

Cantargia reports new results from clinical studies investigating nadunolimab in several forms of cancer; supporting ongoing strategies

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today announced new clinical results from two nadunolimab combination therapy trials in 54 patients. Positive signals of efficacy were documented in the key areas of nadunolimab development, non-small cell lung cancer and gastrointestinal cancers. In addition to the efficacy signals, nadunolimab appeared to counteract oxaliplatin induced peripheral neuropathy. No unexpected safety findings were observed.

“Nadunolimab results for approximately 200 patients have been reported with clear signals of activity. The new positive results on both efficacy and counteraction of neuropathy support ongoing development in lung cancer and gastrointestinal cancers and adds information on future positioning,” said Göran Forsberg, CEO of Cantargia.

The clinical trials are CESTAFOUR and CAPAFOUR. CESTAFOUR investigated nadunolimab in combination with three different chemotherapies. The CAPAFOUR trial investigated nadunolimab combination therapy with FOLFIRINOX in first line pancreatic cancer, PDAC. Nadunolimab dose levels starting at 0.5 mg/kg, followed by escalation up to 2.5 mg/kg were planned in the two trials.

The first arm in CESTAFOUR investigated combination with gemcitabine/cisplatin in 14 patients and generated the strongest signal of efficacy. In the five heavily pretreated (2-11 lines of previous therapy) patients with non-small cell lung cancer, NSCLC, the response rate was 40% according to RECIST 1.1 and PFS 10.2 months. The eight patients, predominantly second line, with biliary tract cancer also showed promising results with a response rate of 13% and PFS of 6.4 months.

The second arm in CESTAFOUR investigated combination therapy with FOLFOX in 14 patients with 8 different cancer forms and varying treatment history. Interestingly, three patients had a confirmed partial response, one 4th line colorectal cancer, one first line gastric cancer and one receiving third line treatment of testicular cancer. The PFS in this heterogenous group of patients was 4.6 months.

The third arm in CESTAFOUR investigated combination with docetaxel included eight second- or third-line patients with NSCLC. The protocol was designed to allow frequent dose reductions during the dose finding phase and the efficacy results are therefore not conclusive.

The CAPAFOUR study included 18 PDAC patients receiving first line nadunolimab and FOLFIRINOX. The initial safety part at different dose levels is successfully concluded, allowing for start of a future phase 2 trial. The first part of the CAPAFOUR trial allowed frequent dose reductions which limits efficacy conclusions. Future studies in a larger number of patients will be designed to evaluate efficacy.

Neuropathy is a major and serious side effect of several chemotherapies like taxanes and oxaliplatin. Adding nadunolimab to nab-paclitaxel in the previously reported CANFOUR trial correlated with a lower incidence and a slower onset of chemotherapy induced neuropathy. Higher dose levels of nadunolimab correlated with a beneficial effect. Interestingly the results from CAPAFOUR and CESTAFOUR are in line with the previous data set. In the FOLFOX and FOLFIRINOX groups, higher doses of nadunolimab correlated with a later onset and reduced incidence of neuropathy.

Safety in the trials was acceptable with a side effect profile expected based on previously communicated results of nadunolimab in combination with chemotherapy. Additional biomarker analyses are ongoing.

As communicated previously, due to the changing global market situation during 2022, Cantargia made the strategic decision to stop recruitment already during the dose finding part of these trials and did not initiate the dose expansion parts designed to give robust efficacy data. Patients who had started treatment continued in accordance with the protocols. As the number of patients in the two trials was lower than planned, there are limitations in the conclusions that can be made.

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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 2024-10-28 14:45 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 interim 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 systemic sclerosis and myocarditis.

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-1alpha and IL-1beta 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.

Attachments

[Cantargia reports new results from clinical studies investigating nadunolimab in several forms of cancer; supporting ongoing strategies](#)