Press release

Cantargia AB
556791-6019
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Cantargia reports positive interim data from ongoing phase IIa combination study with antibody CAN04

Cantargia AB today announced the first interim data with antibody CAN04 in combination with chemotherapy in the ongoing phase IIa CANFOUR study. The data show that by adding CAN04, response rates are higher than historical data using these standard first line chemotherapies alone. 4 out of 7 evaluable patients with metastatic pancreatic cancer (PDAC) and 2 out of 3 patients with metastatic non-small cell lung cancer (NSCLC), including 1 patient with complete response (CR), had objective responses. No major side effects were observed apart from those expected with chemotherapy or CAN04. The completion of recruitment is expected early Q2 2020 (PDAC) and early Q3 2020 (NSCLC).

"This early-stage analysis of safety and efficacy in patients with metastatic cancer is really exciting. Response rates are higher than historical data and includes a patient with complete response. This fits with the hypothesis that CAN04 can be synergistic with chemotherapy and counteract chemoresistance", said Göran Forsberg, CEO at Cantargia.

Cantargia develops antibody-based pharmaceuticals against the interleukin 1 receptor accessory protein (IL1RAP). The antibody CAN04 binds IL1RAP with high affinity and functions through both ADCC and blockade of IL-1α and IL-1β signaling. CAN04 is investigated in the open label phase I/IIa clinical trial, CANFOUR, examining first line chemotherapy combination with two different standard regimes in patients with advanced NSCLC or PDAC, as well as monotherapy in late stage patients (www.clinicaltrials.gov).

So far in the combination arms, 4 patients with PDAC and 4 with NSCLC have initiated CAN04 therapy at 5 mg/kg, and 6 PDAC patients have started at 7.5 mg/kg. The current status and new results are summarized in the table below and show response rates higher than expected with chemotherapy alone.

	Initiated	On therapy	Evaluable	CR/PR	SD	PD
PDAC	10	7	7	4*		3**
NSCLC	4	3	3	2*	1	

*All patients except 1 PDAC and 1 NSCLC have responses confirmed on second scan. 3 of 4 PDAC patients with objective response has a sustained decrease of >90 % of CA19-9. In NSCLC, 1 patient has a confirmed complete response (CR). **1 patient has ongoing tumor shrinkage after initial progression and a strong reduction in CA19-9. 1 patient terminated after rapid clinical progression without CT-scan.

Of the 7 metastatic PDAC patients that have been evaluated for efficacy, 4 patients have partial response (PR), of whom 3 have more than 90% decrease in CA19-9, a biomarker for pancreatic cancer tumor burden. The 3 remaining patients have radiological or clinical progressive disease (PD) but notably, 1 of these patients got tumor shrinkage after the initial progression and a strong decrease in CA19-9, thus indicating a so-called pseudo progression sometimes observed with immunotherapy and indicative of treatment benefit. Thus, 5 patients have objective response or pseudo progression and 4 patients have a >90% decrease in CA19-9 after start of therapy. Of the 10 patients included to date, 7 are still on therapy, including all 3 patients in the first safety cohort starting more than 6 months ago. 3 patients have stopped therapy: 1 after clinical progression, 1 after radiological progression and 1 withdrew consent after first infusion.

In the treatment arm metastatic NSCLC, 1 patient has a confirmed CR, 1 patient has PR and 1 patient stable disease (SD). Also in this indication, 1 patient withdrew consent after the first infusion. All the NSCLC patients have previously received first line immunotherapy (pembrolizumab) before entering the CANFOUR trial.

For reference, historical response rates with the investigated chemotherapies are 23% in PDAC[1] and 22-28% in first line NSCLC[2,3] patients. CR is reported in 1% of patients or less. Historically, a >90% reduction of CA19-9 is reported in 31% of PDAC patients after gemcitabine/abraxane therapy[1].

"After I presented the CAN04 monotherapy data at ASCO 2019, the CANFOUR trial has advanced with the combination therapy. The initial results are very encouraging in non-small cell lung cancer (pretreated with checkpoint inhibitor) and pancreatic cancer and suggest that CAN04 could be a valuable contribution to improve

the chemotherapy regimes in these diseases", said Prof Ahmad Awada, coordinating investigator for the CANFOUR trial at Institute Jules Bordet, Brussels, Belgium.

The most predominant side effect observed with CAN04 is in line with the previously reported phase I data, i.e. a low-grade infusion related reaction during the first infusion. Besides this side effect, the adverse events observed are those expected with chemotherapy. The most common grade 3 and 4 toxicities include neutropenia, thrombocytopenia, fatigue.

The recruitment in PDAC essentially follows communicated timelines, with last patient in expected early Q2 2020. Recruitment in NSCLC has been slightly slower, and therefore additional sites are being initiated in Estonia, Latvia, Lithuania and Spain. Last NSCLC patient in is expected early Q3 2020.

In addition to chemotherapy combination, CANFOUR includes a phase IIa monotherapy arm primarily analyzing safety and biomarkers in patients with late-stage disease. Biopsy and biomarker analyses are ongoing from patients treated at 10 mg/kg with results expected during Q1 2020. Treatment at 15 mg/kg has started, and up to 12 patients will be included with results expected in Q2 2020.

[1] Von Hoff et al, N Engl J Med 2013; 369: 1691–703
[2] Schiller et al, N Engl J Med 2002; 346: 92–98
[3] 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 10.30 CET on 2 December 2019.

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 in the clinical phase I/IIa CANFOUR with a primary focus on non-small cell lung cancer and pancreatic cancer. The study is conducting both monotherapy and combination therapy. Cantargia's other project, CANxx, is in the research phase and is aiming to develop a IL1RAP binding antibody optimized for the treatment of autoimmune and inflammatory diseases.

Cantargia is listed on Nasdaq Stockholm (ticker: CANTA). More information about Cantargia is available at http://www.cantargia.com..

About CAN04
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