

Cantargia intensifies development of nadunolimab in pancreatic cancer with new controlled phase IIb clinical trial following strong phase IIa efficacy results

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today announced intensified development of its lead asset, the antibody nadunolimab (CAN04), in pancreatic cancer (PDAC), through a new randomized controlled phase IIb trial. This trial will build on the strong interim phase IIa efficacy results presented at the AACR Annual Meeting 2023. Regulatory submission is planned for H2 2023 with top line data planned for 2025. Financial resources previously earmarked for the Precision Promise trial, will be used for this phase IIb trial.

"Our recent promising results for nadunolimab in pancreatic cancer have been met with great interest and increase the likelihood of success for the program. This three-armed phase IIb trial is a first step in our refined development strategy, and we believe this is the most time- and cost-effective alternative to quickly obtain robust, randomized data, ahead of a registrational trial," said Göran Forsberg, CEO of Cantargia.

The new phase IIb clinical trial will evaluate two different dose levels of nadunolimab in a randomized setting in combination with gemcitabine and nab-paclitaxel, with the chemotherapy as active control arm, and will in addition to standard endpoints further analyze the impact of tumor IL1RAP levels on efficacy.

Promising interim efficacy results were recently presented from the phase I/IIa clinical trial CANFOUR which evaluates nadunolimab with gemcitabine and nab-paclitaxel in PDAC patients. The data demonstrated a strong overall efficacy of the combination therapy, particularly pronounced in a subgroup of patients with high tumor levels of IL1RAP which showed a significantly prolonged median overall survival compared to patients with low IL1RAP levels (14.2 vs 10.6 months; $p=0.017$; $n=27$ and 19 , respectively).

This validating signal of activity will be fundamental for the continued development in PDAC and will be confirmed in a larger patient cohort of 150-200 patients in Europe and the US in the new phase IIb trial. The results will be important for increasing the likelihood of success of a subsequent registrational trial. An application to start the trial, designed in line with Project Optimus, an initiative introduced by the US FDA to reform dose optimization and selection in oncology, is planned for submission in H2 2023, with the goal to start patient enrollment early 2024. Top-line data for the trial are expected in 2025.

Cantargia previously entered a collaboration with the Pancreatic Cancer Action Network (PanCAN) with the ambition to include nadunolimab in PanCAN's adaptive phase II/III trial Precision Promise. While Cantargia's partnership with PanCAN will continue, the two have agreed to put on hold nadunolimab's potential participation in Precision Promise until results from the new phase IIb trial are available.

"Our relationship with PanCAN has been very positive and has generated several valuable contacts. We intend to continue our collaboration with PanCAN outside the Precision Promise trial, and our joint efforts to provide patients with new treatment options," said Dominique Tersago, CMO of Cantargia.

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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 2023-05-15 14:30 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 6.8 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](#)).



PRESS RELEASE

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Attachments

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