Press release

Cantargia AB
556791-6019
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Cantargia successfully concludes toxicity study with CAN10 antibody ahead of phase I clinical trial application

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today announced that the Good Laboratory Practice (GLP) toxicity study for its anti-inflammatory IL1RAP-binding antibody CAN10 has been concluded. Data from the study show that CAN10 was well tolerated when administered over six weeks. Cantargia plans to initiate the phase I clinical trial for CAN10 during the first half of 2023.

In the present GLP toxicity study, CAN10 was given intravenously once weekly for six weeks at doses up to 50 mg/kg, which is well above the intended clinical dose levels. CAN10 was also administered subcutaneously at 5 mg/kg. There were no adverse findings associated with the intravenous or subcutaneous administrations of CAN10. No safety signals were detected in body weight, or on respiratory, cardiovascular or neurological functions, attributed to the administration of the antibody. There were also no changes in clinical pathology (e.g. hematology, serum chemistry, coagulation, and urinalysis), anatomic pathology, or microscopic evaluation of selected tissue. Completion of the GLP toxicity study is required by regulatory authorities prior to initiation of clinical trials.

As a next step in the development of CAN10, once additional administrative procedures have been finalized, Cantargia plans to submit an application to regulatory authorities to start the phase I clinical trial. The study start is dependent on timelines for regulatory review, but treatment of healthy volunteers could be initiated shortly following approval of the application, as early as the first half of 2023.

CAN10 is Cantargia's second development program and extends the reach of Cantargia's IL1RAP platform beyond oncology to inflammatory and autoimmune disease, with initial focus on systemic sclerosis and myocarditis. During 2022, Cantargia presented preclinical data demonstrating strong treatment effects of a CAN10 surrogate antibody in several different in vivo disease models. For example, the CAN10 surrogate antibody was shown to reduce skin and lung fibrosis and affect relevant proinflammatory markers in models of systemic sclerosis. It also reduced inflammation and disease severity in models of viral and autoimmune myocarditis. These effects are a consequence of the broad and specific mechanism by which CAN10 modifies the activity of the target molecule IL1RAP.

"We are truly excited about the progress in the CAN10 program, demonstrating a good safety profile and potent treatment effects in several models of life-threatening inflammatory diseases. We are now ready to apply for approval to start the first clinical trial for this unique and promising lead candidate," 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 12:00 CET on 13 January 2023.

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 development program, the antibody CAN10, blocks signaling via IL1RAP in a different manner than nadunolimab and 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. The initial focus of CAN10 will be on two severe diseases: myocarditis and systemic sclerosis. In preclinical in vivo models of myocarditis, a CAN10 surrogate antibody significantly reduced the development of inflammation and fibrosis, and significantly counteracted the deterioration of the cardiac function. The CAN10 surrogate also inhibited disease development in models of systemic sclerosis, atherosclerosis, psoriasis, psoriatic arthritis, and peritonitis. CAN10 is currently in late-stage preclinical development and the first clinical trial is expected to begin in the first half of 2023.