Press release

Cantargia AB
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Cantargia presents positive interim data for nadunolimab combination therapy at ESMO Congress

Cantargia AB today presented novel interim results in non-small cell lung cancer (NSCLC) patients for nadunolimab (CAN04) in combination with gemcitabine/cisplatin at the ESMO Congress. The data read-out was conducted in August 2021 and the efficacy analysis includes 27 patients. In summary, compared to historical controls, the efficacy was higher than for chemotherapy alone, with an overall response rate (ORR) of 53 % in non-squamous NSCLC. In the total population, ORR was 48% and median progression-free survival (PFS) 7.2 months. Notably, the ORR is highest in patients with non-squamous NSCLC previously treated with pembrolizumab monotherapy. These data strongly support the most advanced development activities of nadunolimab in NSCLC; combination with chemotherapy in patients with non-squamous NSCLC after progression on immune therapy.

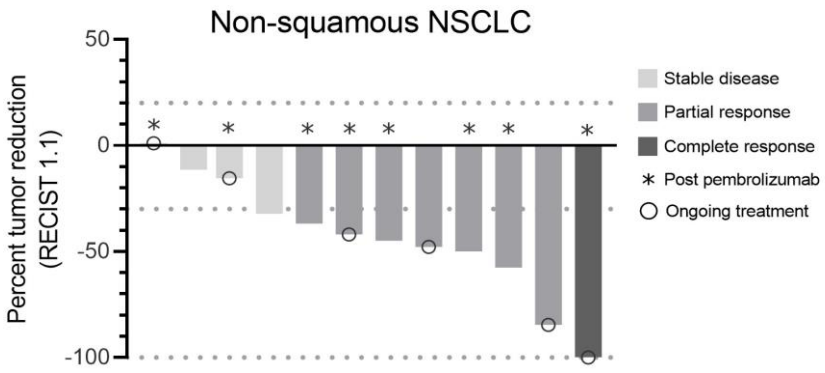
Cantargia today presented the poster titled "Nadunolimab (CAN04), a first-in-class monoclonal antibody against IL1RAP, in combination with chemotherapy in subjects with pancreatic cancer (PDAC) and non-small cell lung cancer (NSCLC)" at the ESMO Congress. The NSCLC data were compiled in August 2021 and include 27 patients available for efficacy analysis. The PDAC data are identical to those presented in May 2021 and include 33 patients evaluated for efficacy. Overall, the interim results indicate that nadunolimab together with chemotherapy adds benefit to both PDAC and NSCLC patients, compared to historical controls for chemotherapy alone. Several patients are still being treated and the plan is to present updated interim results in PDAC during Q4 2021 and in NSCLC during H1 2022. The poster is available at www.cantargia.com.

Summary of key interim results

	Total NSCLC (27 pts)	*Historical control*[1,2]	**Non-squamous NSCLC (15 pts)**	*Historical control*[3]	**Squamous NSCLC (11 pts)**	*Historical control*[4]	**PDAC (33 pts)**	*Historical control*[5]
ORR	48%	*22-28%*	53%	*19%*	36%	*38%*	27%*	*23%*
PFS	7.2 mo	*5.1 mo*	NR**		NR**		7.8 mo	*5.5 mo*
Ongoing treatment	11 pts (41%)		6 pts (40%)		5 pts (45%)		7 pts (21%)	

*15% additional patients benefit with a pseudoprogression-like response
**NR (not reported); will be analyzed with more mature data

Non-squamous NSCLC:
The 15 NSCLC patients with non-squamous histology showed a more pronounced benefit compared to those with squamous histology. The ORR was 53% (1 complete response (CR), 6 partial responses (PR) and 1 PR in a patient on therapy awaiting second confirmatory scan) with 6 patients still on therapy. Notably, the subgroup of 8 patients previously treated with pembrolizumab monotherapy showed an ORR of 75% (1 CR, 4 PR and 1 PR awaiting second confirmatory scan). These response rates are notably higher in comparison to historical control data for first line non-squamous NSCLC patients, showing an ORR of 19% for platinum-based chemotherapy[3]. Analyses for PFS and other efficacy parameters in this subgroup will be performed with more mature data, but as presented in the poster, a stronger efficacy in patients with non-squamous NSCLC is supported by the current results. The CANFOUR trial is currently expanded to allow 40 additional patients with non-squamous NSCLC to be treated with nadunolimab and the standard platinum doublet, carboplatin/pemetrexed. In parallel, preparations for a randomized trial are ongoing.



NSCLC total population:
By including all 27 patients into the analysis (15 non-squamous, 11 squamous and 1 uncharacterized), treatment with nadunolimab in combination with gemcitabine/cisplatin, shows an ORR of 48% (1 CR, 10 PR and 2 PR awaiting second confirmatory scan), which compares favorably to historical control data of 22-28% for chemotherapy alone[1,2]. These interim data include 11 patients still being treated, including 4 with tumor shrinkage scored as stable disease. Following treatment, so far only 54% of the patients have a progression event, resulting in a current median PFS of 7.2 months. These data show a stronger efficacy compared to NSCLC patients receiving first line gemcitabine/cisplatin alone, which show a median PFS of 5.1 months[2].

During the COVID-19 pandemic, recruitment and retention of NSCLC patients has been challenging, especially during periods of high infection rates. Four patients starting the combination treatment withdrew well ahead of the first efficacy analysis. Reasons include withdrawn consent and COVID-19 infection. These patients are included in the analysis.

PDAC:
Nadunolimab was also combined with gemcitabine/nab-paclitaxel for first line treatment of advanced PDAC and, similar to NSCLC, the results show efficacy stronger than expected from historical control data with chemotherapy alone. The most pronounced effects include a median iPFS of 7.8 months and overall survival (OS) of 12.6 months. Notably, in addition to a 27% ORR, a further 15% of patients had a pseudoprogression-like response leading to prolonged benefit. The historical control data show a median PFS of 5.5 months, median OS of 8.5 months and ORR of 23%[5]. The benefits in PFS and OS are driven by the durable responses and pseudoprogression-like events. Pseudoprogression has been reported for immune therapy in other cancer forms but is very rare in PDAC.

Safety:
Overall, the safety was acceptable and the observed side effects similar to those expected from the chemotherapy regimens. The exception is the higher incidence of neutropenia and febrile neutropenia of grade 3 or 4, observed primarily during the first cycle of chemotherapy. To prevent this, the protocol now advices more proactive use of G-CSF and/or dose reductions. Interestingly, no serious cases of neuropathy have been observed, which is a serious and common side effect of gemcitabine/nab-paclitaxel used in the combination therapy for PDAC patients. Neuropathy can lead to discontinuation of the chemotherapy in responding patients, and these data indicate that nadunolimab may counteract this problem.

"We are happy to present these updated positive clinical results at one of the major clinical oncology conferences. The results strongly support our development strategies for nadunolimab to increase efficacy with chemotherapy in both NSCLC and PDAC and provide valuable information on patients most likely to benefit. We are grateful to the patients and clinical centres participating in the trial, and their extra-ordinary contributions during the COVID-19 pandemic." said Göran Forsberg, CEO of Cantargia.

References:
[1] Schiller et al, N Engl J Med 2002; 346:92–98
[2] Scagliotti et al, J Clin Oncol 2008; 26:3543–3551
[3] Gandhi et al, N Engl J Med 2018; 378:2078-2092
[4] Paz-Ares et al, N Engl J Med 2018; 379:2040-2051
[5] von Hoff et al, N Engl J Med. 2013, 369(18),1691-1703

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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 16 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.