Press release

Cantargia AB
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Cantargia reports positive safety data from CIRIFOUR clinical study on nadunolimab and pembrolizumab combination

Cantargia AB today reported an interim update on the first part of the phase Ib clinical study CIRIFOUR. Fifteen cancer patients no longer responding to checkpoint inhibitor therapy received nadunolimab as an add-on to Keytruda® (pembrolizumab) with the primary objective to evaluate safety. The results show a very favorable safety profile, with only one treatment-related grade 3 toxicity identified. As one third of patients are still on therapy, efficacy is planned to be reported in Q2 2022. The next stage of CIRIFOUR will investigate this combination with chemotherapy in non-small cell lung cancer (NSCLC).

"It is encouraging that the two immune therapies nadunolimab and pembrolizumab can be safely combined. These results open up for several interesting opportunities and while efficacy results are maturing, we are eager to start investigating addition of chemotherapy to this combination," said Göran Forsberg, CEO of Cantargia.

Nadunolimab, an antibody targeting interleukin-1 receptor accessory protein (IL1RAP), is Cantargia's most advanced program. CIRIFOUR, a phase Ib clinical study conducted in the US, evaluates nadunolimab with pembrolizumab in cancer patients progressing on previous checkpoint inhibitor therapy. A favorable safety profile for this combination is today reported.

A total of 15 patients with head and neck cancer, NSCLC or malignant melanoma were enrolled in the first part of CIRIFOUR, evaluating safety of 5 mg/kg nadunolimab as an add-on to pembrolizumab in patients no longer responding to immune checkpoint inhibitors. The safety results are very encouraging with only one patient having a treatment-related side effect of grade 3 (febrile neutropenia). No patient has terminated treatment due to side effects. The last patient started treatment in August 2021 and treatment of five patients is still ongoing. Among these, two patients have been on therapy for over 31 weeks and another two for over 49 weeks. Efficacy analyses are still premature but are planned for reporting in Q2 2022. Biomarker analyses of tumor biopsies and blood samples are ongoing.

The favorable safety profile reported in CIRIFOUR is the basis for the addition of further therapies to the combination of nadunolimab and pembrolizumab. CIRIFOUR will therefore expand to study safety, biomarkers, and efficacy of this combination with carboplatin/pemetrexed in non-squamous NSCLC as first line treatment. Treatment in this new arm is expected to start in Q1 2022.

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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 09.30 CET on 3 February 2022.

About Cantargia
Cantargia AB (publ), reg. no. 556791-6019, is a biotechnology company that develops antibody-based treatments for life-threatening diseases and has established a platform based on the protein IL1RAP, involved in a number of cancer forms and inflammatory diseases. The main project, the antibody nadunolimab, is being studied clinically in combination with chemotherapy or immune therapy with a primary focus on non-small cell lung cancer and pancreatic cancer. Positive interim data from the combination with chemotherapy indicate stronger efficacy than would be expected from chemotherapy alone. 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 www.cantargia.com.

About nadunolimab (CAN04)

The antibody CAN04 binds strongly to its target IL1RAP and functions by inducing ADCC and blocking IL-1α and IL-1β signaling. Thereby, CAN04 can counteract the contribution of the IL-1 system to the immune suppressive tumor microenvironment and development of resistance to chemotherapy. CAN04 is investigated in multiple ongoing clinical trials. In the phase I/IIa study CANFOUR, first line combination therapy is investigated with standard chemotherapies in patients with PDAC (gemcitabine/nab-paclitaxel) and patients with NSCLC (cisplatin/gemcitabine) (NCT03267316). Positive interim data for the combination therapies show durable responses or pseudoprogression in patients with PDAC, resulting in median iPFS of 7.2 months and median survival of 12.7 months. Stronger efficacy was also observed in NSCLC patients with median PFS of 7.2 months. A response rate of 53% was observed in non-squamous NSCLC patients, with even higher responses in patients previously treated with pembrolizumab. These results show stronger efficacy than expected from chemotherapy alone. CAN04 is investigated with chemotherapy also in the phase I study CAPAFOUR, with the FOLFIRINOX regimen for first line treatment of metastatic PDAC (NCT04990037), and in two further clinical studies, CESTAFOUR (NCT05116891) and TRIFOUR (NCT05181462), in additional forms of cancer, including biliary tact cancer, colorectal cancer and triple negative breast cancer. CAN04 is also evaluated with the immune checkpoint inhibitor pembrolizumab, with or without chemotherapy, in the phase I study CIRIFOUR (NCT04452214).