Press release

Cantargia AB
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Cantargia expands nadunolimab development in non-squamous NSCLC

Cantargia AB today announced the clinical development status and next steps of nadunolimab (CAN04) in combination with platinum-based chemotherapy in non-small cell lung cancer (NSCLC). As therapies differ between subgroups of NSCLC, future development needs to address segments in parallel and Cantargia will prioritize patients most likely to benefit. New interim data to be presented at the ESMO Congress, September 16-21, 2021, indicate the strongest anti-tumor effect in non-squamous NSCLC. In the next planned step, up to 40 patients with non-squamous NSCLC will be treated with nadunolimab and carboplatin/pemetrexed in the CANFOUR study. The first patient is expected to be enrolled during Q4 2021. In parallel, a randomized clinical study in this patient group is planned to start by the end of 2022. Development in other segments of NSCLC continue according to plan.

In the CANFOUR phase I/IIa trial, 30 out of the planned 31 patients with NSCLC have started combination treatment with first line chemotherapy and the last patient is expected to be enrolled during Q3 2021. The project has thus reached a stage where it is important to prioritize the development on the patient subgroup most likely to benefit from the therapy and combine nadunolimab with the standard therapy used in that segment.

Interim data in NSCLC from the CANFOUR study, which is carried out in treatment-naïve patients or relapsed on previous immunotherapy with pembrolizumab, was reported in September 2020 and showed much higher response rates for the nadunolimab combination than expected from chemotherapy alone. Updated results from the trial, to be presented in more detail at the ESMO Congress, September 16-21, 2021, reveal that the increased anti-tumor response by the nadunolimab combination compared to historical controls is more pronounced in patients with non-squamous NSCLC.

Supported by these new interim data and as a first step in a focused late-stage clinical development strategy, nadunolimab is now being advanced in non-squamous NSCLC, the largest subgroup of NSCLC, which constitutes about 70-80 per cent of all NSCLC cases[1]. The most frequently used first line platinum-based chemotherapy for this patient group is carboplatin/pemetrexed and up to 40 patients will receive this together with nadunolimab in a new arm in the CANFOUR protocol. The first patient is planned to be enrolled in Q4, 2021. In parallel, a randomized trial in this form of NSCLC is planned to start by the end of 2022. The design is dependent on e.g. emerging data and input from external experts as well as regulatory agencies.

"Based on the positive outcome of the extended analysis in CANFOUR, we are excited to take the next important step in the development of nadunolimab in NSCLC to address the high unmet needs in this area. As treatment strategies differ for patient groups with lung cancer, we are taking the opportunity to focus on patient groups most likely to benefit and advance other groups separately", said Göran Forsberg, CEO of Cantargia.

The interleukin-1 receptor accessory protein (IL1RAP)-binding antibody nadunolimab is Cantargia's most advanced program and is investigated in multiple clinical trials evaluating nadunolimab in combination with different chemotherapy regimens in NSCLC, pancreatic cancer and other forms of cancer. CANFOUR, a phase I/IIa trial, investigates nadunolimab first line combination with gemcitabine and nab-paclitaxel in patients with advanced pancreatic cancer, as well as with gemcitabine and cisplatin in NSCLC (https://clinicaltrials.gov/ct2/show/NCT03267316). In parallel, nadunolimab treatment of NSCLC is also investigated in combination with pembrolizumab, with or without chemotherapy, and in combination with docetaxel in second or third line. The next steps for development of nadunolimab in squamous NSCLC are currently further investigated.

Reference:
[1] Paz-Ares et al, N Engl J Med 2018; 379:2040-2051

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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 three ongoing clinical trials. In the first phase I/IIa-study, CANFOUR, first line combination therapy is investigated using two different standard chemotherapies in patients with NSCLC (gemcitabine/cisplatin) and patients with PDAC (gemcitabine/nab-paclitaxel), as well as monotherapy in late stage patients (https://clinicaltrials.gov/ct2/show/NCT03267316). Phase I monotherapy data from 22 patients were presented at ASCO 2019 and showed good safety with infusion-related reaction being the most common side effect. In addition, the biomarkers IL-6 and CRP decreased during treatment. Positive interim data from the combination therapies show durable responses or pseudoprogression in patients with PDAC, resulting in iPFS of 7.8 months, and also a higher response rate of patients with NSCLC, compared to chemotherapy alone. A phase I study, CAPAFOUR, was initiated in H1 2021 and will investigate CAN04 in combination with the chemotherapy regimen FOLFIRINOX for first line treatment of metastatic PDAC (https://clinicaltrials.gov/ct2/show/NCT04990037). A 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 are planned to start during 2021.

About NSCLC
Lung cancer is the most common cancer worldwide and in 2020, around 2.2 million new cases of lung cancer were diagnosed globally. More people die of lung cancer every year than any other cancer type resulting in more than 1.7 million people having lost their lives as a result of the disease. Around 85 per cent of all lung cancers are non-small cell lung cancer (NSCLC), which can be further subdivided into squamous and non-squamous, wherein the latter is the largest subgroup and accounts for 70-80 per cent of all cases. Treatment options are limited for people with lung cancer who experience cancer growth or progression while on standard of care treatments. The five-year survival rate for lung cancer is currently less than 20 per cent. Sales of drugs for non-small cell lung cancer totaled USD 19 billion in 2019 and are projected to increase to USD 33 billion by 2029.