Press release

Cantargia AB
556791-6019
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Cantargia: Phase I safety evaluation part of CANFOUR trial of antibody CAN04 completed and phase IIa part being initiated

Cantargia AB (publ) today announces that all patients in the phase I part of the CANFOUR clinical trial have completed the formal safety evaluation phase of the trial. No dose limiting toxicities (DLTs) were reported at the highest dose level investigated, 10 mg/kg. According to the study protocol, the patients continue CAN04 (nidanilimab) treatment for biomarker and efficacy evaluation. Based on the positive outcome of the phase I safety evaluation, the phase IIa part of the trial can be started as planned.

Cantargia is developing the antibody CAN04 for treatment of cancer. The ongoing phase I/IIa trial is primarily focused on treatment of non-small cell lung cancer (NSCLC) and pancreatic cancer. CAN04 is directed against interleukin-1 receptor accessory protein (IL1RAP) which is found on tumor cells from a wide range of cancer forms. IL1RAP is also found on inflammatory immune cells involved in cancer progression. Interim phase I data from 16 patients was presented at the ESMO conference in October 2018 and showed a good safety profile up to 6 mg/kg, a decrease in the biomarkers IL-6 and CRP and stable disease in 38 % of patients.

The formal phase I safety evaluation part has now been completed at 10 mg/kg and no DLTs were observed at this dose level. In total, 22 patients have received CAN04 and the safety profile is good with the most common side effects being infusion related reactions associated with the first infusion. The trial will continue into the phase IIa part which will study both CAN04 as monotherapy as well as combination therapy in patients with NSCLC or pancreatic cancer. Combination agents will be cisplatin and gemcitabine in NSCLC and gemcitabine and nab-paclitaxel in pancreatic cancer. The phase IIa part is planned to be performed at approximately 20 clinical sites in up to 7 countries and include 80-90 patients. Screening of patients for phase IIa is now being initiated, with the aim to start treatment as soon as possible.

”We are very excited to have passed one additional important milestone. The safety profile of CAN04 continue to look very good and I am very happy that we can advance into phase IIa clinical development,” said Göran Forsberg, CEO of Cantargia.

Several patients from phase I are still being treated with CAN04 and have not yet been evaluated for biomarkers and efficacy. Cantargia plans to present the complete phase I data during a scientific conference during first half of 2019. Based on the positive outcome of phase I, Cantargia plans to start the discussions with the US FDA with the goal to obtain an IND during H1 2019.

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This constitutes information that Cantargia AB is required to publish under the EU's Market Abuse Regulation. The information was submitted for publication through the above contact person on December 7, 2018, at 15:30 CET.

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 (nidanilimab) is being studied in the clinical phase I/IIa CANFOUR with a primary focus on non-small cell lung cancer and pancreatic cancer. The study is conducting both monotherapy and combination therapy. Cantargia's other project, CANxx, is in the research phase and is aiming to develop a IL1RAP binding antibody optimised for the treatment of autoimmune and inflammatory diseases.

Cantargia is listed on Nasdaq Stockholm (ticker: CANTA). More information about Cantargia is available at http://www.cantargia.com.