PRESS RELEASE
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Cantargia announces preliminary topline efficacy results from the phase 2 TRIFOUR trial of nadunolimab in advanced triple-negative breast cancer (TNBC)

- Nadunolimab added to carboplatin and gemcitabine (GC) did not impact the safety profile of the chemotherapy and was well tolerated with neutropenia and asthenia as the most common side effects
- The primary endpoint, overall response rate (ORR), was similar in the nadunolimab plus carboplatin/gemcitabine treated group and the carboplatin/gemcitabine reference group

TRIFOUR is an exploratory open label randomized Phase 1b/2 clinical study conducted by the Spanish Breast Cancer Group (GEICAM). The objective is to evaluate early signals of efficacy of Cantargia's IL1RAP antibody nadunolimab in TNBC, with unconfirmed ORR as primary endpoint. The ORR was 40% in the Ph2 study in the nadunolimab plus GC treated patients. As reference, the ORR in the GC group was 43%. Subgroup analyses of the data are ongoing.

The tolerability of the combination was acceptable and in line with previous trials combining nadunolimab and chemotherapy. Most common side effects in this trial were neutropenia and asthenia with no notable differences between the two study arms.

"TNBC is a heterogeneous and difficult to treat disease, with a high unmet medical need. We welcome the efforts to explore new treatments and appreciate the learnings we are making from the TRIFOUR study. We now await the outcome of further analyses from the study, including overall survival," said Dr. Eva Carrasco, CEO of GEICAM.

"We are pleased to have the opportunity to collaborate with GEICAM and explore nadunolimab in the TNBC indication. While the preliminary ORR results of the Phase 2 part of the TRIFOUR trial do not match those obtained in the Phase 1b part of the trial, the study continues and we will now await the mature survival data." said Damian Marron, interim CEO of Cantargia. *"Following the signing of our CAN10 agreement earlier this week, we will be undertaking a detailed portfolio discussion to define our plans for the further development of nadunolimab".*

The TRIFOUR Ph1b/2 study first enrolled 15 patients in a preliminary phase 1b dose-ranging part, which showed an acceptable safety profile with promising efficacy including 73% unconfirmed ORR (60% confirmed) in first-line (1L) or second-line (2L) patients with metastatic TNBC. In the Phase 2 part of the trial, patients were randomized to two study groups with nadunolimab + GC treatment in the experimental group (n=51) and GC alone in the reference group (n=48). Nadunolimab (2.5 mg/kg) and GC were given twice per cycle in 3- or 4-week cycles. The objective of the study was to identify early signals of efficacy, with an internal GC group for reference.

RECIST 1.1 criteria were used to evaluate the preliminary ORR which was based on a minimum of 2 CT scans (approx. 3 months treatment) from the 97 TNBC patients included in the efficacy analyses. Among these, 20 patients (40%) showed unconfirmed complete response (CR) or partial response (PR) in the nadunolimab + GC arm vs. 20 patients (43%) in the chemotherapy arm. This data in 1L and 2L patients is higher than the historical response rate of approximately 30% reported for GC alone in 1L, 2L and third-line patients [1], and similar to 1L TNBC patients treated with chemotherapy alone [2].

Nadunolimab has been tested in over 300 patients with metastatic cancer. Previous data in pancreatic ductal adenocarcinoma (PDAC) and non-small cell lung cancer (NSCLC) indications have shown promising results for nadunolimab in combination with chemotherapy in these indications [3,4], and nadunolimab is granted Fast Track designation from the U.S. Food and Drug Administration (FDA) in PDAC patients with high expression levels of IL1RAP. Nadunolimab is currently being tested in patients with acute myeloid leukemia (AML) or myelodysplastic syndrome (MDS) in an investigator-initiated clinical study at The University of Texas MD Anderson Cancer Center.

More details of the TRIFOUR study will be communicated at an upcoming scientific conference.

References

[1] O'Shaughnessy, J Clin Oncol 2014, 32:3840-3847
[2] Cortes N Engl J Med 2022, 387: 217-226
[3] van Cutsem et al, Clin Cancer Res 2024, 30: 5293-5303
[4] Paulus et al, Lung Cancer 2025, https://doi.org/10.1016/j.lungcan.2025.108664

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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-1α and IL-1β signaling. Nadunolimab can thereby counteract the IL-1 system which contributes to the immune suppressive tumor microenvironment and the 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 pancreatic ductal adenocarcinoma (PDAC) (gemcitabine/nab-paclitaxel) or non-small cell lung cancer (NSCLC) (platinum-based chemotherapies). Positive data show durable responses for combination therapy in 73 PDAC patients, resulting in a 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 1b/2 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 220 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 us on Twitter @GEICAM, @GEICAMujer, and on Facebook.com/GEICAM.

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Attachments

Cantargia announces preliminary topline efficacy results from the phase 2 TRIFOUR trial of nadunolimab in advanced triple-negative breast cancer (TNBC)