

## ALLIGATOR BIOSCIENCE ANNOUNCES PUBLICATION HIGHLIGHTING PHASE 1 MITAZALIMAB DATA IN SOLID TUMORS IN PEER- REVIEWED JOURNAL "INVESTIGATIONAL NEW DRUGS"

- Data confirm mitazalimab's manageable safety profile via a thorough dose-escalation approach via intravenous administration
- Pharmacokinetic profile was favorable, typical for a CD40-agonistic monoclonal antibody
- Biomarker profile confirmed the expected biological activity
- Clinical activity observed in this study further support continued development of mitazalimab as a part of immunotherapeutic regimens in solid malignancies
- Mitazalimab is currently in Phase 2 in 1st line pancreatic cancer in combination with mFOLFIRINOX with interim data is due in first weeks of January 2023, and topline primary analysis data in Q1 2024

**Lund, Sweden, December 22, 2022 - Alligator Bioscience (Nasdaq Stockholm: ATORX)** today announces the publication of a peer-reviewed article highlighting data from a Phase 1 dose-escalation study evaluating the safety, dose-limiting toxicities (DLTs), pharmacokinetic (PK) and pharmacodynamic (PD) profile of its lead clinical asset mitazalimab in patients with advanced solid malignancies (NCT02829099).

The publication in the journal *Investigational New Drugs* highlights the manageable safety profile of mitazalimab in multiple advanced solid malignancies. Mitazalimab was administered at doses up to 2000 µg/kg (with pre-infusion corticosteroids) and 1200 µg/kg (without corticosteroids). No Dose-Limiting Toxicities (DLTs) were seen at doses up to 900 µg/kg, the dose which is being pursued in the ongoing clinical study OPTIMIZE-1. Unlike other CD40 agonists, no cytokine release syndrome was reported. Pharmacokinetic profile was favorable, typical of a CD40 agonist mAb. Pharmacodynamic results demonstrated immune activation, as indicated by increased cytokines and chemokines, consistent with its proposed mechanism as a CD40 agonist.

Mitazalimab displayed clinical anti-tumor activity in this study with a partial response observed in a patient with renal cell carcinoma and stable disease (SD) reported in 36.8% of patients with varied tumor types, which lasted for more than six months in 9 patients (thymoma [n=3], sarcoma, adamantinoma, melanoma, cholangiocarcinoma, salivary gland carcinoma, and pancreatic adenocarcinoma [n=1 each]).

Overall, these findings support our ongoing and future trials exploring mitazalimab

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22 December 2022 09:30:00 CET



as an immunomodulatory agent in patients with advanced solid malignancies in combination with standard of care.

The full article, entitled "**A Phase 1 Study of Intravenous Mitazalimab, a CD40 Agonist Monoclonal Antibody, in Patients with Advanced Solid Tumors**", is available online [via this link](#).

*"The data presented in this publication provides further evidence of mitazalimab's good safety and tolerability profile and adds to our growing knowledge about this CD40 agonist and the potential it possesses," said **Søren Bregenholt, CEO of Alligator Bioscience**. "We are very pleased to have these data published as it provides additional insights supporting ongoing clinical development of mitazalimab, particularly the OPTIMIZE-1 trial, which is making great progress towards its 2024 top-line readout."*

Alligator is evaluating mitazalimab in combination with mFOLFIRINOX in OPTIMIZE-1, a Phase 1b/2 trial in first-line metastatic pancreatic cancer (NCT04888312). Data from the Phase 1b dose escalation phase of the trial showed mitazalimab in combination with mFOLFIRINOX is safe and well tolerated at the recommended dose of 900 µg/kg. Interim data from the study is expected the first weeks of January, and top-line data in Q1 2024.

The information was submitted for publication, through the agency of the contact person set out below, at 9:30 a.m. CET on December 22, 2022.

**For further information, please contact:**

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## **About Alligator Bioscience**

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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](https://alligatorbioscience.com).

## **Attachments**

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**Alligator Bioscience Announces Publication Highlighting Phase 1 Mitazalimab Data in Solid Tumors in Peer-Reviewed Journal "Investigational New Drugs"**