

## **Cantargia to present promising nadunolimab efficacy in non-small cell lung cancer at ASCO 2023, including two complete responses**

**Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today reported it will present updated interim efficacy data for 39 non-small cell lung cancer (NSCLC) patients treated with nadunolimab (CAN04) and platinum-based chemotherapy at the ASCO Annual Meeting (ASCO 2023) in Chicago on June 4, 2023. The results have demonstrated improvement since the previous update with objective response rate (ORR), progression-free survival (PFS) and overall survival (OS) comparing very favorably to historical data for chemotherapy alone. Notably, two non-squamous NSCLC patients with similar biomarker profiles achieved complete response, including one patient during nadunolimab monotherapy after termination of chemotherapy.**

*"The updated results provide further evidence that nadunolimab can play an important role in the huge and competitive lung cancer field, either as combination therapy in a subgroup of patients or potentially as monotherapy after termination of chemotherapy. Following our recent very promising results in pancreatic cancer, these new data further indicate that nadunolimab provides additional benefit to chemotherapy in several types of cancer,"* said Göran Forsberg, CEO of Cantargia.

The two non-squamous NSCLC patients with complete response received nadunolimab with cisplatin/gemcitabine and had previously progressed on therapy with Keytruda®. Analyses of tumor biopsies taken at trial entry showed that both lacked PD-L1 positive tumor cells but had high levels of PD-L1 positive immune cells and CD8 positive T cells. One of the complete responses was achieved after almost 9 months of nadunolimab monotherapy, given after termination of chemotherapy, while the other had a rapid response to the combination therapy that has been maintained for over 3 years.

In total, 44 NSCLC patients received nadunolimab and platinum-based chemotherapy across two clinical studies, with 39 long enough to be evaluable for efficacy. Of these, 30 received nadunolimab at 1, 2.5 or 5 mg/kg with cisplatin/gemcitabine in the phase IIa part of the CANFOUR trial. Efficacy analyses for these patients showed an ORR of 53%, with median OS and PFS of 13.7 months and 7.0 months, respectively, and a dose-response trend for PFS. The strongest clinical benefit was observed in 16 patients with non-squamous NSCLC, including 15.9 months median OS. These data are stronger than historical data for chemotherapy only and are summarized below:

Efficacy parameter	All (n=30)	Historical control [1,2]	Non-squamous (n=16)	Non-squamous, historical control [3]
Median OS	13.7 mo	10.3 mo	15.9 mo	11.3 mo
Median PFS	7.0 mo	5.1 mo	7.3 mo	4.9 mo
ORR	53%	22-28 %	56%	19%
Complete response	6.7% (n=2)	<1%	12.5% (n=2)	<1%

Ten additional non-squamous NSCLC patients received nadunolimab with carboplatin/pemetrexed in the CANFOUR trial, with five long enough for initial efficacy assessment. Of these, three showed partial response and two stable disease (preliminary ORR 60%). Also, four third-line or beyond NSCLC patients were given nadunolimab and cisplatin/gemcitabine in the phase I/II CESTAFOUR trial, and two showed confirmed partial responses (preliminary ORR 50%). Collectively, this indicates consistently high response rates to nadunolimab in combination with platinum doublets in different lines of therapy. These patients are now monitored to provide more mature data for ORR, PFS and OS.

Further analyses show that the therapy decreased blood levels of CRP and several tumor-stimulating biomarkers, e.g. HGF, MCP-2, MCP-3 and MCP-4, linked to nadunolimab's mechanism of action. These changes were observed during combination therapy, as well as after termination of chemotherapy when patients were only given nadunolimab monotherapy.

These clinical data are based on read-outs conducted in March-April 2023 and will be presented in a poster session at ASCO 2023 on June 4, 2023 with additional details below. An abstract based on data from September 2022 is now published at the ASCO website ([www.asco.org/abstracts](http://www.asco.org/abstracts)). At the time of presentation, the poster will also be made available at Cantargia's webpage ([www.cantargia.com/en/research-development/publications](http://www.cantargia.com/en/research-development/publications)).

**Abstract Number and Title:** #9089 Safety, efficacy and biomarker data in non-small cell lung cancer patients treated with the anti-IL1RAP antibody nadunolimab in combination with platinum doublet

**Session:** Lung Cancer – Non-Small Cell Metastatic

**Session Date and Time:** Sunday, June 4, 2023 at 8:00 AM-11:00 AM CDT

**Presenter:** Dr. Luis Paz-Ares

### 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

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*This information is information that Cantargia is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-05-25 23:00 CEST.*

**About Cantargia**

Cantargia AB (publ), reg. no. 556791-6019, is a biotechnology company that develops antibody-based treatments for life-threatening diseases and has established a platform based on the protein IL1RAP, involved in a number of cancer forms and inflammatory diseases. The main program, the antibody nadunolimab (CAN04), is being studied clinically primarily in combination with chemotherapy with a focus on pancreatic cancer, non-small cell lung cancer and triple-negative breast cancer. Positive interim data for the combinations indicate stronger efficacy than would be expected from chemotherapy alone. Cantargia's second development program, the antibody CAN10, blocks signaling via IL1RAP in a different manner than nadunolimab and 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](http://www.cantargia.com).

**About nadunolimab (CAN04)**

The antibody nadunolimab binds strongly to its target IL1RAP and functions by inducing ADCC and blocking IL-1alpha and IL-1beta signaling. Nadunolimab can thereby counteract the IL-1 system which contributes to the immune suppressive tumor microenvironment and development of resistance to chemotherapy. Nadunolimab is investigated in multiple clinical trials; the phase I/IIa trial CANFOUR evaluates nadunolimab in combination with standard chemotherapies in patients with PDAC (gemcitabine/nab-paclitaxel) or NSCLC (platinum-based chemotherapies) ([NCT03267316](#)). Positive interim data show durable responses for the combination therapy in 73 PDAC patients, resulting in median iPFS of 7.2 months and median OS of 12.9 months. An even higher median OS of 14.2 months was observed in a subgroup of patients with high tumor levels of IL1RAP. Strong efficacy was also observed in 30 NSCLC patients with median PFS of 7.0 months and a response rate of 53%; even higher responses were observed in non-squamous NSCLC patients. Early efficacy data from the phase Ib/II trial TRIFOUR ([NCT05181462](#)) also shows signs of promising efficacy in TNBC with a 50% response rate for nadunolimab combined with carboplatin/gemcitabine. Nadunolimab is also investigated with chemotherapy in the clinical trials CAPAFOUR ([NCT04990037](#)) and CESTAFOUR ([NCT05116891](#)), and with the checkpoint inhibitor pembrolizumab in the CIRIFOUR trial ([NCT04452214](#)).

**Attachments**

**[Cantargia to present promising nadunolimab efficacy in non-small cell lung cancer at ASCO 2023, including two complete responses](#)**