

Cantargia and GEICAM present updated phase 1 clinical data and new translational results on nadunolimab treatment in advanced triple negative breast cancer at San Antonio Breast Cancer Symposium

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today reported updated results from the phase 1b study in 15 advanced triple negative breast cancer (aTNBC) patients treated with nadunolimab combined with platinum-based chemotherapy. The results confirm previous positive findings on safety, and promising antitumor activity. The clinical results along with new biomarker studies will be presented in a poster session at the upcoming San Antonio Breast Cancer Symposium (SABCS), 2024.

“Besides the strong clinical results already reported in pancreatic and lung cancers, we are excited to present these data in triple negative breast cancer. The presentation includes value-adding information around nadunolimab and its potential effects on the immune system’s ability to counteract cancer progression,” said Göran Forsberg, CEO of Cantargia.

The TRIFOUR phase 1b part evaluated nadunolimab at 1 mg/kg (n=3) and 2.5 mg/kg (n=12) combined with gemcitabine and carboplatin (GC) in 15 previously treated aTNBC patients. Initial results were presented in 2023, and the updated results confirm an acceptable safety profile with a promising efficacy of 60% response rate, 6.2 months progression-free survival (PFS), and 12.8 months overall survival (OS).

Analysis of patient samples was performed to identify features connected to nadunolimab/GC treatment. A significant reduction in the neutrophil to lymphocyte ratio (NLR) and C-reactive protein (CRP) was detected, both related to the nadunolimab mode of action. Additionally, a significant decrease in IL-8 levels was associated with a trend towards longer OS. These findings suggest that nadunolimab exerts beneficial effects on immune cells involved in tumor-promoting inflammation.

Using a larger, separate set of pre-treatment tumor biopsies and blood samples, a characterization of IL1RAP expression was also performed. This analysis showed IL1RAP expression on tumor, stromal and tumor-infiltrating immune cells. Detailed analysis of circulating cells showed IL1RAP expression on myeloid cells, including myeloid-derived suppressor cells highlighting the relevance of IL1RAP as a promising target in aTNBC.

The trial is currently enrolling patients for the randomized phase 2 part at the 2.5 mg/kg dose of nadunolimab with GC vs. only GC. Initial results for this part of the study are expected late H1 2025.

The study is done in collaboration with GEICAM (Spanish Breast Cancer Research Group) and will be presented in a poster session at the 47th annual San Antonio Breast Cancer symposium (SABCS), Dec 10-13, 2024.

More information on the poster session is found below:

Poster number: SESS-3615

Poster title: Updated safety, efficacy and emerging biomarker data from the Phase Ib part of a Phase Ib/II clinical study of nadunolimab in combination with gemcitabine and carboplatin in patients with advanced triple negative breast cancer (TRIFOUR study)

Session date and time: December 11, 2024 (12:30 - 2:00 PM CST)

The poster will be presented at the SABCS, 2024 in San-Antonio, Texas on Dec 11 from 12:30 – 2:00 PM local time by Dr Marta Santisteban Eslava, member of the GEICAM working group for triple negative disease, and one of the Chief Investigators of the TRIFOUR study. The poster related to the presentation will be uploaded on Cantargia's webpage www.cantargia.com.

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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. Cantargia's oncology 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 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 hidradenitis suppurativa and systemic sclerosis.

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-1 α and IL-1 β 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 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 40 NSCLC patients with median PFS of 7.2 months and a response rate of 55%; 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.

About GEICAM

GEICAM is the leader group in breast cancer research in Spain with a recognized worldwide prestige. It is formed by more than 900 experts, who work in 200 institutions throughout Spain. Since its establishment in 1995 until now GEICAM has performed more than a hundred of studies in which almost 68,000 women and men have participated.

It has a large multidisciplinary team specialized in the management of clinical trials and other studies, which collaborates with clinical researchers in the design and implementation of clinical trials, as well as in their execution and dissemination in forums and high-impact scientific journals. For more information, you can visit the official website <http://www.geicam.org> or follow GEICAM on Twitter @GEICAM, @GEICAMujer, and on Facebook.com/GEICAM.

Attachments

[Cantargia and GEICAM present updated phase 1 clinical data and new translational results on nadunolimab treatment in advanced triple negative breast cancer at San Antonio Breast Cancer Symposium](#)