



Press release

Cantargia AB
556791-6019
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Cantargia presents clinical interim results at ASCO 2022 highlighting the potential of nadunolimab in combination with checkpoint inhibitor

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today reported new results from the phase Ib clinical trial CIRIFOUR in 15 solid tumor patients, no longer responding to PD-(L)1 inhibitor therapy, treated with nadunolimab (CAN04) as an add-on to Keytruda® (pembrolizumab). The results are positive, with favorable safety. Disease control for at least 30 weeks was also achieved by the combination in a patient subgroup, identified by lower levels of the biomarkers CRP and IL-6 and higher levels of immune cells in the tumor tissue at baseline. These results will be presented at the ASCO 2022 Annual Meeting on 5 June 2022.

"We are enthusiastic about these initial positive results using nadunolimab in combination with PD-1-targeting antibody. It is intriguing that biomarkers such as CRP and IL-6 indicate a better outcome with the combination treatment, an observation in line with other immune therapies. The overall results support continued studies of the combination," said Göran Forsberg, CEO of Cantargia.

Nadunolimab, an antibody targeting IL1RAP (Interleukin-1 Receptor Accessory Protein), is Cantargia's most advanced program. CIRIFOUR ([NCT04452214](https://clinicaltrials.gov/ct2/show/study/NCT04452214)), conducted in the United States, evaluates nadunolimab with the checkpoint inhibitor pembrolizumab in cancer patients progressed on previous PD-(L)1 inhibitor therapy. The trial includes a total of 15 patients with head and neck cancer, non-small cell lung cancer or malignant melanoma, evaluating safety and efficacy of 5 mg/kg nadunolimab as an add-on to pembrolizumab. The last patient started therapy in August 2021. These data are based on a read-out of performed in April 2022.

The safety results are positive with only few patients demonstrating any adverse events of grade 3 or higher, and no specific pattern raising potential safety concerns. Disease control for at least 30 weeks (up to 58 weeks) was achieved by the combination therapy in 6 of 15 patients, including one partial response. These six patients had a distinct biomarker profile with lower baseline levels of CRP and IL-6, factors previously linked to tumor progression. The combination reduced blood levels of CRP and IL-6 in these patients. Biopsies also revealed that these patients had higher levels of immune cells, such as CD8-positive T cells and NK cells, in the tumor tissue before start of treatment. Four patients are still being treated in the trial.

The data will be presented in a poster session at ASCO 2022. An abstract based on earlier data from January 2022 has now been published on the ASCO website (www.asco.org/abstracts). The poster will be available at the Cantargia website (www.cantargia.com/en/research-development/publications) following the presentation.

Abstract Number and Title: #2527 Safety, tolerability, and preliminary efficacy of nadunolimab, a first-in-class monoclonal antibody against IL1RAP, in combination with pembrolizumab in subjects with solid tumors

Session: Developmental Therapeutics – Immunotherapy

Session Date and Time: Sunday, June 5, 2022, 8:00 AM-11:00 AM CDT

Presenter: Dr. Shekeab Jauhari

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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 23.00 CET on 26 May 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-1 α and IL-1 β 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 in 73 patients with PDAC, resulting in median iPFS of 7.2 months and median survival of 12.7 months. Stronger efficacy was also observed in 30 NSCLC patients with median PFS of 6.8 months. A response rate of 53% was achieved, with even higher responses in non-squamous NSCLC 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 tract 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](#)).