Press release

Cantargia AB
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Cantargia reports first non-squamous NSCLC patient treated with nadunolimab, Keytruda® and chemotherapy

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today reported that the first patient has been treated in a new arm of the phase Ib clinical trial CIRIFOUR. The new arm adds Cantargia's lead asset, the IL1RAP-binding antibody nadunolimab (CAN04), to the recently established first line therapy for non-small cell lung cancer (NSCLC). Up to 24 non-squamous NSCLC patients will be treated with a combination of nadunolimab, the checkpoint inhibitor Keytruda® (pembrolizumab) and platinum-based chemotherapy. The objective is to assess safety, efficacy, and biomarkers.

"We are thrilled to advance nadunolimab development in the first line segment of non-squamous NSCLC. Chemotherapy combined with pembrolizumab is the most common first line of treatment in NSCLC and based on our preliminary findings recently presented at ASCO, we have strong reasons to believe that nadunolimab may further potentiate this combination," said Göran Forsberg, CEO of Cantargia.

The interim data recently presented at the ASCO Annual Meeting indicate that nadunolimab improves antitumor effects of platinum-based chemotherapy and that it can be safely combined with pembrolizumab. The ASCO data suggest that, in contrast to single-pathway blocking antibodies, nadunolimab's dual action in blocking both IL-1α and IL-1β can combat the emergence of resistance to therapy. The new arm of CIRIFOUR investigates nadunolimab's potential synergistic activity in the specific context of non-squamous NSCLC.

The phase Ib clinical trial CIRIFOUR (NCT04452214) investigates nadunolimab in combination with pembrolizumab. The first stage of CIRIFOUR indicated the potential to add further therapy to the nadunolimab/pembrolizumab combination. The new arm of CIRIFOUR represents a second stage expansion to evaluate nadunolimab/pembrolizumab with carboplatin/pemetrexed, a platinum-based chemotherapy commonly used in tandem with pembrolizumab for first-line treatment of non-squamous NSCLC.

The design of CIRIFOUR's second stage includes a dose escalation phase followed by an optional evaluation phase for the optimal dose. Up to 12 non-squamous NSCLC patients are expected to receive dose-escalated nadunolimab combined with standard doses of pembrolizumab and carboplatin/pemetrexed. The optimal dose of nadunolimab may be evaluated in a further 12 patients. The primary objective is safety with secondary objectives including assessment of antitumor activity and effects on biomarkers. Patients will be recruited across up to five clinical centers in the US and the dose escalation phase is expected to take up to 12 months.

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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 08.30 CET on 22 September 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 https://cantargia.com/en/.

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 in 73 patients with PDAC, resulting in median iPFS of 7.2 months and median survival of 12.7 months. Stronger efficacy was also observed in 30 NSCLC patients with median PFS of 6.8 months. A response rate of 53% was achieved, with even higher responses in non-squamous NSCLC 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 checkpoint inhibitor pembrolizumab, with or without chemotherapy, in the phase I study CIRIFOUR (NCT04452214).