Press release

Cantargia AB
556791-6019
22 September 2021

Cantargia: FDA grants Orphan Drug Designation to nadunolimab for treatment of pancreatic cancer

Cantargia AB today announced that the US Food and Drug Administration (FDA) has granted Orphan Drug Designation in the US to nadunolimab (CAN04) for the treatment of pancreatic cancer. This provides access to various incentives in the continued clinical development of nadunolimab in pancreatic cancer.

The interleukin-1 receptor accessory protein (IL1RAP)-binding antibody nadunolimab is Cantargia's lead program and is investigated in multiple clinical trials evaluating combination with chemotherapy regimens in various forms of cancer, including pancreatic ductal adenocarcinoma, PDAC, which accounts for more than 90% of all cases of pancreatic cancer.

The Orphan Drug Designation Program provides orphan status to drugs and biologics which are defined as those intended for the safe and effective treatment, diagnosis or prevention of rare diseases/disorders 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 rare diseases and the Orphan Drug Designation Program is available on www.fda.gov.

Nadunolimab is currently evaluated in ongoing clinical trials for treatment of PDAC. In CANFOUR, a phase I/IIa study, nadunolimab is investigated in approximately 70 patients with gemcitabine and nab-paclitaxel as first line combination in advanced PDAC, and in the phase Ib trial CAPAFOUR together with FOLFIRINOX as first line therapy in patients with metastatic PDAC. Interim efficacy data from 33 PDAC patients in the CANFOUR study show that the nadunolimab combination therapy results in durable responses or pseudoprogression, leading to prolonged progression-free survival (iPFS) and overall survival (OS) compared to historical control data. Preparations are ongoing for late-stage development in PDAC, to be initiated during 2022.

"*The Orphan Drug Designation by FDA provides several strategic advantages and is a valuable step forward in the development of nadunolimab. The designation also confirms Cantargia's strong commitment to provide new effective treatment options to patients with pancreatic cancer."* 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 16.30 CET on 22 September 2021.

About Cantargia
Cantargia AB (publ), reg. no. 556791-6019, is a biotechnology company that develops antibody-based treatments for life-threatening diseases. The basis for this is the protein IL1RAP that is involved in a number of diseases and where Cantargia has established a platform. The main project, the antibody CAN04, is being studied clinically as combination therapy 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 nadunolimab (CAN04)
The antibody CAN04 binds strongly to the target IL1RAP and functions both through ADCC as well as 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) https://clinicaltrials.gov/ct2/show/NCT03267316. Positive interim data for the combination therapies show durable responses or pseudoprogression in patients with PDAC, resulting in iPFS of 7.8 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. A phase I study, CAPAFOUR, was initiated in H1 2021 and investigates CAN04 in combination with the chemotherapy regimen FOLFIRINOX for first line treatment of metastatic PDAC (https://clinicaltrials.gov/ct2/show/NCT04990037). Another phase I study, CIRIFOUR, is also currently investigating CAN04 combined with an immune checkpoint inhibitor, with or without chemotherapy, and was started H2 2020 (https://clinicaltrials.gov/ct2/show/NCT04452214). Additional clinical combination studies with CAN04 are planned to initiate treatment of patients during 2021.