**PRESS RELEASE**
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# ALLIGATOR BIOSCIENCE'S PHASE 2 MITAZALIMAB PANCREATIC CANCER DATA PUBLISHED IN THE LANCET ONCOLOGY

- Publication in world-leading clinical oncology journal validates the quality and potential implications of Phase 2 OPTIMIZE-1 results
- The study reported Objective Response Rate (ORR) of 40.4% in 57 evaluable patients, primary endpoint was met.
- The novel combination of mitazalimab and mFOLFIRINOX and the unique dosing schedule resulted in an unprecedented Duration of Response (DoR, median 12.5 months) together with a prolonged Overall Survival (OS, median 14.3 months).
- These results compare favorably to the historically reported outcomes for FOLFIRINOX alone and most other standard of care or investigational therapies.
- These data were also presented at the ASCO annual meeting on June 1; updated data with longer follow-up are expected end of June 2024.

**Lund, Sweden – Alligator Bioscience (Nasdaq Stockholm: ATORX)** today announced the publication of **positive Phase 2 data** on its lead drug candidate mitazalimab in first line metastatic pancreatic cancer in *The Lancet Oncology*. The journal is an internationally trusted source of clinical, and global health knowledge. With an Impact Factor of 51.1, it is the world-leading clinical oncology research journal.

With a 5-year overall survival rate of less than 5%, current systemic therapies for metastatic pancreatic ductal adenocarcinoma (mPDAC) are associated with poor outcomes. Data presented in *The Lancet Oncology,* from the OPTIMIZE-1 trial of mitazalimab in combination with mFOLFIRINOX, showed a confirmed ORR of 40.4% in 57 evaluable patients (unconfirmed ORR was 50.9%). Median DoR was 12.5 months and the median OS was 14.3 months. Median Progression Free Survival (PFS) was 7.7 months. These data compare favorably to the historically reported outcomes with FOLFIRINOX (ORR 31.6%, mDoR 5.9 months, mOS 11.1 months and mPFS 6.4 months)**[1]**. The recently approved new treatment regimen of NALIRIFOX was associated with an ORR of 42%, mDoR of 7.3 months, mPFS 7.4 months and a mOS of 11.1 months.**[2]**

*"The long-lasting responses and related biomarker associations reported in OPTIMIZE-1 are highly encouraging, demonstrating a critical immunomodulatory contribution of mitazalimab. The increase in ORR and PFS, compared to FOLFIRINOX alone, are superior outcomes and we believe that the reported depth and duration of response are strong indicators that the observed increases in survival will remain evident,"* said **Prof. Jean-Luc van Laethem, Head of the**

**Digestive Oncology Department of Erasme Hospital (ULB) Brussels, Principal Investigator of the OPTIMIZE-1 trial and lead author of the article in The Lancet Oncology.** *"Furthermore, mitazalimab showed a favorable safety profile and it could offer better quality of life for pancreatic patients who currently have few treatment options. The data from OPTIMIZE-1 are very promising and are strongly supportive of the continued development of mitazalimab and mFOLFIRINOX in mPDAC, in a confirmatory trial."*

**OPTIMIZE-1**, an open-label, single-arm, multicenter, Phase 1b/2 study, assessed the safety and efficacy of mitazalimab (CD40 mAb agonist) in combination with standard of care chemotherapy mFOLFIRINOX.

The DoR and OS are expected to improve further, as a majority of the patients were still alive at the time of the analysis (cut-off date November 2023). The OPTIMIZE-1 results compare favorably to the previously reported outcomes with FOLFIRINOX[1] as well as more recently reported data of the NALIRIFOX regimen in the NAPOLI 3 Phase 3 trial[2]. The OS at 12 months in OPTIMIZE-1 was 59.3%, compared to 48.1% for FOLFIRINOX[1] and 45.6% for NALIRIFOX[2].

*"This publication in The Lancet Oncology is an important validation of the highly promising results of our OPTIMIZE-1 mitazalimab study. A substantial number of patients were either in the treatment or in the follow-up* ***at the time of the primary analysis****. Consequently, the 18-month survival follow-up data, which we expect at the end of June 2024, should provide further important insights into the potential of mitazalimab,"* said **Søren Bregenholt, CEO of Alligator Bioscience.**

**Click here** for the full article in *The Lancet Oncology*.

**Title:**
*Combining CD40 agonist mitazalimab with mFOLFIRINOX in previously untreated metastatic pancreatic ductal adenocarcinoma (OPTIMIZE-1): a single-arm, multicentre phase 1b/2 study.*
Provisional Publication Date: June 1st, 2024
Article Number: *24TLO0432*

Two posters (abstracts 2569 and 4133) detailing the positive OPTIMIZE-1 data were presented on June 1 at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting.

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**[1]** Conroy et al., **N Engl J Med 2011; 364:1817-1825; DOI: 10.1056/NEJMoa1011923**
**[2]** Wainberg et al., **Lancet 2023; 402(10409):1272-1281; DOI: 10.1016/S0140-6736 (23)01366-1**

**About pancreatic cancer**

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Pancreatic cancer is the 12th largest cancer by number of patients. It is expected to become the second leading cause of cancer death in the western world by 2030. There are about 200,000 annual cases in the U.S. and the EU, with very poor prognosis: five-year survival is about 10% and median survival about 6 months. For 80% of patients, the only option is chemotherapy that offers only marginal benefit. FOLFIRINOX is expected to be the preferred first line regimen in the U.S. and the EU for patients with good performance status.

Sources: POLARIS Market Research, KOL event

**For further information, please contact:**

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**Alligator Bioscience**
Søren Bregenholt, CEO
E-mail: **soren.bregenholt@alligatorbioscience.com**
Phone: +46 (0) 46 540 82 00

**Cohesion Bureau**
**Investors**
Frank Hoerning Andersen
E-mail: **frank.hoerning@cohesionbureau.com**
Phone: +45 25 66 86 02

**Media**
Sam Cage
E-mail: **sam.cage@cohesionbureau.com**
Phone: +45 24 37 63 42

## 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's Phase 2 mitazalimab Pancreatic Cancer Data Published in The Lancet Oncology**