the antibody nadunolimab (CAN04) in combination with carboplatin/gemcitabine for the treatment of patients with advanced triple negative breast cancer (TNBC). The trial will investigate the safety and efficacy of the combination in this difficult to treat breast cancer. The total number of patients is estimated to be up to 120 and includes a randomized part after initial safety lead in. The protocol is planned to be submitted during Q2 2021.

Cantargia develops antibody-based pharmaceuticals against interleukin-1 receptor accessory protein (IL1RAP). The antibody CAN04 binds IL1RAP with high affinity and functions through both blockade of IL-1 signaling and Antibody-Dependent Cellular Cytotoxicity (ADCC). Preclinical data show that CAN04 can increase the efficacy of chemotherapy. CAN04 is investigated in an open label phase I/IIa clinical trial, CANFOUR, examining combination with two different frequently used chemotherapy regimes in patients with advanced non-small cell lung cancer (NSCLC) or pancreatic cancer (PDAC) (https://clinicaltrials.gov/ct2/show/NCT03267316) in the first line chemotherapy setting. A second trial, CIRIFOUR, investigates CAN04 in combination with pembrolizumab in four different solid tumor indications (https://clinicaltrials.gov/ct2/show/NCT04452214) and a third trial will investigate CAN04 in combination with FOLFIRINOX for first line treatment of PDAC.

TNBC is an aggressive and difficult to treat form of breast cancer. It affects approximately 200.000 persons each year globally corresponding to 10-15% of all breast cancer cases. It is more common in people aged below 50. If metastasized, it is treated with platinum-based chemotherapy combinations with taxanes or gemcitabine with a 5 year survival rate of 12%. TNBC is a disease overexpressing IL1RAP at levels higher than other forms of breast cancer.

Cantargia and GEICAM will join forces in this new trial in TNBC with the aims of testing the safety of the CAN04 combination and its efficacy as first or second line treatment. The initial stage will investigate safety, biomarkers and early efficacy in an open label design. If reaching prespecified milestones, the trial will be expanded into a randomized phase II part investigating CAN04 plus carboplatin/gemcitabine vs. carboplatin/gemcitabine. In total up to approximately 120 patients are planned for the study. The clinical trial protocol is planned to be submitted during Q2 2021 with first patient in during Q4. The trial will be carried out at approximately 40 clinical centers in Spain.

This trial has been expanded and broken out from a parallel trial investigating CAN04 in combination with chemotherapy in different cancer forms. That trial is planned to be performed in patients with colorectal cancer, biliary tract cancer or NSCLC. Submission is planned for Q2 2021.

"The IL-1 pathway is a very attractive target for the TNBC subgroup. The clinical and preclinical results available with CAN04 are very promising and indicate that our patients may benefit from the combination of CAN04 with platinums. This collaboration also reinforces the commitment of GEICAM in the development of novel drugs" says Prof. Miguel Martín, President of GEICAM.

"We are very happy to start this study with GEICAM, a leading group in breast cancer research. With this advancement of our clinical activities, we now have parallel development of CAN04 in three indications", says 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 16.45 CET on 6 May 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 show a higher response rate 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 GEICAM
GEICAM is the leading collaborative group in breast cancer research in Spain with a recognized worldwide scientific prestige. It is formed by more than 800 experts. One of its main goals is to promote independent clinical, epidemiological and translational research in breast cancer. Since its establishment in 1995 until now GEICAM has performed more than 145 studies in which almost 64,000 women have participated.

For more information, visit the official website www.geicam.org.

About 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 two clinical trials. In the first phase I/IIa-study, CANFOUR, first line combination therapy is investigated using two different standard chemotherapies in 31 patients with NSCLC (gemcitabine/cisplatin) and 31 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 IL6 and CRP decreased during treatment. Positive interim data from the combination arms was presented during H2 2020 and showed a higher response rate than expected from chemotherapy alone. A phase I study investigating CAN04 in combination with an immune checkpoint inhibitor started H2 2020 (https://clinicaltrials.gov/ct2/show/NCT04452214). Additional clinical combination studies are planned to start during 2021.