PRESS RELEASE
29 January 2024 07:30:00 CET

ALLIGATOR BIOSCIENCE ANNOUNCES POSITIVE MITAZALIMAB OPTIMIZE-1 PHASE 2 RESULTS MEETING PRIMARY ENDPOINT AND DEMONSTRATING CLINICALLY RELEVANT SURVIVAL BENEFITS IN 1ST LINE PANCREATIC CANCER

- **Top-line readout demonstrates Objective Response Rate of 40.4%, meeting primary endpoint and confirming the benefit of mitazalimab in combination with mFOLFIRINOX**
- **Median Overall Survival of 14.3 months at the time of analysis, and expected to improve further as more than half of the patients remain alive**
- **Median Duration of Response of 12.5 months compares favorably to the standard of care FOLFIRINOX of 5.9 months**
- **Discussions with the FDA confirm a clear approval pathway with Phase 3 registration study on track to start in early 2025**

Webcast to discuss top-line data with Key Opinion Leader Dr. Zev Wainberg, Professor of Medicine at University of California, Los Angeles (UCLA) and co-director of the UCLA Gastrointestinal (GI) Oncology Program - Monday 29th January 2024 – 4 pm CET / 10 am ET - **Link to event**

Lund, Sweden, January 29, 2024 – Alligator Bioscience (Nasdaq Stockholm: ATORX) today announces positive top-line results from the OPTIMIZE-1 Phase 2 study of the company's lead asset mitazalimab in 1st line metastatic pancreatic cancer. The open-label, multi-center study assessed the safety and efficacy of mitazalimab (CD40 mAb agonist) in combination with standard of care chemotherapy mFOLFIRINOX, in previously untreated, chemotherapy naive patients.

The study achieved its primary endpoint with the top-line results demonstrating a confirmed Objective Response Rate (ORR) of 40.4%, an unconfirmed ORR of 50.9% and a disease control rate (DCR) of 79% in 57 evaluable patients, as per the Response Evaluation Criteria in Solid Tumors (RECIST 1.1). This compares favorably to the ORR of 31.6% reported in a similar patient population treated with FOLFIRINOX alone.[1]

The cut-off time for analysis was November 14, 2023 with a median follow-up duration of 12.7 months. At the time of the analysis, a total of 29 (51%) patients were still alive, of these 18 (32%) were still on treatment. The longest ongoing treatment duration was 23 months. Three patients demonstrated complete remission of their target lesions. The study further demonstrated:

- Median Overall Survival (mOS) of 14.3 months at the time of analysis and expected to improve as majority of the patients remain alive, comparing favorably to the 11.1 months demonstrated by FOLFIRINOX[1], and more recently by NALIRIFOX in the NAPOLI 3 Phase 3 trial[2]
- An unprecedented median Duration of Response (DoR) of 12.5 months, compared to 5.9 months with FOLFIRINOX[1], and the 7.3 months demonstrated by NALIRIFOX[2]
- The 12-month survival rate was 59.3% compared to 48.1% for FOLFIRINOX[1] and 45.6% for NALIRIFOX[2]
- Median Progression Free Survival (PFS) of 7.7 months, compared to 6.4 months with FOLFIRINOX[1], and the 7.4 months demonstrated by NALIRIFOX[2]
- Mitazalimab's manageable safety and tolerability profile supporting long-term administration in combination with mFOLFIRINOX was confirmed

As the majority of patients remain alive at the time of analysis, Overall Survival and Durability of Response are expected to improve further with ongoing treatment and follow-up.

"We are very pleased to announce that the OPTIMIZE-1 study has successfully met its primary endpoint, with the data demonstrating that when combined with mFOLFIRINOX, mitazalimab provides significant survival benefit to pancreatic cancer patients compared to the standard of care," said **Søren Bregenholt, CEO of Alligator Bioscience.** *"The unprecedented duration of response is to us a clear confirmation of the strong immune activation that mitazalimab triggers, which translates into a much improved overall survival. As of today, more than half of the patients are still in the study and we expect these promising data to improve even further."*

"It is very rewarding for us to see the OPTIMIZE-1 top-line results demonstrate the clear clinical signal and survival benefit of mitazalimab in combination with mFOLFIRINOX," said **Prof. Jean-Luc van Laethem, Head of the Digestive Oncology Clinic in the Gastroenterology Department of Erasmus Hospital (ULB) Brussels and Principal Investigator of the OPTIMIZE-1 trial.** *"Metastatic pancreatic cancer is particularly hard to treat due to its highly complex and aggressive nature, so for mitazalimab to have delivered such data in previously untreated patients is a remarkable and promising outcome."*

"Successfully meeting its primary endpoint, together with a very long durability of response and median overall survival, is a highly encouraging result for the OPTIMIZE-1 study, which demonstrates mitazalimab's potential in pancreatic cancer," said **Dr. Zev Wainberg, Professor of Medicine at University of California, Los Angeles (UCLA) and co-director of the UCLA Gastrointestinal (GI) Oncology Program.** *"With current therapeutic options so limited, I remain highly optimistic that mitazalimab can have a significant impact on the way pancreatic cancer is treated and I look forward to the next stage of its clinical development. These data also warrant a broader evaluation of mitazalimab in other tumor types."*

Phase 3 expected to start in early 2025
Alligator Bioscience has undertaken discussions with the US Food and Drug Administration (FDA) and has been able to establish a clear development and approval pathway for mitazalimab in pancreatic cancer. Based on the emerging data from the OPTIMIZE-1 study, FDA has provided additional guidance and has endorsed OPTIMIZE-1 as a Phase 3 enabling study. Consequently, mitazalimab can proceed directly to a global Phase 3 registration study, which Alligator is preparing to initiate in early 2025.

Mitazalimab has been granted orphan drug designation in pancreatic cancer by both **FDA** and the **European Medicines Agency (EMA).**

Webcast – Monday 29th January 2024 – 4 pm CET / 10am ET
A webcast will be held today, January 29th 2024, at 4pm CET / 10am ET, to discuss the top-line data of the mitazalimab OPTIMIZE-1 Phase 2 study with Dr. Zev Wainberg, Professor of Medicine at University of California, Los Angeles (UCLA) and co-director of the UCLA Gastrointestinal (GI) Oncology Program. A formal presentation will be followed by a Question and Answer Session.

Please use **the following link** to connect to the webcast via Alligator's Youtube channel.

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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**

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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**.

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Attachments

Alligator Bioscience Announces Positive Mitazalimab OPTIMIZE-1 Phase 2 Results Meeting Primary Endpoint and Demonstrating Clinically Relevant Survival Benefits in 1st Line Pancreatic Cancer