**PRESS RELEASE**
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# ALLIGATOR BIOSCIENCE ANNOUNCES FDA AUTHORIZATION TO INITIATE MITAZALIMAB OPTIMIZE-2 PHASE 2 TRIAL IN UROTHELIAL CARCINOMA

- **OPTIMIZE-2 is a Phase 2 study to assess the safety and efficacy of mitazalimab in combination with a PD-1 inhibitor in patients affected by urothelial carcinoma**
- **Mitazalimab in combination with mFOLFIRINOX is currently in Phase 2 clinical development in pancreatic cancer (OPTIMIZE-1 trial)**

**Lund, Sweden – Alligator Bioscience (Nasdaq Stockholm: ATORX)** today announced that the U.S. Food and Drug Administration (FDA) has cleared the company's Investigational New Drug (IND) application, allowing the company to initiate the OPTIMIZE-2 Phase 2 trial evaluating its lead asset mitazalimab in urothelial carcinoma.

Urothelial carcinoma accounts for approximately 90 percent of bladder cancers, which is the most common malignancy involving the urinary system**[1]**, with 83,000 new patients and 16,700 deaths each year in the U.S.**[2]**

This open-label, multi-center study aims to assess the safety and efficacy of an immunotherapeutic combination of mitazalimab (CD40 mAb) and a PD-1 inhibitor, in adult patients with histologically confirmed urothelial carcinoma, and who have progressed following prior treatment with PD-(L)1 therapy. The study will take place in approximately 15 to 20 clinical sites across the U.S. and Europe.

*"This IND approval allows us to advance our lead asset mitazalimab into clinical development in a new indication, urothelial carcinoma, the most common type of bladder cancer,"* said **Søren Bregenholt, CEO of Alligator Bioscience.** *"We have demonstrated the clinical activity of mitazalimab in combination with chemotherapy in an interim analysis of OPTIMIZE-1, showing its potential to provide significant clinical benefit over standard of care. The experiences and data from the mitazalimab program thus far was used to de-risk and enhance the design of OPTIMIZE-2, and we strongly believe in mitazalimab's potential to benefit patients with urothelial carcinoma that has become refractory to prior checkpoint inhibitor-therapy."*

OPTIMIZE-2 will consist of a dose-finding phase with two mitazalimab dose levels in combination with a PD-1 inhibitor to select a recommended Phase 2 dose (RP2D). Thereafter, patient enrolment will be expanded at the RP2D, enabling primary analysis. Objective response rate as per RECIST 1.1 criteria will be the primary efficacy endpoint of the study.

Alligator Bioscience expects the OPTIMIZE-2 study to begin in H1 2024, or earlier, subject to operational feasibility.

Mitazalimab is currently being evaluated in OPTIMIZE-1, a Phase 1b/2 study assessing its safety and efficacy in combination with mFOLFIRINOX in patients with previously untreated metastatic pancreatic cancer. **Interim efficacy results from the Phase 2 part of the trial announced in January** demonstrated a 52% objective response rate. Top-line data from this trial are expected in Q1 2024.

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**[1]** Saginala, Kalyan et al. “Epidemiology of Bladder Cancer.” Medical sciences (Basel, Switzerland) vol. 8,1 15. 13 Mar. 2020, doi:10.3390/medsci8010015
**[2]** American Cancer Society

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*The information was submitted for publication, through the agency of the contact person set out above, at 8:00 a.m. CEST on April 3, 2023.*

## About Alligator Bioscience

Alligator Bioscience AB is a clinical-stage biotechnology company developing tumor-directed immuno-oncology antibody drugs. Alligator's portfolio includes several promising drug candidates, with the CD40 agonist mitazalimab as its key asset. Furthermore, Alligator is co-developing ALG.APV-527 with Aptevo Therapeutics Inc., several undisclosed molecules based on its proprietary technology platform, Neo-X-Prime™, and novel drug candidates based on the RUBY™ bispecific platform with Orion Corporation. Out-licensed programs include AC101/HLX22, in Phase 2 development, by Shanghai Henlius Biotech Inc. and an undisclosed target to Biotheus Inc.

Alligator Bioscience's shares are listed on Nasdaq Stockholm (ATORX) and is headquartered in Lund, Sweden.

For more information, please visit **alligatorbioscience.com**.

## Attachments

**Alligator Bioscience Announces FDA Authorization to Initiate Mitazalimab OPTIMIZE-2 Phase 2 Trial in Urothelial Carcinoma**