



Press release

Cantargia AB
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Cantargia reports updated encouraging survival data from CANFOUR trial with nadunolimab and chemotherapy in pancreatic cancer

Cantargia AB today announced updated interim results from the CANFOUR phase I/IIa clinical trial investigating nadunolimab in first line therapy of pancreatic cancer (PDAC) in combination with chemotherapy. The updated dataset from the initial 33 patients eligible for efficacy analysis continue to show stronger results than expected from chemotherapy only. Median survival is 12.7 months, median immune progression-free survival (iPFS) is 7.2 months, and 1-year survival rate is 55%. At the time of analysis, 12 patients were still alive and two patients were on therapy. Safety and response rates are similar to the previous update from May 2021.

"Our view on nadunolimab is strengthened by these updated interim results indicating durable effects of combination therapy, with a median survival of 12.7 months in pancreatic cancer, a disease with very poor prognosis. This gives us further motivation to advance nadunolimab into late-stage development in first line therapy of this form of cancer." said Göran Forsberg, CEO of Cantargia.

The interleukin-1 receptor accessory protein (IL1RAP)-binding antibody nadunolimab is Cantargia's lead program and is investigated in multiple clinical trials evaluating various combination therapy regimens in different forms of cancer, with PDAC being the most extensively studied. To date, more than 70 PDAC patients have received treatment with nadunolimab in combination with gemcitabine and nab-paclitaxel in the phase I/IIa clinical study CANFOUR. The update reported today is based on the first group of 33 patients evaluated for efficacy.

In the updated interim analysis, with a longer follow-up period than previous readouts resulting in a more robust analysis, median survival is 12.7 months and 1-year survival rate is 55%. Median iPFS is 7.2 months with a 6-month iPFS of 56%. In comparison, historical data in first line treatment of PDAC patients with gemcitabine and nab-paclitaxel show median survival of 8.5 months with a 1-year survival rate of 35%, and median PFS of 5.5 months with a 6-month PFS of 44%¹. At the time of analysis, two patients were still receiving treatment and 12 patients were still alive. Interestingly, 6 patients (18%) in the trial have received treatment for longer than one year.

The safety profile is essentially unchanged from the previous update with incidence of neutropenia and febrile neutropenia being higher than expected from chemotherapy alone. Notably, febrile neutropenia is observed only during the first cycle of therapy and can be largely prevented with prophylactic treatment by the granulocyte growth factor G-CSF. Interestingly, no cases of severe (grade 3 or higher) neuropathy, a common side effect of gemcitabine and nab-paclitaxel, have been observed.

Furthermore, 40 additional PDAC patients are investigated in an extension of the CANFOUR trial. Results from this part of the trial are expected to mature for presentation during H1 2022. Cantargia is currently preparing for a randomized and potentially pivotal trial in first line pancreatic cancer. Design and timelines will be disclosed once preparatory discussions with major regulatory authorities have been concluded.

References

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

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This is information that Cantargia AB is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact person set out above, at 14.15 CET on 29 December 2021.

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 project, the antibody nadunolimab (CAN04), is being studied clinically in combination with

chemotherapy or immune therapy with a primary focus on non-small cell lung cancer and pancreatic cancer. Positive interim data from the combination with chemotherapy indicate stronger efficacy than would be expected from chemotherapy alone. Cantargia's second project, the antibody CAN10, 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 CAN04 binds strongly to its target IL1RAP and functions by inducing ADCC and blocking IL-1 α and IL-1 β signaling. Thereby, CAN04 can counteract the contribution of the IL-1 system to the immune suppressive tumor microenvironment and development of resistance to chemotherapy. CAN04 is investigated in multiple ongoing clinical trials. In the phase I/IIa study CANFOUR, first line combination therapy is investigated with standard chemotherapies in patients with PDAC (gemcitabine/nab-paclitaxel) and patients with NSCLC (cisplatin/gemcitabine) ([NCT03267316](https://clinicaltrials.gov/ct2/show/study/NCT03267316)). Positive interim data for the combination therapies show durable responses or pseudoprogression in patients with PDAC, resulting in median iPFS of 7.2 months and median survival of 12.7 months. Stronger efficacy was also observed in NSCLC patients with median PFS of 7.2 months. A response rate of 53% was observed in non-squamous NSCLC patients, with even higher responses in patients previously treated with pembrolizumab. These results show stronger efficacy than expected from chemotherapy alone. CAN04 is investigated with chemotherapy also in the phase I study CAPAFOUR, with the FOLFIRINOX regimen for first line treatment of metastatic PDAC ([NCT04990037](https://clinicaltrials.gov/ct2/show/study/NCT04990037)), and in two further clinical studies, CESTAFOUR ([NCT05116891](https://clinicaltrials.gov/ct2/show/study/NCT05116891)) and TRIFOUR, in additional forms of cancer, including biliary tract cancer, colorectal cancer and triple negative breast cancer. CAN04 is also evaluated with the immune checkpoint inhibitor pembrolizumab, with or without chemotherapy, in the phase I study CIRIFOUR ([NCT04452214](https://clinicaltrials.gov/ct2/show/study/NCT04452214)).