

Cantargia presents new clinical data at AACR 2023 strongly supporting nadunolimab development in pancreatic cancer

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today presented updated interim clinical efficacy data including subgroup analyses of first-line pancreatic cancer (PDAC) patients treated with the antibody nadunolimab (CANO4) and chemotherapy in the phase I /IIa CANFOUR trial. Efficacy in the 73 patients treated was superior to historical data for chemotherapy only. Even stronger efficacy was observed in patients with high tumor levels of IL1RAP, the target of nadunolimab, including significantly prolonged median overall survival (OS) compared to patients with low IL1RAP levels (14.2 vs 10.6 months; p=0.017). The data were presented at the AACR Annual Meeting 2023 (AACR 2023), held in Orlando.

"The new results show a clear link between the levels of nadunolimab's target in the tumor and efficacy of nadunolimab in combination with chemotherapy. These observations reinforce previous positive findings and provide a clear indication that nadunolimab can make a meaningful difference to pancreatic cancer patients. We are excited about nadunolimab's potential and are looking forward to advancing into late-stage clinical trials," said Göran Forsberg, CEO of Cantargia.

The median OS for PDAC patients treated with nadunolimab combined with chemotherapy in the CANFOUR trial was 12.9 months, well above that achieved by chemotherapy alone [1]. New data also show a trend for higher response rates, with deeper and more durable responses, in a subgroup of patients with high tumor levels of IL1RAP compared to those with low levels of IL1RAP. This resulted in a statistically significant survival advantage for the IL1RAP high subgroup, compared to the IL1RAP low group. Efficacy parameters for the total PDAC cohort, the two subgroups, and historical control data are summarized below.



Efficacy parameter according to iRECIST1.1	All (n=73)	IL1RAP high (n=27)	IL1RAP low (n=19)	Historical control [1] (n=431); RECIST
Overall survival (OS); median	12.9 mo	14.2 mo	10.6 mo	8.5 mo
Progression-free survival (iPFS); median	7.2 mo	8.0 mo	5.8 mo	5.5 mo (PFS)
1-year survival	58%	69%	40%	35%
Overall response rate (iORR)	33%	52%	32%	23%
Duration of response (iDoR); median	7.3 mo	9.5 mo	5.6 mo	NA

Collectively, these data strongly suggest that target engagement by nadunolimab is of high importance for the efficacy of the combination therapy and indicate that development in the IL1RAP high subgroup could increase the likelihood of success in the program. The updated clinical data are based on a readout conducted in March 2023. A total of 73 PDAC patients received nadunolimab with gemcitabine and nab-paclitaxel in the CANFOUR trial; two patients were still receiving treatment at data cut-off and deaths had been recorded in 52 patients. Tumor biopsies were obtained from 46 patients; analyses of these identified two patient subgroups with either high or low levels of IL1RAP on tumor cells.

Additional biomarker analyses showed that decreased levels of IL-8 following treatment significantly correlated with prolonged OS in the total PDAC cohort. The combination therapy also reduced multiple IL-1-related markers capable of altering the tumor microenvironment.

The results, presented at AACR 2023 in a poster with details found below, are now also available on Cantargia's webpage (https://cantargia.com/en/research-development/publications).

Published abstract number: 2172

Abstract title: Tumor IL1RAP levels and reduction in serum biomarkers correlate with response in PDAC patients treated with nadunolimab, an anti-IL1RAP monoclonal antibody, in combination with gemcitabine and nab-paclitaxel

Session category: Clinical Research Excluding Trials
Session title: Biomarkers of Therapeutic Benefit 3
Session date and time: Monday Apr 17, 2023 9:00 AM - 12:30 PM ET

Presenter: Dr. David Liberg

An R&D Day focusing on Cantargia's development strategy, including the new PDAC results, is scheduled for April 24, 2023 2:00-3:30 PM CET (8:00-9:30 AM ET). A live webcast of the event will be available at the following **link**.

References

[1] Von Hoff et al, N Engl J Med 2013; 369:1691-1703



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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 2023-04-17 15:00 CEST.

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. The main 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/Ila trial CANFOUR evaluates nadunolimab in combination with standard chemotherapies in patients with PDAC (gemcitabine/nab-paclitaxel) or NSCLC (cisplatin/gemcitabine) (NCT03267316). Positive interim data show durable responses for the combination therapy in 73 PDAC patients, resulting in median iPFS of 7.2 months and median OS of 12.9 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 30 NSCLC patients with median PFS of 6.8 months and a response rate of 53%; 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 50% response rate for nadunolimab combined with carboplatin/gemcitabine. Nadunolimab is also investigated with chemotherapy in the clinical trials CAPAFOUR (NCT04990037) and CESTAFOUR (NCT05116891), and with the checkpoint inhibitor pembrolizumab in the CIRIFOUR trial (NCT04452214).

Attachments

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