PRESS RELEASE
10 March 2025 14:50:00 CET

Cantargia's TRIFOUR phase 2 study investigating nadunolimab in triple negative breast cancer fully recruited

- **TRIFOUR is Cantargia's first randomized, controlled study of nadunolimab**
- **First preliminary efficacy results expected mid-2025**

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today announced that all patients in the TRIFOUR clinical study are recruited. This phase 1b/2 study in advanced triple-negative breast cancer (TNBC) patients focuses on evaluating the efficacy of nadunolimab (CAN04) in combination with platinum-based chemotherapy compared to a control group receiving the same regime of chemotherapy alone. The first preliminary analysis of the primary objective, overall response rate (ORR), is expected in mid-2025.

"We are excited to have reached this important milestone in the first randomized clinical trial with nadunolimab involving a control group. We expect the first preliminary efficacy analysis reporting overall response rates in mid-2025" said Damian Marron, Interim CEO of Cantargia. *"These data in TNBC will add to the highly promising data with nadunolimab in pancreatic ductal adenocarcinoma (PDAC), with best response in PDAC patients with high interleukin-1 receptor accessory protein (IL1RAP) expression".*

There is a huge need for novel therapies against advanced TNBC. Around 200,000 patients per year are diagnosed with TNBC worldwide and even with recent advances in treatment, there remains a high need for more efficacious and better tolerated treatments.

TRIFOUR investigates nadunolimab in combination with platinum-based chemotherapy (gemcitabine/carboplatin) for the treatment of advanced TNBC. The study is performed in collaboration with the Spanish Breast Cancer Group, GEICAM. The randomized phase 2 part of the trial has now enrolled a total of 102 first- or second-line TNBC patients across 22 centers in Spain, randomized to receive either 2.5 mg/kg of nadunolimab in combination with chemotherapy or chemotherapy alone.
The previously communicated results from 15 metastatic TNBC patients in the phase 1b dose-finding part demonstrated encouraging data including a promising ORR of 60%, median progression-free survival (PFS) of 6.6 months, and overall survival (OS) of 12.8 months.

More information on the study can be found at **clinicaltrials.gov** (**NCT05181462**).

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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 leading 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.

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Attachments

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