PRESS RELEASE
27 August 2024 10:55:00 CEST

Cantargia reports timelines for nadunolimab clinical trials in leukemia and triple negative breast cancer

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today reported currently expected timelines for nadunolimab clinical trials. The US FDA has granted MD Andersson Cancer Center the IND for nadunolimab related to the upcoming phase 1b/2a clinical trial of patients with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) with an estimate for trial initiation during Q4 2024. The first results on safety and short-term efficacy in the ongoing phase 2 clinical trial in triple negative breast cancer (TNBC), in collaboration with GEICAM, is expected during H1 2025.

"The granted IND is an important milestone for the development of nadunolimab in leukemia. The remaining steps, including IRB review, are currently in process before the trial can be initiated" said Göran Forsberg, CEO of Cantargia. "*We are also looking forward to completing the Phase 2 study with nadunolimab in triple negative breast cancer and obtaining the results during H1 2025."*

The new phase 1b/2a clinical trial is designed to investigate nadunolimab in up to 20 patients with AML and 20 with MDS. The trial is sponsored by a grant from the US Department of Defense, DOD, to The University of Texas MD Anderson Cancer Center which will be responsible for conducting the trial. More details on the trial, including estimated timelines will be disclosed once the trial has received full IRB approval, which is expected during Q3 2024, followed by initiation during Q4 2024.

Based on the positive phase 1 clinical data previously presented for nadunolimab combination therapy in TNBC, the randomized, controlled phase 2 clinical trial in approximately 100 patients with TNBC is advancing even though recruitment temporarily slowed down during summer. The first results of the trial, including safety and short-term efficacy, are therefore expected during H1 2025.

Cantargia will present new clinical results using nadunolimab at the upcoming ESMO conference in Barcelona Sep 13-17, 2024. Details on the presentation will be disclosed when abstracts become public Sep 9, 2024.

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This information is information that Cantargia is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2024-08-27 10:55 CEST.

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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. Cantargia's oncology 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

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