



APIM Therapeutics announces FDA Acceptance of IND Application for ATX-101 in Ovarian Cancer.

10 May 2021

APIM Therapeutics AS (“APIM Therapeutics” or the “Company”), an oncology focused biotechnology company developing innovative anti-cancer treatments targeting stress responses in tumor cells, is pleased to announce that the U.S. Food and Drug Administration (FDA) has accepted its Investigational New Drug application (IND) for a Phase 1b/2a clinical trial to investigate ATX-101 in combination with platinum-based therapy in ovarian cancer. The trial will be conducted in Australia, South Korea and Taiwan.

“The acceptance of the IND is an important milestone for the Company” the Chief Executive Officer of APIM Therapeutics, Kostas Alevizopoulos, commented. “It is the next step in our global development strategy aiming to demonstrate proof of concept of our lead compound ATX-101.”

The clinical trial will investigate ATX-101 in combination with a platinum-based chemotherapy in platinum sensitive recurrent ovarian, fallopian tube or primary peritoneal cancer (ClinicalTrials.gov identifier: NCT04814875). Based on strong evidence from preclinical data, the trial was designed to demonstrate safety and potentiating efficacy of ATX-101 when administered in combination with standard of care (SoC). “Although new compounds like PARP inhibitors improve the clinical outcome of currently available treatments, recurrent ovarian cancer remains a devastating disease.” Jens-Peter Marschner, APIM Therapeutic’s Chief Medical Officer said. “We believe that the addition of our first-in-class compound ATX-101 to SoC will help patients to fight their cancer.”

The study, sponsored by THERAPIM PTY LTD, a subsidiary of APIM Therapeutics, will start in Q2 2021 with the first patient treated in Q3 2021. Safety and first efficacy data are expected in the second half 2022.

For further information, please contact:

Kostas Alevizopoulos, CEO
contact@apimtherapeutics.com
Tel: +47 73 49 4838

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 Proliferating Cell Nuclear Antigen, a key organizer protein modulating stress responses in cancer cells of a broad variety of tumor entities. The first-in-class lead candidate ATX-101 is currently entering Phase 2 in clinical development.