PRESS RELEASE
06 September 2023 08:00:00 CEST

Cantargia: FDA grants Orphan Drug Designation to CAN10 for treatment of systemic sclerosis

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today announced that the US Food and Drug Administration (FDA) has granted Orphan Drug Designation in the US to CAN10 for the treatment of systemic sclerosis. This designation provides a range of incentives in the continued clinical development of CAN10 in systemic sclerosis.

"The Orphan Drug Designation by the FDA is another crucial milestone in the clinical development of CAN10, highlighting the urgent need for new treatment options for systemic sclerosis patients, as well as the potential of CAN10. We look forward to advancing the program and presenting initial data from the ongoing phase I safety trial for CAN10 in 2024," said Göran Forsberg, CEO of Cantargia.

The FDA Office of Orphan Products Development provides orphan status to drugs and biologics which are intended to treat, diagnose, or prevent rare diseases that affect fewer than 200,000 people in the US. Orphan Drug Designation qualifies sponsors for incentives, including tax credits for qualified clinical trials, exemption from user fees, and potential seven years of market exclusivity after approval. More information about the Orphan Drug Designation program is available at **www.fda.gov**.

Systemic sclerosis is a life-threatening autoimmune disease characterized by inflammation and subsequent fibrosis, i.e. uncontrolled scar tissue formation, in skin and various internal organs. The medical need for systemic sclerosis is high, with few approved drugs currently available.

The CAN10 antibody strongly binds IL1RAP and simultaneously blocks the function of the signaling molecules IL-1, IL-33 and IL-36, which play key roles in several autoimmune and inflammatory diseases. CAN10 has previously shown promising effects in several models of such diseases, including the lead indications systemic sclerosis and myocarditis. A clinical phase I trial investigating the safety and tolerability of CAN10 in healthy volunteers and psoriasis patients is ongoing. Up to 80 subjects may be included in the trial, and initial data from the trial are expected in 2024.

For further information, please contact
Göran Forsberg, CEO
Telephone: +46 (0)46-275 62 60
E-mail: **goran.forsberg@cantargia.com**

This information is information that Cantargia is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-09-06 08:00 CEST.

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 program, the antibody nadunolimab (CAN04), is being studied clinically primarily in combination with chemotherapy with a focus on pancreatic cancer, non-small cell lung cancer and triple-negative breast cancer. Positive interim data for the combinations 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, psoriasis, psoriatic arthritis, atherosclerosis and peritonitis. CAN10 is currently evaluated in a phase I clinical trial, with initial data expected in 2024.

Attachments
Cantargia: FDA grants Orphan Drug Designation to CAN10 for treatment of systemic sclerosis