Press release

Cantargia AB
556791-6019
4 May 2020

Cantargia IND application for CAN04 approved by FDA

Cantargia AB today announced that the IND application regarding the antibody CAN04 has been approved by the US FDA. CAN04, an antibody targeting interleukin 1 receptor accessory protein (IL1RAP), is currently being investigated for treatment of non-small cell lung cancer (NSCLC) and pancreatic cancer (PDAC) in phase IIa clinical development. CAN04 development can now be expanded to the US with a new phase Ib clinical trial investigating CAN04 in combination with immunotherapy in selected cancer forms overexpressing IL1RAP.

Cantargia develops antibody-based pharmaceuticals against IL1RAP. The antibody CAN04 binds IL1RAP with high affinity and its anti-tumor activity consists both of stimulation of immune cells to eradicate cancer cells as well as blockade of interleukin 1 signaling. CAN04 is investigated in an open label phase I/IIa clinical trial, CANFOUR, examining two different first line chemotherapy combinations in patients with non-small cell lung cancer or pancreatic cancer, as well as monotherapy in late stage patients. For more information see (https://www.clinicaltrials.gov/ct2/show/NCT03267316).

Cantargia is now in the process of broadening the development activities and the next step is a phase Ib trial investigating CAN04 in combination with the PD1 binding antibody pembrolizumab (Keytruda®). The FDA has now approved the trial. Upcoming next steps before patients can start treatment include IRB approvals as well as some other administrative procedures. Even though the COVID-19 pandemic makes estimates complex, first patient in is planned during Q3 2020.

The trial is planned to be conducted at three US clinical centres with University of Pennsylvania being the lead centre. Up to 18 patients will be treated and the primary endpoint is safety, with biomarkers and tumor measurements being additional key parameters. Four different cancer forms overexpressing IL1RAP will be investigated i.e. NSCLC, head and neck cancer, urothelial cancer or malignant melanoma. These patients should previously have been treated with, and benefitted from, immune checkpoint therapy. The patients will start therapy at 5 mg/kg CAN04 and can receive treatment until disease progression. Additional details and updates of the trial will continuously be posted to www.clinicaltrials.gov from Q2 2020.

"Starting clinical development of CAN04 in USA is a key strategic goal for Cantargia which will lead to additional awareness. It is a strength that US FDA has reviewed our documentation and approved clinical activities in the US. The granted IND also enables future activities on regulatory designations aimed at accelerating development of promising drugs", 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 08.30 CET on 4 May 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-1α and IL-1β 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 during 2020.