

Cantargia presents Phase 2 clinical data in pancreatic cancer with nadunolimab at ESMO Gastrointestinal Cancer Congress 2024

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today announced that nadunolimab (CAN04) combination therapy results in advanced/metastatic pancreatic cancer (PDAC) will be presented at ESMO Gastrointestinal Cancer Congress 2024 in Munich June 26-29. Efficacy in the 73 patients treated was better than expected for chemotherapy only based on historical data. Strongest efficacy was observed in patients with high tumor levels of IL1RAP, the target of nadunolimab, with median survival (OS) of 14.2 months. Notable new data highlight the relevance of tumor promoting KRAS mutations and correlations of nadunolimab's mechanism of action, further arguing for nadunolimab as a therapy of PDAC.

"The new results put an additional exciting perspective on nadunolimab as it highlights a relationship between tumor promoting KRAS mutations and the tumor promoting signals nadunolimab has been designed to counteract. This gives further support on the importance of the nadunolimab data generated in pancreatic cancer," said Göran Forsberg, CEO of Cantargia.

Patients with metastatic PDAC have a poor prognosis, and survival probability is <5% at 5 years. The disease is often associated with tumor promoting KRAS mutations. The tumor microenvironment in pancreatic cancer has a stroma with cancer-associated fibroblasts and immune cells, creating an environment which involves upregulation of IL1RAP and tumor promoting IL-1 signaling with associated downstream pro-tumor cytokines. The new data show a correlation between KRAS mutations and an activated IL-1 system, a signaling pathway nadunolimab has been designed to counteract.

In the CANFOUR trial, 73 first line PDAC patients were treated with nadunolimab and gemcitabine /nab-paclitaxel (GN). The median OS of 13.2 months is longer than OS reported in Phase 3 trials for GN alone (8.5-9.2 months), FOLFIRINOX (11.1 months), or NALIRIFOX (11.1 months)(1). In patients with available baseline tumor biopsies IL1RAP expression was measured on tumor cells. A high expression of IL1RAP correlated with better efficacy outcomes including a median OS of 14.2 months vs. 10.6 months for the IL1RAP low subgroup (p=0.026; n=29 and 20, respectively). Addition of nadunolimab to GN was generally well tolerated, although with an increased incidence of grade 3/4 neutropenia and febrile neutropenia, unless managed with prophylactic use of growth factor support.

Notably, the incidence of peripheral neuropathy was lower than expected from chemotherapy treatment. IL-1 driven inflammation likely plays a role in paclitaxel induced neuropathy. Only one grade 3 event was observed and a statistically significant (p=0.042) relationship between dose level and onset of neuropathy was observed. These data suggest that nadunolimab may confer a protective effect on the development of neuropathy.

The abstract has been published on the conference website, the poster will be presented June 27. It will also be available at the Cantargia website when presented at the conference

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. 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 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](#).



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Attachments

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