PRESS RELEASE
12 March 2025 07:00:00 CET

First patient enrolled in Cantargia's leukemia study with nadunolimab

- **Open label study in forty AML and MDS patients**
- **Study financed by the US Department of Defense**

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today announced that the first subject has been enrolled in a study with patients with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS). This phase 1b/2a study is an investigator-initiated clinical study and will investigate safety and early efficacy after treatment with nadunolimab and standard of care chemotherapy. A total of 40 subjects including up to 20 for AML and 20 for MDS are estimated to be enrolled in the trial. Full recruitment is expected in 2027.

"The potential for nadunolimab as anti-cancer therapy is expanded by this important investigator led initiative treating patients with leukemias. This is the first study of nadunolimab in hematological malignancies, and complements the promising results achieved with nadunolimab plus chemotherapy in solid tumor indications" said Dominique Tersago, Chief Medical Officer of Cantargia.

The study is financed by the US Department of Defense, with Dr Gautam Borthakur, professor of Leukemia at The University of Texas MD Anderson Cancer Center as the principal investigator.

The study builds on an original discovery made by Professor Fioretos and Doctor Järås at Lund University, which showed that leukemia stem cells express a protein on their surface, IL1RAP, that is not expressed on normal hematopoietic stem cells. By binding IL1RAP, nadunolimab blocks IL-1 mediated leukemia promoting signals in addition to potent killing of tumor cells, indicating its therapeutic potential across multiple subtypes of leukemia. Preclinical and translational results 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.

"I am thrilled to see the collaboration with the team at MD Anderson result in a study treating patients diagnosed with MDS and AML, since IL1RAP was initially discovered as a therapeutic target in patients diagnosed with these disorders" said Dr Thoas Fioretos, professor at Lund University and a co-founder of Cantargia AB.

The primary objective of this study is to evaluate safety and the recommended dosage of nadunolimab in combination with standard chemotherapies for leukemia (azacitidine and/or venetoclax). The secondary objectives include assessment of anti-tumor efficacy by measuring overall response rates and duration of response in AML and MDS patients. Furthermore, the study aims to evaluate an extensive package of translational assessments by investigating

biomarkers, alterations in hematopoietic subpopulations, and effects on leukemic cells in blood and bone marrow, including single cell multimodal analysis, which will be performed in the laboratory of Professor Fioretos at Lund University, Sweden. Additional details on the trial will be found at **clinicaltrials.gov** (**NCT06548230**).

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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 2025-03-12 07:00 CET.

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 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 hidradenitis suppurativa and systemic sclerosis.

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-1α and IL-1β signaling. Nadunolimab can thereby counteract the IL-1 system which contributes to the immune suppressive tumor microenvironment and the 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 pancreatic ductal adenocarcinoma (PDAC) (gemcitabine/nab-paclitaxel) or non-small cell lung cancer (NSCLC) (platinum-based chemotherapies). Positive data show durable responses for combination therapy in 73 PDAC patients, resulting in a 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 40 NSCLC patients with median PFS of 7.2 months and a response rate of 55%; even higher responses were observed in non-squamous NSCLC patients. Early efficacy data from the phase 1b/2 trial TRIFOUR, **NCT05181462**, also shows signs of promising efficacy in TNBC with a 60% response rate for nadunolimab combined with carboplatin/gemcitabine.

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Attachments
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