Press release

Cantargia AB
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Cantargia reports positive results in ongoing phase IIa clinical trial in pancreatic cancer using nadunolimab and chemotherapy

Cantargia AB today announced positive results from the ongoing CANFOUR trial investigating nadunolimab (CAN04) in combination with gemcitabine/nab-paclitaxel (Abraxane®) for first line treatment of patients with advanced pancreatic cancer (PDAC). The efficacy analysis included 33 patients. Overall, the efficacy compares favorably to historical control data. Median iPFS was 7.8 months and other notable findings include five patients with durable benefit beyond initial progression (pseudoprogression), and an additional nine patients with confirmed partial response with a median duration of response of 6.8 months. An ongoing retrospective central review of CT scans revealed one confirmed complete responder and otherwise similar efficacy data. Currently, the median survival is 12.6 months with 58% of patients still alive. The side effects were manageable with neutropenia and febrile neutropenia higher than expected from the chemotherapy alone, while chemotherapy-related neuropathy and fatigue were less common. Neutropenia can be managed by prophylactic use of growth factor therapy and dose modifications.

Cantargia develops antibody-based pharmaceuticals against interleukin-1 receptor accessory protein (IL1RAP). The antibody CAN04 binds IL1RAP with high affinity and functions through both blockade of IL-1 signaling and Antibody-Dependent Cellular Cytotoxicity (ADCC). Preclinical data show that CAN04 can increase the efficacy of chemotherapy. CAN04 is investigated in an open label phase I/IIa clinical trial, CANFOUR, examining combination with two different frequently used chemotherapy regimes in patients with advanced non-small cell lung cancer (NSCLC) or PDAC (https://clinicaltrials.gov/ct2/show/NCT03267316) in the first line chemotherapy setting. A second trial, CIRIFOUR, investigates CAN04 in combination with pembrolizumab in four different solid tumor indications (https://clinicaltrials.gov/ct2/show/NCT04452214), and a third trial will investigate CAN04 in combination with FOLFIRINOX for first line treatment of PDAC. Additional clinical trials are in preparation.

In CANFOUR, 36 patients with advanced PDAC were included in the first line setting at either 5 or 7.5 mg/kg of CAN04 weekly. Three of these patients withdrew consent after occurrence of infusion-related reaction during the first administration and did not receive chemotherapy. Subsequently, the efficacy analysis was performed in the 33 remaining patients. The last patient in the trial started therapy in October 2020 and seven patients are still being treated.

Currently, median iPFS is 7.8 months and median survival is 12.6 months with 58% of the patients still alive. Notably, five (15%) of the 33 patients benefitted from the continuation of treatment after initial progressive disease with either shrinking or stable tumor size, and a decrease in the biomarker CA19-9. This is considered as evidence of a pseudoprogression-like response, which is very uncommon in PDAC[1], and these patients continued receiving CAN04 and chemotherapy following the protocol. Two of these patients are still on treatment after 14 and 7 months. Nine (27%) additional patients had confirmed partial response with a median duration of response of 6.8 months. The long-term efficacy compares favorably with published historical control data (PFS 5.5 months; duration of response 3.5 months; and survival 8.5 months)[2,3]. The antitumor effects are confirmed using a retrospective central review of the CT scans, with currently eight confirmed responses including one complete responder. One patient also showed complete eradication of all tumor lesions in a single CT scan. Furthermore, three additional patients are unconfirmed responders in this ongoing central analysis.

The side effects were manageable and in line with expectations from CAN04 and chemotherapy. Compared to historical control data[2] from chemotherapy alone, neutropenia (67% grade 3 or 4) and febrile neutropenia (17%, all grade 3), were more common, while neuropathy (0% grade 3 or 4) and fatigue (6% all grade 3) were less common. Similar to CAN04 monotherapy, infusion-related reaction was reported in 44% of the patients, and these were grade 1 or grade 2 on all occasions but one. In the majority of cases, the reaction did not re-occur at later infusions. The neutropenia, and subsequent risk for infection, can be counteracted by treatment with the granulocyte growth factor, G-CSF, or by dose modifications.

The coordinating investigator of the trial, Prof. Ahmad Awada from Institute Jules Bordet in Brussels, Belgium, will present the results from this trial at the Cantargia R&D day, May 20, 2021 at 15.00 CET. The results will then be discussed by Dr. Manuel Hidalgo from Weill-Cornell, New York. More details on how to access the event can be found at Cantargia's webpage www.cantargia.com.

"These data are intriguing and indicate that addition of CAN04 to standard chemotherapy generates beneficial long-term effects for patients with advanced pancreatic cancer. Antitumor effects in the form of pseudoprogression-like events, as well

as decrease in serious side effects such as neuropathy and fatigue are unique features in this trial", said Prof. Ahmad Awada at Institute Jules Bordet, Brussels, Belgium, who is the coordinating investigator of the trial.

"The positive results support previous findings that CAN04 may enhance the efficacy of various chemotherapies. We are therefore very pleased with the outcome of this trial and are preparing next development steps of CAN04 to meet the high medical need in pancreatic cancer", said Göran Forsberg, CEO at Cantargia.

The CANFOUR trial in PDAC is currently recruiting up to 40 additional patients in an extension phase. The purpose with this is to generate additional data on lower doses, to strengthen the clinical data set prior to pivotal trials, including results on CAN04 pharmacokinetics, and pharmacodynamics of the combination therapy. In the parallel combination arm of CANFOUR in NSCLC, recruitment is in the final stage with results expected to be presented during Q3, 2021.

References
1 Parseghian et al, J Immunother. 2018, 41(6), 284-
2 von Hoff et al, N Engl J Med. 2013, 369(18),1691-
3 Fernandez et al, BMC Cancer 2018, 18, 1185-

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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 23.00 CET on 19 May 2021.

About Cantargia
Cantargia AB (publ), reg. no. 556791-6019, is a biotechnology company that develops antibody-based treatments for life-threatening diseases. The basis for this is the protein IL1RAP that is involved in a number of diseases and where Cantargia has established a platform. The main project, the antibody CAN04, is being studied clinically as combination therapy 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 the target IL1RAP and functions both though ADCC as well as blocking IL-1α and IL-1β 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 two clinical trials. In the first phase I/IIa-study, CANFOUR, first line combination therapy is investigated using two different standard chemotherapies in patients with NSCLC (gemcitabine/cisplatin) and patients with PDAC (gemcitabine/nab-paclitaxel), as well as monotherapy in late stage patients (https://clinicaltrials.gov/ct2/show/NCT03267316). Phase I monotherapy data from 22 patients were presented at ASCO 2019 and showed good safety with infusion-related reaction being the most common side effect. In addition, the biomarkers IL6 and CRP decreased during treatment. Positive interim data from the combination therapies show durable responses or pseudoprogression in patients with PDAC, resulting in iPFS of 7.8 months, and also a higher response rate of patients with NSCLC, compared to chemotherapy alone. A phase I study, CIRIFOUR, investigating CAN04 in combination with an immune checkpoint inhibitor, started H2 2020 (https://clinicaltrials.gov/ct2/show/NCT04452214). Additional clinical combination studies are planned to start during 2021.