

Cantargia announces new nadunolimab clinical trial in leukemia financed by external US grant

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today announced award of a \$1.1 million grant from the US Department of Defense for investigation of Cantargia's lead asset, the IL1RAP-binding antibody nadunolimab (CAN04), in a phase Ib/IIa clinical trial in patients with myelodysplastic syndrome (MDS) or acute myeloid leukemia (AML). The grant is awarded to Professor Gautam Borthakur at The University of Texas MD Anderson Cancer Center who will lead the trial.

"We are very grateful for the important financial support from the US Department of Defense, as this grant will provide a valuable opportunity for Cantargia to expand its promising clinical results for nadunolimab to hematological cancers," said Göran Forsberg, CEO of Cantargia.

The trial will investigate nadunolimab alone or in combination with the chemotherapy azacytidine in patients with intermediate or high-risk MDS. Nadunolimab will also be evaluated with azacytidine and the targeted therapy drug venetoclax in patients with relapsed/refractory AML. The primary objective of this investigator-initiated trial is to assess the safety of different dose levels of nadunolimab; early efficacy and various biomarkers will be evaluated as secondary objectives. The trial may include a total of 40 patients. The trial will be managed by MD Anderson who will submit a clinical trial application.

IL1RAP (Interleukin-1 Receptor Accessory Protein), the target of nadunolimab, was originally discovered as a promising therapeutic target on leukemia stem cells by Dr. Marcus Järås and Dr. Thoas Fioretos and at Lund University, Sweden. The group has published strong therapeutic effects of IL1RAP-targeting antibodies in several advanced preclinical models of leukemia. Nadunolimab has also shown signals of clinical activity in combination with chemotherapy in pancreatic cancer, triple-negative breast cancer and non-small cell lung cancer, and clinical trials are ongoing in these diseases.

"Having documented the presence of IL1RAP on leukemia stem cells and strong anti-leukemia activity by nadunolimab in multiple preclinical models, I believe this upcoming clinical trial constitutes crucial progress towards our goal to provide new treatment options for patients with a very high unmet medical need," said Dr. Thoas Fioretos, Professor at Lund University, Sweden, co-founder and senior scientific advisor of Cantargia.

AML is a type of blood cancer, or leukemia, that originates from immature cells in the bone marrow. It is a highly lethal disorder and the most common form of acute leukemia among adults. MDS constitutes a group of cancers which impact stem cells in the bone marrow, and patients with high-risk MDS have a high risk of progressing into AML.

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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 2023-09-18 07:30 CEST.

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 evaluates nadunolimab in combination with standard chemotherapies in patients with PDAC (gemcitabine/nab-paclitaxel) or NSCLC (platinum-based chemotherapies) ([NCT03267316](#)). 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 12.9 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 50% 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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