Press release

Cantargia AB
556791-6019
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Cantargia advance antibody CAN04 development after positive pre-IND meeting

Cantargia AB announced today that the pre-IND meeting regarding the clinical development of antibody CAN04 was held with the US FDA. The purpose of the meeting was to discuss the available information on CAN04, including data from the first-in-human phase I trial, and a proposed new phase I clinical trial with CAN04 in combination with an immune checkpoint inhibitor under a US IND. As a result of the meeting, Cantargia is advancing the development of CAN04 and will apply for a US IND around New Year's.

Cantargia develops antibody-based pharmaceuticals targeting the interleukin-1 receptor accessory protein (IL1RAP). The antibody CAN04 binds IL1RAP with high affinity and functions as an anti-cancer agent through both ADCC and blockade of interleukin-1 signaling. CAN04 is currently being investigated in an open label three-armed phase I/IIa clinical trial in Europe, CANFOUR, examining CAN04 combination with two different standard chemotherapy regimens in patients with advanced non-small cell lung cancer or pancreatic cancer not previously treated with chemotherapy and monotherapy in patients with late stage cancer (NCT03267316, www.clinicaltrials.gov).

Cantargia is now expanding clinical development to investigate CAN04 in combination with an immune checkpoint inhibitor. The trial is planned to be performed at major clinical centres in the US. The coordinating investigator will be Prof. Roger Cohen at University of Pennsylvania. The purpose of the trial is primarily to investigate safety of the combination of CAN04 and an immune checkpoint inhibitor in patients with IL1RAP-expressing cancers that include non-small cell lung cancer, head and neck squamous cancer and bladder cancer. The patients in the trial will be eligible if they have progressed on prior PD1/PDL-1 antibody therapy containing regimens. Up to 18 patients will initially be enrolled. In addition to safety, exploratory biomarkers and efficacy will also be studied. The study protocol is being finalized for a planned IND-filing in January 2020.

"CAN04 is directed against a novel target and has immunological anti-tumor activities that could be synergistic with immune checkpoint inhibitors. This is an important trial in our efforts to generate additional effective therapeutic options for patients with cancer who are no longer benefitting from existing approved immune therapies", says Prof Roger Cohen who will serve as the coordinating investigator at the Abramson Cancer Center at the University of Pennsylvania.

"Based on the positive outcome of the pre-IND meeting, we are ready for the next step in the development of CAN04. Generating data on CAN04 in combination with immunotherapy is an important part of our strategies", says Göran Forsberg, Cantargia's CEO.

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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 13.30 CET on 15 November 2019.

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.