**PRESS RELEASE**
20 February 2024 16:10:00 CET

# Cantargia reports US regulatory approval to start pancreatic cancer phase IIb trial with nadunolimab

**Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today reported that after both FDA and IRB review, regulatory approval has been granted to start recruiting patients in a controlled phase IIb trial in metastatic pancreatic cancer (PDAC) investigating nadunolimab as first line combination therapy. The trial is planned to start mid-2024 with initial results 2025.**

*"The US regulatory approval to start the phase IIb trial in pancreatic cancer is a major milestone for Cantargia. Based on the promising results we have obtained so far with nadunolimab in pancreatic cancer, we look forward to advance this important program for patients with a serious disease" said Göran Forsberg, CEO of Cantargia.*

The planned phase IIb trial (PANFOUR) in metastatic PDAC will investigate first line treatment of nadunolimab in combination with standard of care chemotherapy (gemcitabine/nab-paclitaxel). Two different dose levels of nadunolimab will be investigated and the study will include a control arm with chemotherapy only. Each arm will consist of approximately 50 patients, totaling 150 patients in the trial, with a data review after approximately 60 patients. Patients will be enrolled in the US and in a number of European countries where regulatory approval is awaited. The current plan is to start the trial during mid-2024 although the exact time point is pending ongoing financing discussions.

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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 2024-02-20 16:10 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. 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**

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