

Cantargia reports promising CAN10 phase 1 data from first multiple dose cohort, and FDA and Key Opinion Leader feedback

- Promising multiple dose PK data continue to support 4-weekly dosing
- FDA advice received supporting phase 2 design in HS
- Strong Key Opinion Leader (KOL) support for CAN10 in HS

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today reported promising pharmacokinetic (PK) data from the first group of subjects receiving multiple dosing (MAD) subcutaneously (sc) in the phase 1 clinical study with CAN10. These data align with data from the single dose phase of the study, further supporting potential 4-weekly dosing. Additionally, feedback from the FDA, through a pre-IND meeting, has been received supporting our proposed phase 2 HS study design, and a scientific advisory board (SAB) with clinical US and European experts strongly endorsed CAN10 development in this indication.

“These first MAD CAN10 clinical data underscore the potential for sc dosing every 4th week. This would be a competitive advantage in the market for HS treatments. The FDA feedback and SAB endorsement encourage us as we move towards our planned phase 2 study in HS towards the end of this year.”, said Damian Marron, Interim CEO of Cantargia.

CAN10 is an antibody against IL1RAP designed to potently inhibit the activity of the pro-inflammatory and disease promoting cytokines IL-1, IL-33 and IL-36. CAN10 is currently being evaluated in a phase 1 clinical trial with safety as the primary objective. So far, healthy participants have been dosed via intravenous administration in 10 single ascending dose (SAD) cohorts. MAD cohorts with sc administration are currently being conducted in both healthy participants and participants with mild to moderate plaque psoriasis. The first cohort with healthy subjects has completed dosing at this time and will be followed by the higher dose cohort.

Pharmacokinetic results for the 10 SAD cohorts suggest dose proportionality at clinically relevant dose levels. Observed exposures from the SAD cohorts together with modelling results suggest that 4-weekly dosing is feasible. This is now strengthened by the initial, observed exposure profiles from the first MAD cohort in healthy participants. Further evaluations and simulations will be performed once the complete PK data are available from this first MAD cohort.

Preparations for a phase 2 study in HS are ongoing. This study will be performed to demonstrate clinical proof of concept as well as to identify the dose level and regimen for further development in patients with moderate to severe HS.

Cantargia has successfully completed a pre-IND meeting with the FDA. The purpose of the meeting was to gain FDA feedback on the proposed phase 2 study design, as well as the adequacy of the proposed nonclinical and CMC information to support opening the IND. The FDA provided written responses. The phase 2 study design was considered reasonable by the FDA and the primary endpoint has been clarified, in line with the expected endpoint for regulatory approval. Additional comments will be incorporated in the final protocol. The IND submission is on track for H2 2025.

A SAB was also held with HS clinical experts from the US and Europe. They provided strong support for the development of CAN10 for the treatment of HS based on the biology of the disease and our preclinical mechanistic data. Although there have been recent approvals and development of new treatments for HS, the KOLs clearly stated that there remains a high unmet medical need, and additional options for treatment are needed. Feedback on study population and endpoints was consistent with that of FDA and are being implemented in the final study design.

For further information, please contact

Damian Marron, Interim CEO

Telephone: +46 (0)46-275 62 60

E-mail: damian.marron@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 2025-03-05 10:30 CET.

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. Cantargia's oncology 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 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 hidradenitis suppurativa and systemic sclerosis.

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: hidradenitis suppurativa (HS) and systemic sclerosis. In preclinical in vivo models of inflammatory diseases, such as systemic sclerosis, psoriasis, psoriatic arthritis, atherosclerosis, myocarditis and peritonitis, a CAN10 surrogate antibody significantly reduced the development of the disease. A clinical phase 1 study, investigating CAN10 in healthy volunteers and psoriasis patients, is ongoing. Good safety is shown at the completed dose levels, and additional data are expected continuously during 2025.

Attachments

[Cantargia reports promising CAN10 phase 1 data from first multiple dose cohort, and FDA and Key Opinion Leader feedback](#)