Press release

Cantargia AB
556791-6019
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Cantargia reports treatment of first triple negative breast cancer patient in TRIFOUR study

Cantargia AB today reported treatment of the first triple negative breast cancer (TNBC) patient with nadunolimab and chemotherapy in the phase Ib/II clinical trial TRIFOUR. This trial, performed in collaboration with the Spanish Breast Cancer Group, GEICAM, will evaluate nadunolimab in combination with gemcitabine and carboplatin in up to 113 patients. Initially, the trial will focus on the safety of this combination and the first part is expected to be completed within 6-9 months.

The interleukin-1 receptor accessory protein (IL1RAP)-binding antibody nadunolimab is Cantargia's most advanced program and is investigated in multiple clinical trials. Approval to start the phase Ib/II clinical trial TRIFOUR, which evaluates nadunolimab combined with chemotherapy in TNBC, was recently obtained. The first patient has now started treatment in the TRIFOUR trial.

In the most advanced clinical programs, nadunolimab is evaluated in non-small cell lung cancer or pancreatic cancer patients in combination with chemotherapy. As these programs are advancing and have shown positive interim results, Cantargia's goal is to gain a better understanding of the applicability of nadunolimab in other forms of cancer. For this reason, the clinical development of nadunolimab has been broadened to include other types of cancer, including TNBC, an aggressive and difficult to treat form of cancer that expresses IL1RAP at higher levels compared to other types of breast cancer.

In TRIFOUR, TNBC patients are treated with nadunolimab in combination with gemcitabine and carboplatin. The primary objective in the initial stage is to evaluate safety and tolerability of nadunolimab in combination with this chemotherapy regimen. Biomarkers and early signs of efficacy will also be evaluated at this stage. This part is estimated to be carried out over 6-9 months. If prespecified objectives are reached, the trial will be expanded into a randomized phase II part, which will investigate the efficacy of nadunolimab combination with gemcitabine and carboplatin in comparison to a control group receiving the same chemotherapy alone. The trial is estimated to include up to 113 patients at approximately 24 clinical centers in Spain. More information on the study can be found at clinicaltrials.gov (NCT05181462).

"We are excited to reach this milestone and broaden the development of nadunolimab to include a new group of patients. TNBC is a rational choice for this expansion as it is a disease which is difficult to treat and is driven by biological mechanisms targeted by nadunolimab." 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 14.00 CET on 14 January 2022.

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, 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 7.2 months and median survival of 12.7 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 (NCT05116891) and TRIFOUR (NCT05181462), 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).