Cantargia presented positive phase I clinical data with lead candidate CAN04 at ESMO

- The antibody CAN04 was well tolerated and 6 mg/kg is a safe dose
- Effects on biomarkers and 5 of 13 evaluable patients achieved stable disease
- 10 mg/kg currently investigated before start of phase IIa during Q4 2018

Cantargia AB (publ) today presented interim results from its clinical Phase I/II trial CANFOUR of lead candidate CAN04 (nidanilimab) in a poster presentation at the ESMO Congress 2018 in Munich, Germany. Data from 16 patients with advanced cancer treated with weekly infusions between 1 mg/kg and 6 mg/kg were presented.

The poster presentation – with the title A first-in-class, first-in-human phase I/IIa trial of CAN04, targeting Interleukin-1 Receptor Accessory Protein (IL1RAP), in patients with solid tumors – was given by the coordinating investigator Professor Ahmad Awada, Institut Jules Bordet, Université Libre de Bruxelles, Brussels, Belgium. The poster is available on Cantargia’s website, www.cantargia.com.

The presentation included data from the cutoff date, October 5, 2018, on 16 heavily pretreated patients with advanced colorectal cancer (9), non-small cell lung cancer (3) or pancreatic cancer (4) treated with weekly infusions at escalating dose levels from 1 mg/kg to 6 mg/kg. Prior to CAN04, the patients had received an average of 4 different cancer therapies.

The most common side effects of CAN04 were infusion related reactions and related events, such as nausea, fatigue and fever. These side effects were generally associated with the first dose and were reversible. It can be concluded that 6 mg/kg is a safe dose and the maximum tolerated dose of CAN04 is higher. The trial is now investigating treatment at 10 mg/kg of CAN04 before moving into phase IIa.

“I am very pleased with the results obtained so far. CAN04 has generally been well tolerated using repeated dosing. The good safety profile and initial effects are encouraging and supportive for the next step in the trial, which is combination with chemotherapy”, said Prof. Ahmad Awada, the coordinating investigator of the CANFOUR trial.

The initial biomarker analysis shows that the serum levels of IL-6 were reduced in 11 out of 14 patients after two weeks and serum levels of CRP were reduced in 9 out of 11 patients with available samples. Levels of IL-6 and CRP are often increased in cancer patients and are associated with disease progression. Preliminary efficacy results show that five patients achieved stable disease, eight progressed and three could not be evaluated. One patient with NSCLC had stable disease for six months.

“Presenting the first clinical data set from CAN04 treatment of patients with advanced cancer at a major cancer conference is an important milestone for Cantargia. The results have strengthened our view that CAN04 can become an important future cancer therapy. We look forward to the last step in the Phase I part and the initiation of Phase IIa in NSCLC and pancreatic cancer using an expanded number of clinical sites,” said Göran Forsberg, CEO of Cantargia.

The primary objective of the Phase I part of CANFOUR is to assess safety and tolerability of weekly CAN04 in order to define the Maximum Tolerated Dose/Recommended Phase II Dose. Patients with relapsed or refractory non-small cell lung cancer (NSCLC), pancreatic ductal adenocarcinoma (PDAC), breast or colorectal cancer are eligible in the initial part of the trial using a 3+3 dose escalation design.

The Phase I part of the trial is currently in the final stage and is planned to be finalized during Q4 2018 with phase IIa also starting Q4 2018. Besides monotherapy, combination with cisplatin/gemcitabine in NSCLC or gemcitabine/nab-paclitaxel in pancreatic cancer at an earlier stage of the disease will be studied in phase IIa. More details on the trial design can be found at www.clinicaltrials.gov.
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About Cantargia
Cantargia AB (publ), reg.no. 556791-6019, is a biotech company that is developing antibody-based treatments for life-threatening diseases. The original discovery by the research team behind Cantargia was the overexpression of a specific target molecule, interleukin 1 receptor accessory protein (IL1RAP) in leukemic stem cells. Subsequent research has also identified IL1RAP in many other forms of cancer. The company’s main project, the CAN04 (nidanilimab) antibody targeted against IL1RAP, is being studied in the CANFOUR clinical phase I/IIa study, where the primary focus is on non-small cell lung cancer and pancreatic cancer. CAN04 (nidanilimab) has two modes of action: it blocks the function of IL1RAP and stimulates the immune system to destroy tumour cells. Cantargia’s second project, currently in the research phase, is aimed at developing an IL1RAP-binding antibody that is optimised for treatment of autoimmune and inflammatory diseases.