



Press release

Cantargia AB
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Cantargia provides update on development projects CAN04 and CAN10

Cantargia AB today provided an update on the progress in its development antibody projects CAN04 and CAN10 in response to the ongoing COVID-19 pandemic. The initial dose escalation period of CAN04 has been concluded for both non-small cell lung cancer (NSCLC) and pancreatic cancer (PDAC). Recruitment of remaining patients is ongoing. Timeline estimates are difficult due to COVID-19, but with a normalization in Q2 2020, last patient in each arm is expected to be recruited during Q3 2020 (PDAC) and Q4 2020 (NSCLC). Parts of the CAN10 project, are affected since US suppliers have been forced to temporarily close their facilities. Several contingency measurements have been implemented, the start of the phase I clinical trial will be moved to early 2022.

CAN04

Development progress: dose level selected

CAN04 is in phase IIa clinical development for non-small cell lung cancer (NSCLC) and pancreatic cancer (PDAC) in the CANFOUR trial. Despite the COVID-19 outbreak, CAN04 has until this stage followed previously communicated timelines. So far, in the combination therapy arms, 17 patients with PDAC and seven patients with NSCLC have started therapy. The initial dose escalation period has been concluded for both indications. The trial will from now on investigate 5 mg/kg of CAN04 in combination with respective chemotherapy, the same dose level as for the interim data presented in December 2019. This dose was selected based on efficacy results and analysis of blood levels of CAN04 suggesting sufficient levels for IL1RAP targeting. The side effects observed are in line with those expected from chemotherapy or CAN04.

Impact by the COVID-19 pandemic

During the current circumstances the situation is followed carefully, incorporating new guidelines from the European Medical Agency (EMA) and local authorities on the management of clinical trials during the COVID-19 pandemic. All measurements are taken to respect the safety of the participants in the trial and not expose them to unnecessary risks. All patients in the trial continue therapy as planned. Recruitment of remaining patients is ongoing with some patients planned to start therapy during the next couple of weeks. The number of active hospitals in the trial has, however, decreased as some territories have imposed temporary restrictions on clinical trials.

With the current uncertainty around the COVID-19 outbreak and future pressure on global healthcare, timeline estimates are difficult, but assuming a normalization during Q2 2020, last patient in the PDAC arm is expected during Q3 2020 and Q4 2020 in the NSCLC arm. A longer outbreak may extend these timelines. In addition, analysis of biomarker data from monotherapy and combination therapy has been delayed a few months. Other activities, such as production, initiation steps of the next clinical trial and preclinical activities are on track and have not been materially affected.

CAN10

Certain activities temporarily on hold while preclinical efficacy studies progress

CAN10 is an antibody in preclinical development for systemic sclerosis and myocarditis. Several parts of the project have been initiated during 2020 as planned, with animal studies in models of inflammatory disease, systemic sclerosis or myocarditis ongoing. Other parts of the project, concerning biochemistry and production, are affected, as critical parts have been performed with partners in the US that have been forced to temporarily close their facilities. Alternative strategies and partners have been identified in order to minimize the impact, but despite these measurements, the start of the phase I clinical trial is moved to early 2022.

“Cantargia has managed to perform most critical activities during this initial phase of the outbreak with a minimal impact on development timelines. Most importantly, the initial dose escalation phase in the CANFOUR trial has been finalized and a dose level of 5 mg/kg has been selected for CAN04 combination therapy. However, as the outbreak continues, we expect deviations to previously communicated timelines. In this globally challenging situation, we are taking all measurements not to risk the safety of the participants in our clinical trials or the integrity and quality of ongoing activities”, said Göran Forsberg, CEO of Cantargia.

For further information, please contact

Göran Forsberg, CEO

Telephone: +46 (0)46-275 62 60

E-mail: goran.forsberg@cantargia.com

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 12.00 CET on 7 April 2020.

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 in the clinical phase I/IIa CANFOUR study with a primary focus on non-small cell lung cancer and pancreatic cancer. The study is focused on combination therapies, but also includes a monotherapy arm. Positive interim data from the combination therapies were presented in December 2019. 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 <http://www.cantargia.com>.

About CAN04

The antibody CAN04 binds IL1RAP with high affinity and functions through both ADCC and blockade of IL-1 α and IL-1 β signaling. CAN04 is investigated in an open label phase I/IIa clinical trial, CANFOUR, examining first line chemotherapy combination with two different standard regimes in 31 patients with NSCLC (gemcitabine/cisplatin) and 31 patients with PDAC (gemcitabine/nab-paclitaxel) as well as monotherapy in late stage patients (www.clinicaltrials.gov). The phase I monotherapy data from 22 patients were presented at ASCO 2019 and showed a good safety with infusion related reaction being the most common side effect. In addition, the biomarkers IL6 and CRP were decreased with treatment and 9/21 patients had stable disease. Positive interim data from the combination therapies were presented in December 2019. A phase I trial investigating CAN04 in combination with an immune checkpoint inhibitor is planned to start H1 2020.