

Cantargia to present clinical phase Ib data on nadunolimab in triple-negative breast cancer at ESMO Congress 2023

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today announced that clinical data from the phase Ib TRIFOUR trial, investigating the IL1RAP-binding antibody nadunolimab (CAN04) in triple-negative breast cancer (TNBC), will be presented in a poster at ESMO 2023 in Madrid. The abstract has now been published and shows that combination therapy was well tolerated with a preliminary response rate of 50% in 12 patients evaluable for efficacy. Additional and more mature data from a recent read-out in 15 patients will be presented on October 21, 2023.

"We are very enthusiastic about the promising signals of nadunolimab clinical activity generated thus far and are looking forward to presenting our new data in triple-negative breast cancer at the ESMO Congress," said Göran Forsberg, CEO of Cantargia.

In the phase Ib/II TRIFOUR trial, conducted in close collaboration with the Spanish Breast Cancer Group (GEICAM), 15 first- or second-line patients with metastatic TNBC have been treated in the initial dose-escalation stage. Among twelve patients evaluable for efficacy analysis, one showed confirmed complete response (CR) and five showed confirmed partial responses (PR), bringing a preliminary total response rate (RR) to 50%. This compares favorably to the historical response rate of approximately 30% reported for gemcitabine and carboplatin alone [1], the chemotherapy doublet used in combination with nadunolimab in the trial. Among the other six evaluated patients, four showed stable disease and two showed progressive disease. The combination was well tolerated, in line with previous trials combining nadunolimab and chemotherapy. Notably, prophylactic use of G-CSF was incorporated to the study protocol to control neutropenia.

The abstract can now be accessed at the ESMO Congress 2023 website ([link](#)) and is based on results obtained in connection with the press release issued on February 23, 2023. Additional and more mature data will be presented in a poster session at the conference; see more information below. At the time of presentation, the poster will also be made available at Cantargia's webpage ([link](#)).

Abstract title: Phase Ib safety and efficacy of nadunolimab/gemcitabine/carboplatin (NadGC) in metastatic triple negative breast cancer (mTNBC)

Date and time: October 21, 2023, 12:00 – 1:00 PM CEST

Presenter: Dr. Sara López-Taruella

TRIFOUR, which is conducted at 24 clinical sites in Spain, has progressed to the randomized phase II part, which may include up to 98 additional patients.

References

[1] O'Shaughnessy, J Clin Oncol 2014, 32:3840-3847

For further information, please contact

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E-mail: goran.forsberg@cantargia.com**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 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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