Press release

Cantargia AB
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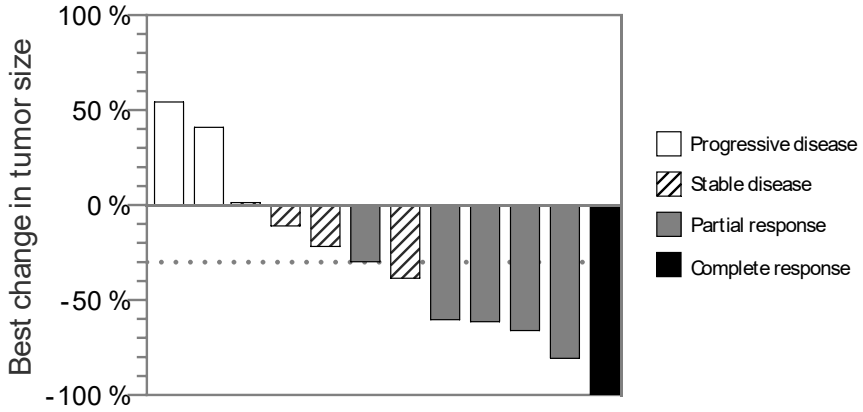
Cantargia advances TRIFOUR trial to randomized stage following promising early safety and efficacy of nadunolimab in triple-negative breast cancer

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today reported favorable safety and promising early signs of efficacy following an initial analysis of the phase Ib part of the clinical trial TRIFOUR. In collaboration with the Spanish Breast Cancer Group (GEICAM), this trial investigates the IL1RAP-binding antibody nadunolimab (CAN04) in combination with chemotherapy for treatment of triple-negative breast cancer (TNBC). In 12 patients treated long enough for evaluation, the response rate was well above previously reported data for chemotherapy alone. The trial is now expanding into the randomized phase II part where the combination will be compared to a control group given chemotherapy only.

TNBC is a difficult-to-treat disease which accounts for 10-15% of all breast cancer cases. To date, 15 first- or second-line patients with metastatic TNBC have been enrolled and treated in the dose-escalation part of the phase Ib/II trial TRIFOUR. In an early efficacy assessment based on 12 patients, one showed confirmed complete response, while five showed confirmed partial response, equaling a preliminary response rate of 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 showed an acceptable safety profile, in line with previous trials combining nadunolimab and chemotherapy. Notably, prophylactic use of G-CSF was incorporated to the study protocol to control neutropenia. TRIFOUR, which is conducted at 24 clinical sites in Spain, will immediately progress to the randomized phase II part, which may include up to 98 additional patients. An interim futility analysis is planned for Q4 2023. Data from the study are also planned for presentation in H2 2023.

"These initial results in triple-negative breast cancer are exciting for several reasons. Most importantly, they show an early signal of efficacy in line with our previous data in pancreatic cancer and non-small cell lung cancer, which further illustrates the magnitude of opportunities for nadunolimab. Based on these results, we look forward to immediately progressing into the controlled part of this trial, and continuing our fruitful collaboration with GEICAM," said Göran Forsberg, CEO of Cantargia.

"Triple-negative breast cancer is a very aggressive type of breast cancer with limited therapeutic options. The initial results from the TRIFOUR trial are very promising, and certainly warrant further investigation of nadunolimab in the subsequent, randomized, part of the study," said Dr. Agostina Stradella, medical oncologist, member of GEICAM, and Principal Investigator in TRIFOUR at the Catalan Institute of Oncology, Duran i Reynals Hospital.

Additionally, various biomarker analyses will be performed on patient samples collected in TRIFOUR. The FERO Foundation, a private Spanish entity dedicated to the promotion of cancer research, recently awarded GEICAM with a grant for a research

project aiming to identify predictive markers of nadunolimab efficacy. This project will be based on TRIFOUR patient samples and provide further insights into the mechanisms behind the apparent synergy between nadunolimab and chemotherapy.

References

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

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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 08.00 CET on 23 February 2023.

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 (CAN04), 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 for the combination with chemotherapy 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 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 66,000 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.

More information about GEICAM is available at www.geicam.org.

About nadunolimab (CAN04)

The antibody nadunolimab binds strongly to its target IL1RAP and functions by inducing ADCC and blocking IL-1α and IL-1β 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. In the phase I/IIa trial 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. Nadunolimab is also investigated with chemotherapy in the clinical trials CAPAFOUR (NCT04990037), CESTAFOUR (NCT05116891) and TRIFOUR (NCT05181462), and with the checkpoint inhibitor pembrolizumab in the CIRIFOUR trial (NCT04452214).

About TRIFOUR

TRIFOUR (NCT05181462) is a phase Ib/II clinical trial investigating nadunolimab (CAN04) in combination with the chemotherapy doublet carboplatin and gemcitabine for treatment of triple negative breast cancer (TNBC). TRIFOUR is performed at 24 clinical sites in Spain in collaboration with the Spanish Breast Cancer Group, GEICAM, and may include up to 113 patients. The primary objective in the initial dose-escalation stage is to evaluate the safety and tolerability of nadunolimab in combination with the chemotherapy doublet. Early signs of anti-tumor activity and biomarkers are also evaluated at this stage. In Q1 2023, TRIFOUR will expand to a randomized phase II part, to investigate the efficacy of the nadunolimab combination with carboplatin and gemcitabine, compared to a control group receiving the chemotherapy doublet alone.