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Cantargia: new data from two clinical studies strongly support nadunolimab efficacy after relapse on PD1-inhibitors

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today reported data from two clinical trials including nadunolimab combination therapy in 55 cancer patients. Both trials show strong antitumor effects as well as very encouraging median survival times in patients previously treated with pembrolizumab. These clinical data combined with baseline biopsy analyses suggest a unique role of nadunolimab acting on immunosuppressive cells in the tumor microenvironment. The data will be presented Sept 14 at the ESMO Congress 2024 in Barcelona.

The immunotherapy pembrolizumab is one of the most important cancer treatments with sales around US\$ 25 B 2023. New data from two clinical trials in 55 patients highlight a unique opportunity using nadunolimab in patients after they have progressed on pembrolizumab treatment.

"The new data, from two separate clinical trials, show a long median survival in nadunolimab treated patients after previous therapy using pembrolizumab. These patients have a tumor microenvironment containing immune suppressive cells that can be targeted with nadunolimab" said Göran Forsberg, CEO of Cantargia. "These findings clearly support additional studies as the vast number of patients who progress on immunotherapy have limited treatment options".

The first trial, CANFOUR, investigated nadunolimab in combination with platinum doublet chemotherapy in 40 first- or second-line non-small cell lung cancer, NSCLC, patients. Stronger efficacy was seen in 2L pts (n=18 in total; n=17 post-pembrolizumab) compared to 1L pts (n=22) (ORR 72% vs 41%; PFS 7.6 mo vs 6.7 mo, p = 0.038; OS 15.7 mo vs 11.5 mo). Biopsy analyses showed that 2L pts had a higher number of IL1RAP-positive immune cells, CD163+ macrophages, CD56+ NK cells and CD8+ T cells in the tumor at baseline. Efficacy results were most pronounced in second line non-squamous pts (n=12; ORR 92%, OS 28.9 mo; PFS 13.0 mo) including two complete responders. The data suggest that nadunolimab may mediate its antitumor activity by blocking tumor promoting cells within the TME. The safety results of the combination have been presented previously and show an acceptable side effect profile.

The second trial, CIRIFOUR, investigated nadunolimab combination therapy with pembrolizumab in 15 heavily pretreated patients who had previously progressed on pembrolizumab monotherapy or combination treatments. Nine patients had head and neck cancer, 5 NSCLC and 1 melanoma. In this trial, the median survival was 19.7 months and the disease control rate was 60%. Similar to the CANFOUR data, the strongest benefits were observed in the group of patients with a specific profile of immune and immunosuppressive cells in the tumor microenvironment. The combination therapy was well tolerated.



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The two posters will be presented at the ESMO Congress 2024 in Barcelona on Saturday, September 14th by Dr Luis Paz-Ares, Hospital Universitario 12 de Octubre, Madrid, Spain and Dr Roger Cohen, University of Pennsylvania, Philadelphia, PA, US, respectively. The results above are based on the abstracts submitted May 2024 and updated data will be presented at the conference. In parallel to the presentations, the poster can will be published on Cantargia's webpage www.cantargia.com. The abstracts are now available at the conference website www.cantargia.com. The abstracts are now available at the conference website www.cantargia.com. The abstracts are now available at the conference website www.cantargia.com. The abstracts are now available at the conference website www.cantargia.com. The abstracts are now available.

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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 2024-09-09 00:05 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. 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.



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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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