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# Cantargia's announces publication of clinical data demonstrating potential of nadunolimab plus pembrolizumab in solid tumors

- Results published in the peer-reviewed journal Investigational New Drugs
- Study in heavily pre-treated patients with solid tumor indications who had progressed on prior immune checkpoint inhibitors
- Median overall survival of 19.7 months, with greatest survival benefit in patients with high baseline levels of infiltrating immune cells in the tumor microenvironment

Cantargia (Cantargia AB; Nasdaq Stockholm: CANTA) today announced the publication of results from a clinical trial with nadunolimab in combination with pembrolizumab in the journal Investigational New Drugs. 15 heavily pre-treated patients with solid tumor indications who had previously progressed on immune checkpoint inhibitors were treated with nadunolimab and pembrolizumab. The trial showed an acceptable safety profile, with encouraging median survival times, especially in patients with a high level of immune cell infiltration in the tumor. These clinical data suggest a unique role of nadunolimab acting on immune cells in the tumor microenvironment.

"The vast number of patients whose cancer progresses on immunotherapy such as pembrolizumab have limited treatment options. These data, showing a long median survival with nadunolimab plus pembrolizumab, suggests that this combination may offer a new way to treat these high need patients." said Dr Roger Cohen from University of Pennsylvania.

Immune checkpoint therapies targeting PD1, including pembrolizumab, have been some of the most transformative cancer treatments. These therapies are, however, subject to resistance mechanisms leading to loss of efficacy with time and many patients do not respond at all. The published data from the CIRIFOUR clinical trial of nadunolimab in combination with pembrolizumab in 15 patients highlights a unique opportunity to use nadunolimab in patients that have lost response to immune checkpoint inhibitors.

The CIRIFOUR trial investigated nadunolimab combination therapy with pembrolizumab in 15 heavily pretreated patients who had previously progressed on treatment with checkpoint inhibitors. Nine patients had head and neck cancer, five non-small cell lung cancer (NSCLC) and one melanoma. The combination therapy was safe and well tolerated, and with an encouraging median survival of 19.7 months and a disease control rate of 60%. The strongest benefits were observed in a group of patients with a specific immune profile with high baseline levels of macrophages and natural killer cells in the tumor microenvironment.

The publication, titled "Safety, tolerability, and preliminary efficacy of nadunolimab, an anti-IL-1 receptor accessory protein monoclonal antibody, in combination with pembrolizumab in patients with solid tumors", by Cohen et al, is available online at the Investigational New Drugs web page and via Cantargia's web page.



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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 and has established a platform based on the protein IL1RAP, involved in a number of cancer forms and inflammatory diseases. Cantargia's oncology 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 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 hidradenitis suppurativa and systemic sclerosis.

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

# **About nadunolimab (CAN04)**

The antibody nadunolimab binds strongly to its target IL1RAP and functions by inducing ADCC and blocking IL-1 $\alpha$  and IL-1 $\beta$  signaling. Nadunolimab can thereby counteract the IL-1 system which contributes to the immune suppressive tumor microenvironment and the development of resistance to chemotherapy. Nadunolimab is investigated in multiple clinical trials; the phase I/IIa trial CANFOUR, NCT03267316, evaluates nadunolimab in combination with standard chemotherapies in patients with pancreatic ductal adenocarcinoma (PDAC) (gemcitabine/nab-paclitaxel) or non-small cell lung cancer (NSCLC) (platinum-based chemotherapies). Positive data show durable responses for combination therapy in 73 PDAC patients, resulting in a median iPFS of 7.2 months and median OS of 13.2 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 40 NSCLC patients with median PFS of 7.2 months and a response rate of 55%; even higher responses were observed in non-squamous NSCLC patients. Early efficacy data from the phase 1b/2 trial TRIFOUR, NCT05181462, also shows signs of promising efficacy in TNBC with a 60% response rate for nadunolimab combined with carboplatin/gemcitabine.

### **Attachments**

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