Press release

Cantargia AB
556791-6019
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Cantargia reports progress in manufacturing process development and provides update on clinical trial preparations for CAN10

Cantargia AB today provided an update on the progress in the development of a manufacturing process for CAN10 and the clinical trial preparations, with minor adjustments to the timeline. Development of a manufacturing process for CAN10 has been successful and high yields have been obtained in initial productions. Due to the high demand for COVID-19 vaccines, there is global shortage of raw materials and consumables required for manufacturing of clinical-grade substances. Therefore, start of the production of CAN10 for use in clinical trials has been moved from Q4 2021 to Q1 2022. Consequently, the first clinical study for CAN10 is planned to start during Q3 2022.

Cantargia develops antibody-based pharmaceuticals against interleukin-1 receptor accessory protein (IL1RAP). The lead project CAN04 (nadunolimab) is in phase IIa clinical development for treatment of cancer while Cantargia's second project, CAN10, is in preclinical development for inflammatory and autoimmune disease.

Cantargia previously communicated that a manufacturing agreement was signed for CAN10, which would provide the drug product needed to conduct toxicology studies as well as the first clinical study. So far, all activities related to development of a manufacturing process have been performed according to plan. This includes cell line development, manufacturing of initial small-scale productions, adaptation of the manufacturing process to medium-scale production, and formulation development. In addition, sufficient amounts of CAN10 for toxicology studies has been produced. Importantly, high yields of the antibody have been obtained in the initial productions and the generated drug product has good stability, suggesting a long shelf-life. Thereby, several risks related to manufacturing of CAN10 have been mitigated.

On a global level, supply of raw materials and consumables required for large-scale manufacturing of clinical-grade substances has become limited, to a large extent due to the high demand in production of COVID-19 vaccines. This has resulted in minor timeline adjustments for the production of CAN10 antibody for the initial clinical trial. The production of drug product required for the clinical phase I study for CAN10 will be carried out during Q1 2022 rather than Q4 2021 as initially intended. As a consequence, Cantargia plans to initiate the clinical phase I study for CAN10 in Q3 2022.

"We are pleased with the progress in the development of a manufacturing process for CAN10 and are excited to initiate the final steps ahead of the clinical trials. In the next couple of months, we plan to meet with regulatory authorities to discuss the design of the first clinical trial for CAN10." said Göran Forsberg, CEO of Cantargia.

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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 15.45 CET on 8 November 2021.

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 (CAN04), 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 CAN10

The CAN10 antibody binds strongly to its target IL1RAP and has a unique capability to simultaneously inhibit signaling via IL-1, IL-33 and IL-36. Inhibition of these signals can be of significant value in the treatment of several inflammatory or autoimmune diseases. Therefore, the initial focus of CAN10 will be on two severe diseases: myocarditis and systemic sclerosis. The efficacy of CAN10 has been demonstrated in preclinical in vivo models where a CAN10 surrogate antibody significantly reduced the development of inflammation and fibrosis in a model of myocarditis and significantly counteracted the deterioration of the cardiac function. CAN10 also inhibited disease development in models of peritonitis, psoriasis and psoriatic arthritis. CAN10 is currently in preclinical development and the first clinical trial is estimated to initiate in Q3 2022.

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 7.8 months and median survival of 12.6 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 and TRIFOUR, 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).