

Cantargia reports progress towards start of DOD-sponsored clinical trial of nadunolimab in leukemia

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today reported on the progress in the upcoming phase Ib/IIa clinical trial investigating nadunolimab in up to 40 patients with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS). This trial is financed through a grant from the US Department of Defense (DOD). With the upcoming submission to the US FDA, the current plan is to commence the trial during the summer of 2024, pending regulatory approval.

"Besides the exciting results generated with nadunolimab in patients with solid tumors, the prestigious grant from the DOD validates the additional potential in leukemia. We are really excited to start treating patients within a few months and look forward to this important clinical trial" said Göran Forsberg, CEO of Cantargia.

Nadunolimab has been investigated to date by Cantargia in approximately 300 patients with solid tumor indications and has shown clear signals of clinical activity. Right now, a controlled phase II clinical trial in triple negative breast cancer is ongoing and a new phase IIb trial investigating two dose levels of nadunolimab and one control group in first line treatment of metastatic pancreatic cancer is currently in the start-up phase.

In the context of cancer, IL1RAP was initially discovered as a therapeutic target in leukemia. Preclinical and translational results on IL-1 biology in various forms of leukemia as well as an overexpression of IL1RAP on both leukemia cells and leukemic stem cells indicate that nadunolimab has the potential to be used in the treatment of several different forms of the disease.

The new phase Ib/IIa clinical trial is designed to investigate nadunolimab monotherapy as well as combination therapy, in up to 20 patients with AML and 20 with MDS. In addition to investigating anticancer effects, the study will include an extensive package of biomarker assessments using blood and bone marrow samples, including single cell multimodal analysis. The trial is sponsored by a grant from the DOD to The University of Texas MD Anderson Cancer Center which will be responsible for conducting the trial, with Dr Gautam Borthakur as principal investigator. More details on the trial will be disclosed once the trial has received regulatory approval from the US FDA and relevant IRB.

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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 program, the antibody nadunolimab (CAN04), is being studied clinically primarily in combination with chemotherapy with a focus on pancreatic cancer, non-small cell lung cancer and triple-negative breast cancer. Positive interim data for the combinations indicate stronger efficacy than would be expected from chemotherapy alone. Cantargia's second development program, the antibody CAN10, blocks signaling via IL1RAP in a different manner than nadunolimab and 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 nadunolimab binds strongly to its target IL1RAP and functions by inducing ADCC and blocking IL-1alpha and IL-1beta signaling. Nadunolimab can thereby counteract the IL-1 system which contributes to the immune suppressive tumor microenvironment and development of resistance to chemotherapy. Nadunolimab is investigated in multiple clinical trials; the phase I/IIa trial CANFOUR, [NCT03267316](#), evaluates nadunolimab in combination with standard chemotherapies in patients with PDAC (gemcitabine/nab-paclitaxel) or NSCLC (platinum-based chemotherapies). Positive interim data show durable responses for the combination therapy in 73 PDAC patients, resulting in median iPFS of 7.2 months and median OS of 13.2 months. An even higher median OS of 14.2 months was observed in a subgroup of patients with high tumor levels of IL1RAP. Strong efficacy was also observed in 30 NSCLC patients with median PFS of 7.0 months and a response rate of 53%; even higher responses were observed in non-squamous NSCLC patients. Early efficacy data from the phase Ib/II trial TRIFOUR, [NCT05181462](#), also shows signs of promising efficacy in TNBC with a 60% response rate for nadunolimab combined with carboplatin/gemcitabine. Nadunolimab is also investigated with chemotherapy in the clinical trials CAPAFOUR, [NCT04990037](#), and CESTAFOUR, [NCT05116891](#), and with the checkpoint inhibitor pembrolizumab in the CIRIFOUR trial, [NCT04452214](#).

Attachments

[Cantargia reports progress towards start of DOD-sponsored clinical trial of nadunolimab in leukemia](#)