

APIM THERAPEUTICS ANNOUNCES THAT THE FIRST PATIENT HAS BEEN TREATED WITH ATX-101 IN A PHASE I/II OVARIAN CANCER STUDY

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APIM Therapeutics (APIM), a clinical stage biotech company, focusing on the development of novel peptide therapeutics targeting PCNA (Proliferating Cell Nuclear Antigen), announced today that the first patient has been treated in a clinical Phase 1b/2a study in ovarian cancer.

The clinical study (ClinicalTrials.gov Identifier: NCT04814875) investigates ATX-101, the lead compound of APIM's development program, in combination with platinum-based chemotherapy in patients suffering from recurrent, platinum sensitive ovarian, fallopian tube and primary peritoneal cancer. The study consists of 2 parts; Part 1 is a safety part with dose limiting toxicity as primary endpoint, Part 2 is an efficacy part with progression free survival as primary endpoint. Approximately 72-78 patients will be treated.

The study started recruitment in Australia; further APAC sites will be opened soon. Prof Tarek Meniawy is the Coordinating Investigator of this study. "Although a lot of progress has been made in the treatment of ovarian cancer over the last years, it remains a life-threatening disease and new treatment approaches are needed." Dr. Meniawy said. "ATX-101 is a first-in-class compound with the potential to boost the effect of standard of care chemotherapy."

"This proof-of-concept study is an important step for APIM Therapeutics. Preclinical data have shown that ATX-101 can potentiate the effect of a wide range of anticancer therapies." said Dr. Kostas Alevizopoulos, CEO of APIM. "In particular, the combination of ATX-101 with platinum-based therapies has shown very promising data. This clinical study is the logical next step in our development program."

ATX-101 has been investigated as single agent in a Phase 1 study which has been finished recently. "Data have shown that ATX-101 infusions are well tolerated and indicate clinical activity in late-stage solid tumors." Dr. Jens-Peter Marschner, CMO of APIM Therapeutics, said. "Ovarian cancer is an appropriate indication to investigate the combination of ATX-101 with platinum-based chemotherapy. We have discussed this development step with experts and authorities, including the FDA. A proof-of-concept for this combination could open the doors for further cancer indications with high medical need."

About ATX-101

ATX-101 is a first-in-class, cell penetrating peptide featuring a novel PCNA-interacting motif (AlkB homolog 2 PCNA Interacting Motif or APIM). In preclinical experiments, it was shown that APIM-containing proteins bind to PCNA and mediate processes of escape mechanisms and survival of cancer cells. ATX-101 competitively inhibits interaction of PCNA with APIM-containing protein complexes resulting in cancer cell death and altered cellular signaling. These properties translate in anticancer effects of ATX-101 as demonstrated in several preclinical models *in vitro* and *in vivo*.

About ovarian cancer

The term "ovarian cancer" also covers cancer of the fallopian tubes and primary peritoneal cancer. Epithelial ovarian cancer (90% of all ovarian cancers) is the gynecological cancer with the highest death rate. 75% of patients treated with initial standard platinum-based chemotherapy are platinum sensitive, i.e., they show a relatively long stabilization of disease. But almost all patients experience tumor progression after some time. New drugs have been approved over the last years which extend the disease stabilization, but ovarian cancer remains a life-threatening disease with a high unmet medical need.

About APIM Therapeutics:

APIM Therapeutics AS is a privately held biotechnology company based on an original discovery by Prof. Marit Otterlei and co-inventors at the Norwegian University of Science and Technology (NTNU) in Trondheim, Norway. The Company targets a new therapeutic intervention point based on selective inhibition of PCNA, a key organizer protein modulating stress responses in cancer cells of a broad variety of tumor entities. Please visit www.apimtherapeutics.com for additional information.

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