Press release

Cantargia AB
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Cantargia: New positive interim results on nadunolimab combination therapy in NSCLC published in abstract for the annual ESMO Congress

Cantargia AB today announced the publication of an abstract disclosing novel clinical interim data from the CANFOUR study. The abstract was submitted in May 2021 for the upcoming ESMO Congress starting 16 September, 2021. In 15 non-small cell lung cancer (NSCLC) patients evaluated for efficacy, nadunolimab (CAN04) combined with gemcitabine/cisplatin showed an overall response rate (ORR) of 60%, a median duration of response (DOR) of 6.2 months and a median progression-free survival (PFS) of 8.2 months. All these efficacy parameters compare favorably to historical control data from gemcitabine/cisplatin only. The safety profile was good. The most notable adverse event was neutropenia occurring more frequently than expected from chemotherapy alone. The neutropenia can be managed with the use of G-CSF and/or by dose reductions. Further updated NSCLC data obtained from a read-out in August 2021 will be presented in the poster which will also be published on Cantargia's website.

Interim results from the phase II part of the ongoing CANFOUR study have been published in an abstract submitted to the upcoming ESMO Congress. In the abstract, new NSCLC data are disclosed and these are based on 22 patients, with 15 treated long enough to be included in an interim efficacy analysis. In summary, the efficacy of nadunolimab combination therapy is favorable compared to historical data for chemotherapy only. The ORR was 60% (1 complete response, 6 confirmed partial responses, and 2 partial responses in patients awaiting a confirmatory scan), which is higher than 22-28% in first line patients published for gemcitabine/cisplatin alone[1,2]. The median DOR of 6.2 months and PFS of 8.2 months compare favorably to historical control data showing median DOR of 5.1 months and PFS of 5.1 months[2]. The data also demonstrate a good safety profile. As previously reported, rates of neutropenia and febrile neutropenia are higher than expected from chemotherapy alone, although this can be controlled by proactive use of G-CSF and/or dose reductions. The abstract further discloses efficacy results from combination therapy in the pancreatic cancer (PDAC) combination arm.

The abstract can now be accessed through the conference website (https://www.esmo.org/meetings/esmo-congress-2021) and is based on results available at the time of submission in early May 2021. After abstract submission, updated results from the PDAC arm were presented on 19 May, 2021. Further updated NSCLC data obtained from a read-out in August 2021, will be presented in the poster.

"Presenting updated interim data at the ESMO conference is an important validation of nadunolimab and we look forward to the publication of a more complete data set at the conference. As communicated, the CANFOUR trial continues to recruit patients in preparation for upcoming randomized trials", 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 various chemotherapy regimens in NSCLC, PDAC and other forms of cancer. CANFOUR, a phase I/IIa clinical study, investigates nadunolimab with gemcitabine and cisplatin as first line combination or on progression after pembrolizumab in NSCLC patients, or with gemcitabine and nab-paclitaxel as first line combination in patients with advanced PDAC (https://clinicaltrials.gov/ct2/show/NCT03267316).

In the CANFOUR study, 30 out of the planned 31 patients with NSCLC have started treatment and the last patient is expected to be enrolled during the third quarter of 2021. An additional cohort of up to 40 patients with non-squamous NSCLC will then be enrolled in a new arm, where first or second line combination with carboplatin/pemetrexed will be evaluated. For PDAC, recruitment to an extension cohort was recently completed and data from this are planned to be presented in the first half of 2022.

References:
[1] Schiller et al, N Engl J Med 2002; 346: 92–98
[2] Scagliotti et al, J Clin Oncol 2008; 26: 3543–3551

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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 00.05 CET on 13 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 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.