PRESS RELEASE
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Cantargia's nadunolimab antibody awarded US FDA Fast Track Designation

- **Fast Track Designation (FTD) granted for the treatment of patients with metastatic PDAC with high IL1RAP expression levels.**
- **Reflects high unmet medical need in metastatic PDAC.**
- **Facilitates further development of nadunolimab with more frequent FDA interactions and eligibility for *Accelerated Approval* and *Priority Review*.**

Cantargia (Cantargia AB (publ); NASDAQ Stockholm: CANTA), today announced that the U. S. Food and Drug Administration (FDA) has granted Fast Track Designation to nadunolimab, Cantargia's anti-IL1RAP antibody for the treatment of patients with previously untreated metastatic pancreatic ductal adenocarcinoma (PDAC) with high expression levels of IL1RAP in combination with gemcitabine and nab-paclitaxel. The FTD follows strong clinical data from the CANFOUR study showing a two-year survival of 35%, an overall survival (OS) of 14.2 months and overall response rate (ORR) of 48% in this patient population.

"The recognition from the FDA for our clinical and translational data on nadunolimab and the future path in pancreatic cancer is an outstanding development for Cantargia. The support from the FDA for the continued development of nadunolimab in the high IL1RAP subset of PDAC patients further strengthens our efforts to bring this potentially important new treatment to these patients who currently lack options", said Damian Marron, CEO of Cantargia.

Fast Track Designation is a tool and a process designed by the FDA to facilitate the development and expedite the review of drugs that treat serious conditions and fill an unmet medical need. The purpose is to get important new drugs to the patient earlier. The benefits of a Fast Track Designation include:

- More frequent meetings and communication with the FDA.
- Eligibility for *Accelerated Approval* and *Priority Review,* if relevant criteria are met.
- *Rolling Review* with the opportunity to submit completed sections of a Biologic License Application (BLA) for review by FDA, rather than waiting until every section of the BLA is completed[1].

Nadunolimab, a fully humanized Fc-enhanced IgG1 monoclonal antibody targeting IL1RAP, is being developed as a treatment for PDAC, a serious and life-threatening malignant neoplasm of the pancreas. The prognosis of metastatic PDAC is invariably poor. Treatment options are limited and overall survival (OS) after first-line treatment for metastatic PDAC is <12 months. 5-year survival probability is <5% for metastatic disease, and the prognosis has not greatly improved over the past 20 years. High levels of IL1RAP, the target of nadunolimab, in the tumor are associated with shorter survival[2].

In the CANFOUR Phase 2 trial, IL1RAP protein expression in tumor biopsies was measured by immunohistochemistry from a total of 49 patients. Notably, the subgroup of patients with high baseline expression of IL1RAP had a significantly higher benefit from treatment than patients with low baseline expression: median OS 14.2 vs. 10.6 months (p=0.012), median PFS 7.4 vs. 5.1 (p=0.012) months and ORR 48% vs. 30% (p=0.205)[3] . 2-year survival rate in the IL1RAP high patients was 35%.

Cantargia is currently preparing for the next stage of clinical development by developing a diagnostic test to identify patients with high IL1RAP expression for inclusion into future clinical studies.

References:

1. **https://www.fda.gov/patients/fast-track-breakthrough-therapy-accelerated-approval-priority-review/fast-track**
2. Hansen et al, Journal for ImmunoTherapy of Cancer (2024) - **Blocking IL1RAP on cancer-associated fibroblasts in pancreatic ductal adenocarcinoma suppresses IL-1 induced neutrophil recruitment**
3. van Cutsem et al, Clinical Cancer Research (2024) - **Efficacy and Safety of the Anti-IL1RAP Antibody Nadunolimab (CAN04) in Combination with Gemcitabine and Nab-Paclitaxel in Patients with Advanced/Metastatic Pancreatic Cancer**

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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-1α and IL-1β 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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