Press release

Cantargia AB
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Cantargia reaches recruitment milestone and focuses nadunolimab development on upcoming randomized studies

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today announced that the clinical trials CAPAFOUR and CESTAFOUR have enrolled enough patients to halt recruitment. Preliminary results show acceptable safety of the chemotherapy combinations with Cantargia's lead asset, the IL1RAP-binding antibody nadunolimab (CAN04), as well as signs of efficacy in a cohort of non-small cell lung cancer (NSCLC) patients treated with nadunolimab and gemcitabine/cisplatin in CESTAFOUR. Consequently, clinical development of nadunolimab will focus on planned randomized trials in the lead indications. Additionally, the CIRIFOUR trial will not continue as planned. Cost-efficient alternatives will instead be explored to investigate nadunolimab with pembrolizumab and chemotherapy.

Nadunolimab has shown positive interim efficacy data with chemotherapy in both pancreatic cancer (PDAC) and NSCLC and is investigated in multiple clinical trials. Two of these trials, CAPAFOUR and CESTAFOUR, have together recruited over 50 patients, which is sufficient to end enrollment. Neither of the two studies will continue to the optional expansion phases, and resources will thereby become available for planned controlled clinical trials in the lead indications, including a potentially pivotal trial in PDAC in collaboration with PanCAN.

In CAPAFOUR, 18 metastatic PDAC patients are studied with nadunolimab as an add-on to first-line FOLFIRINOX. In CESTAFOUR, a total of 36 patients are studied in three arms; nadunolimab in combination with gemcitabine/cisplatin (14 patients, including 8 with biliary tract cancer), FOLFOX (14 patients, including 5 with colorectal cancer) or docetaxel (8 patients, all with NSCLC). Preliminary results from the two trials show acceptable safety of the combinations, in line with previous results. A notable early observation from CESTAFOUR is that two of the four NSCLC patients, treated with the gemcitabine/cisplatin combination, show confirmed partial response. This finding, together with previous positive results for this combination in NSCLC, support the plans for a randomized trial in NSCLC. More mature safety and efficacy from the two trials is planned to be presented in H1 2023.

"The CAPAFOUR and CESTAFOUR trials have progressed well, providing further insights on nadunolimab combined with various chemotherapies and valuable knowledge for future trials. As a result, we are now able to halt recruitment to these studies and fully focus on the planned randomized clinical trials in indications with promising results documented. One interesting preliminary observation in CESTAFOUR is responses in lung cancer patients, further validating the strong data presented earlier this year," said Göran Forsberg, CEO of Cantargia.

CIRIFOUR, a trial evaluating combination with pembrolizumab, has enrolled 16 patients in total and will not continue as planned. Instead, cost-efficient alternatives will be explored to investigate nadunolimab with pembrolizumab and chemotherapy. A final read-out from the patients who received nadunolimab and pembrolizumab in CIRIFOUR is also expected in H1 2023. Patients in the CIRIFOUR, CAPAFOUR and CESTAFOUR trials benefiting from therapy will continue treatment in accordance with the clinical protocols.

Cantargia's other ongoing trials are continuing as planned. Initial data from the TRIFOUR phase Ib/II clinical trial is expected during Q1 2023, ahead of the randomized phase. The CANFOUR phase I/IIa trial is expected to continue recruitment of non-squamous NSCLC patients during H1 2023, to generate results supporting the start of a randomized trial.

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This is information that Cantargia AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 12.00 CET on 14 October 2022.

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 project, the antibody nadunolimab, is being studied clinically in combination with chemotherapy or immune therapy with a primary focus on non-small cell lung cancer and pancreatic cancer. Positive interim

data from the combination with chemotherapy indicate stronger efficacy than would be expected from chemotherapy alone. Cantargia's second project, the antibody CAN10, 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 CAN04 binds strongly to its target IL1RAP and functions by inducing ADCC and blocking IL-1α and IL-1β signaling. Thereby, CAN04 can counteract the contribution of the IL-1 system to the immune suppressive tumor microenvironment and development of resistance to chemotherapy. CAN04 is investigated in multiple ongoing clinical trials. In the phase I/IIa study CANFOUR, first line combination therapy is investigated with standard chemotherapies in patients with PDAC (gemcitabine/nab-paclitaxel) and patients with NSCLC (cisplatin/gemcitabine) (NCT03267316). Positive interim data for the combination therapies show durable responses in 73 patients with PDAC, resulting in median iPFS of 7.2 months and median survival of 12.7 months. Stronger efficacy was also observed in 30 NSCLC patients with median PFS of 6.8 months. A response rate of 53% was achieved, with even higher responses in non-squamous NSCLC patients previously treated with pembrolizumab. These results show stronger efficacy than expected from chemotherapy alone. CAN04 is investigated with chemotherapy also in the phase I study CAPAFOUR, with the FOLFIRINOX regimen for first line treatment of metastatic PDAC (NCT04990037), and in two further clinical studies, CESTAFOUR (NCT05116891) and TRIFOUR (NCT05181462), in additional forms of cancer, including biliary tact cancer, colorectal cancer and triple negative breast cancer. CAN04 is also evaluated with the checkpoint inhibitor pembrolizumab, with or without chemotherapy, in the phase I study CIRIFOUR (NCT04452214).