Press release

Cantargia AB
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Cantargia advances nadunolimab against pancreatic cancer in the PanCAN Precision Promise^{SM} phase 2/3 clinical trial

Cantargia AB today announced that the Pancreatic Cancer Action Network's (PanCAN) Precision Promise^{SM} phase 2/3 clinical trial, carried out at leading clinical US centers, plans to include nadunolimab in combination with chemotherapy as first-line experimental therapy in metastatic pancreatic cancer (PDAC). The trial utilizes a Bayesian platform designed by PanCAN in collaboration with the US Food and Drug Administration (FDA) to provide a basis for marketing approval of therapies in PDAC. The primary endpoint for the trial is overall survival. PanCAN's plan is to submit a Pre-IND application to the FDA in Q2 2022 for including the nadunolimab treatment arm as an experimental arm in Precision Promise.

"*With the positive data obtained with nadunolimab in pancreatic cancer, we are proud to have been selected to advance development in collaboration with PanCAN and its strong clinical network. Cantargia's goal is to provide new therapeutic options to patients with life-threatening diseases. Investigating nadunolimab in Precision Promise fits well with our strategies,*" 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 five clinical trials evaluating combination therapy regimens in various 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 1/2a clinical study CANFOUR. Interim results from 33 PDAC patients, presented at the ESMO Congress in September 2021 and updated in December 2021, show that both median progression-free survival (iPFS) and overall survival are longer than expected for chemotherapy alone, based on historical control data.

Cantargia has reviewed several opportunities to advance the clinical development of nadunolimab in PDAC and are today announcing the decision to take part in PanCAN's adaptive clinical phase 2/3 trial, Precision Promise. In addition to advancing the clinical development in PDAC, ongoing activities for nadunolimab in non-small cell lung cancer will continue according to plan with the aim to start a randomized clinical study late 2022.

PanCAN's Precision Promise adaptive clinical trial platform is currently being conducted in the US at 15 leading clinical centers, with additional sites added as the trial progresses. In the trial, patients will be randomized to receive experimental therapy of nadunolimab combined with gemcitabine and nab-paclitaxel, or a standard of care chemotherapy regime alone. Also, consistent with the platform nature of Precision Promise, other experimental arms will be evaluated simultaneously with the nadunolimab arm. The Bayesian trial design involves enrolling up to 175 patients on each experimental arm while randomizing patients to standard of care control arms. Depending on the arm's results at the time, successful completion of a 100-patient adaptively randomized Stage 1 of the trial may be followed seamlessly by a transition to a 75-patient fixed-randomized Stage 2. Should a transition to Stage 2 of the nadunolimab arm occur, enrollment will continue with no announcements of any of the trial results until the final analysis of the arm's comparison with control. Trial results for the nadunolimab arm are expected to be available in 2027 or earlier.

Before treatment of patients in the nadunolimab arm starts, additional meetings with regulatory authorities will take place, followed by regulatory submission of a pre-IND for this experimental arm. The Pre-IND is planned to be submitted to the US FDA in Q2 2022. Cantargia will fund the nadunolimab arm and will be responsible for supplying the drug.

"*The goal of PanCAN's Precision Promise is to accelerate drug development and bring new pancreatic cancer therapies to patients faster,*" said Anne-Marie Duliege, MD, PanCAN's Chief Medical Officer. "*It is important that we continue to partner with innovative pharmaceutical companies to expand the experimental treatments being studied through this trial and we look forward to working with Cantargia to incorporate nadunolimab into Precision Promise.*"

More information about PanCAN, Precision Promise and participating centers can be found at https://www.pancan.org/research/precision-promise/ and on https://clinicaltrials.gov/ct2/show/NCT04229004.

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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 08.30 CET on 3 January 2022.

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-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 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). 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), and in two further clinical studies, CESTAFOUR and TRIFOUR, in additional forms of cancer, including biliary tact 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).

About PanCAN and Precision Promise^{SM}
The Pancreatic Cancer Action Network (PanCAN) leads the way in accelerating critical progress for pancreatic cancer patients. PanCAN takes bold action by funding life-saving research, providing personalized patient services and creating a community of supporters and volunteers who will stop at nothing to create a world in which all pancreatic cancer patients will thrive. PanCAN's Precision Promise^{SM} is a phase 2/3 clinical platform trial and contains an adaptive design intended for the parallel evaluation of multiple new treatments for pancreatic cancer. It serves as a catalyst to accelerate pancreatic cancer drug development, de-risk industry participation, increase clinical trial enrollment and transform the way clinical research is done for pancreatic cancer patients.