PRESS RELEASE
21 October 2023 07:30:00 CEST

Cantargia: ESMO 2023 presentation of nadunolimab phase I clinical interim data in triple-negative breast cancer shows promising efficacy and safety

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today presented positive efficacy signals and favorable safety from phase Ib of the clinical trial TRIFOUR investigating the IL1RAP-binding antibody nadunolimab (CAN04) in metastatic triple-negative breast cancer (TNBC). Nadunolimab combined with chemotherapy showed a response rate of 60% and median PFS of 6.6 months in the 15 patients included, well above historical control data. The combination was well tolerated with a safety profile similar to chemotherapy only. The data are presented today in a poster session at ESMO 2023 in Madrid. The randomized phase II stage of TRIFOUR is ongoing.

"This new dataset in metastatic triple-negative breast cancer is very exciting, and the ongoing randomized phase II part of the trial is a logical next step. We are very motivated to continue our collaboration with GEICAM on this study, with the aim of providing new therapeutic alternatives for this very difficult-to-treat disease," said Göran Forsberg, CEO of Cantargia.

In the dose escalation stage of the phase Ib/II TRIFOUR trial, five first-line and ten second-line patients with metastatic TNBC were treated with nadunolimab in combination with gemcitabine and carboplatin. Interim analysis of these 15 patients shows one confirmed complete response (CR) and eight confirmed partial responses (PR), bringing a preliminary total response rate (RR) to 60%. The current median progression-free survival (PFS) is 6.6 months, and an early estimate of median overall survival (OS) is 12.3 months. This compares favorably to historical data for gemcitabine and carboplatin alone, which shows 30% RR, 4.1 months median PFS and 11.1 months median OS [1]. The recommended phase II dose of nadunolimab was 2.5 mg/kg, which is currently investigated in the ongoing phase II part of the trial.

The safety profile of the combination is similar to previous reports for the chemotherapy only. The most frequently reported grade 3 or 4 adverse events were neutropenia (53%) and thrombocytopenia (27%), in line with previous trials for this chemotherapy regimen alone (53% and 24%, respectively) [1]. Notably, prophylactic use of G-CSF was used to manage neutropenia.

TRIFOUR, performed in collaboration with GEICAM Spanish Breast Cancer Group, progressed to the randomized phase II part in Q1 2023. Based on the promising phase Ib data presented today, and with no new safety signals emerging in the phase II part, a protocol amendment will be submitted to continue enrollment to TRIFOUR until full recruitment without an interim futility analysis. Implementation of this action requires regulatory and ethics committee approval. Top-line analysis for the complete trial is planned after full recruitment, estimated late 2024 or early 2025.

"Triple-negative breast cancer has the poorest prognosis among breast cancer subtypes and has very limited treatment options. The data presented today indicate a promising early signal of efficacy, which we are very eager to explore further in the randomized stage of TRIFOUR," said Dr. Sara López-Tarruella, member of the Steering Committee of GEICAM, Coordinator of the GEICAM Working Group in Triple Negative Breast Cancer, and one of the Chief Investigators of the TRIFOUR study.

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Details of the poster session at ESMO 2023 can be found below. The poster is also available at Cantargia's webpage (**link**). A poster abstract based on a less mature read-out was disclosed on 16 October 2023.

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-Tarruella

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

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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**.

About GEICAM
Founded in 1995, GEICAM is a non-profit organization leading academic breast cancer research in Spain. Today, GEICAM is comprised of more than 900 experts based over 200 Spanish hospitals and has carried out over 100 studies involving more than 67,000 women and men. GEICAM's mission is to promote independent clinical, epidemiological, and translational research in oncology, with a multidisciplinary approach and under quality criteria, to improve health outcomes, as well as prevention, medical education, and the dissemination of the knowledge of breast cancer to patients and general society.

Image Attachments
ESMO Waterfall Eng

Attachments
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