

Cantargia presents new positive clinical data on nadunolimab counteracting chemotherapy induced neuropathy

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today disclosed new clinical data indicating that nadunolimab counteract the serious problem of chemotherapy induced neuropathy, in addition to previously reported promising antitumor effects. The new data in 73 pancreatic cancer patients receiving nadunolimab and chemotherapy show a statistically significant correlation between nadunolimab dose level and incidence of neuropathy as well as a low level of grade 3 neuropathy, supporting the protective effect of nadunolimab. This positive effect is further strengthened by preclinical in vivo studies on chemotherapy induced neuropathy. The new results will be presented at ASCO Annual Meeting May 31- June 4, 2024.

“The new results highlight the potential of nadunolimab as a cancer therapy providing both antitumor effects while, at the same time, reducing neuropathic side effects when combined with chemotherapy. This finding may also be of relevance in other neuroinflammatory conditions,” said Göran Forsberg, CEO of Cantargia.

Neuropathy is a serious medical condition and a side effect of several classes of chemotherapies. The main symptoms are weakness, pain and numbness in hands and feet. Neuropathy often leads to discontinuation of therapy in patients despite effective antitumor activity. The mechanisms behind chemotherapy induced neuropathy relate to damaged nerve cells and neuroinflammation, where the IL-1 pathway has been indicated as a key driver. With nadunolimab blocking IL-1 activity through its binding to IL1RAP, nadunolimab has the potential to counteract neuropathy during treatment with chemotherapies, such as paclitaxel.

In the CANFOUR trial, 73 first line pancreatic cancer patients were treated with nadunolimab and gemcitabine/nab-paclitaxel. The median survival of 13.2 months and iPFS of 7.2 months are longer than expected from historical control data for the chemotherapy alone (1). The incidence of neuropathy was notably lower than expected from chemotherapy treatment. Only one grade 3 event was observed and a statistically significant ($p=0.042$) relationship between dose level and any grade neuropathy was observed. At 1 mg/kg nadunolimab, 60% of patients had any grade neuropathy with a median time to onset of 112 days. At 2.5 mg/kg or higher, only 36% had any grade neuropathy and median time to onset was not reached.

Studies in mouse models show that several aspects of chemotherapy induced neuropathy, such as sensitivity to mechanical pressure, temperature and decreased grip strength, all were prevented by concomitant treatment with the nadunolimab surrogate antibody. Combination studies were performed with either paclitaxel or vincristine.

The preclinical data were generated in collaboration with Hana Starobova and colleagues at University of Queensland, Australia. The results will be presented by Prof. Eric van Cutsem, UZ Leuven Gashuisberg, Belgium at the ASCO Annual Meeting May 31st - June 4th, 2024, in Chicago, USA. The poster abstract has now been published on the conference website (<https://meetings.asco.org/abstracts-presentations/234309>). The poster will be presented Saturday, June 1st and will then be published on Cantargia's website <http://www.cantargia.com>.

Reference

1) OS 8.5 mo, PFS 5.3 mo, (Von Hoff et al, N Engl J Med 2013); OS 9.2 mo, PFS 5.6 mo, (Wainberg et al, Lancet 2023)

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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. 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 /IIa trial CANFOUR, [NCT03267316](#), evaluates nadunolimab in combination with standard chemotherapies in patients with PDAC (gemcitabine/nab-paclitaxel) or NSCLC (platinum-based chemotherapies). 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 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 30 NSCLC patients with median PFS of 7.0 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 60% 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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