

Cantargia Provides Update on Overall Survival Data from TRIFOUR

Cantargia AB (Publ) (NASDAQ: CANTA.ST) today announced an update on overall survival results from the Phase 1b/2 TRIFOUR study evaluating nadunolimab in triple-negative breast cancer (TNBC). The analysis showed no difference in median overall survival (mOS) between the group treated with nadunolimab plus gemcitabine/carboplatin (GC) and the GC control group. Notably, both groups achieved a survival duration of 26 months, which exceeds historical expectations for this patient population. Earlier findings, reported in July 2025, showed no meaningful difference in the study's primary endpoint, overall response rate (ORR), between the treatment arms. Cantargia does not intend to progress development in TNBC.

"While the combined results, including the primary endpoint and subgroup analyses, indicate that the TRIFOUR study did not meet its objectives, we recognize the valuable insights gained from this trial," said Hilde Steineger, CEO of Cantargia. "Although this is not the outcome we had hoped for, we remain confident in the strong potential of nadunolimab, particularly in pancreatic ductal adenocarcinoma (PDAC), where we see strong scientific rationale, robust data and significant opportunities for impact."

"We view this outcome in TNBC as indication#specific, not predictive and not translating to pancreatic or lung cancer, where the biology, standard of care, and heterogeneity of the TRIFOUR patient population differ significantly." said Dr. Wolfram Dempke, Chief Medical Officer at Cantargia.

The Phase 1b/2 TRIFOUR trial, conducted by the Spanish Breast Cancer Group (GEICAM), randomized 99 metastatic TNBC patients eligible for first- or second-line GC treatment to receive either nadunolimab + GC (n=51) or GC alone (n=48). Nadunolimab (2.5 mg/kg) was administered twice per cycle.

The preliminary mOS was evaluated after 39 events had occurred in the 99 TNBC patients included in the efficacy analyses. Both the nadunolimab + GC and the chemotherapy arms achieved mOS of 26 months, substantially longer than expected for this patient population.

As previously reported, no difference was observed between the two study groups with regards to the primary endpoint of the TRIFOUR study – overall response rate (ORR). Although the trial was exploratory and not powered for statistical significance, no differences in efficacy were observed. Subgroup analyses have shown comparable outcomes across treatment groups. Based on these results, Cantargia will discontinue further development in TNBC.



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Safety was in line with previous nadunolimab data, with neutropenia and asthenia being the most common adverse events and no significant safety differences between treatment groups, confirming that nadunolimab can be added to standard chemotherapy without increasing toxicity.

Since some patients in both groups continue to benefit from the study therapy, treatment and follow-up will continue for ethical reasons, although the overall assessment of the study is unlikely to change. Final TRIFOUR results will be communicated at an upcoming scientific conference and published in a peer-reviewed journal in due course.

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This information is information that Cantargia is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2025-12-05 07:30 CET.

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. In September 2025, the acquisition of CAN10 by Otsuka Pharmaceutical was completed.

Cantargia is listed on Nasdaq Stockholm (ticker: CANTA). More information about Cantargia is available at www.cantargia.com.

About nadunolimab (CAN04)

Nadunolimab is an antibody that 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 has been investigated in multiple clinical trials; the phase I/IIa trial CANFOUR, NCT03267316, evaluated 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. Intriguing efficacy was observed in a small group of non-squamous NSCLC patients post PD(L)-1 therapy.



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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.

Attachments

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