PRESS RELEASE
26 June 2024 08:00:00 CEST

ALLIGATOR BIOSCIENCE ANNOUNCES SUBSTANTIAL OVERALL SURVIVAL BENEFIT AND UNPRECEDENTED DURATION OF RESPONSE IN THE 18-MONTH ANALYSIS FROM MITAZALIMAB OPTIMIZE-1 PHASE 2 STUDY IN 1ST LINE PANCREATIC CANCER

- **Median Overall Survival increased to 14.9 months and survival rate at 18 months was 36.2%, nearly twice as high as the 18.6% previously reported for FOLFIRINOX**
- **Further deepening of tumor shrinkage was evident with additional objective responses over long treatment duration**
- **Results demonstrate an unprecedented median Duration of Response of 12.6 months and confirm immunotherapeutic contribution of mitazalimab when added to chemotherapy**
- **With a median 18-month follow-up duration, these results from the ongoing OPTIMIZE-1 trial validate and strengthen mitazalimab's previously reported robust clinical benefit**

Lund, Sweden, June 26, 2024 – Alligator Bioscience (Nasdaq Stockholm: ATORX) today announces positive 18-month follow-up data 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 naïve pancreatic cancer patients.
The data demonstrated a near doubling of the 18-month survival rate to 36.2% in patients treated with mitazalimab in combination with mFOLFIRINOX, compared to 18.6% reported with FOLFIRINOX**[1]** alone.

The updated Median Overall Survival (mOS) was 14.9 months, up from 14.3 months at the time of **first analysis**, comparing favorably to the 11.1 months demonstrated by FOLFIRINOX[1] and more recently by NALIRIFOX**[2]**.

Median follow-up duration for the updated analysis was 18.2 months, indicating the maturity of these outcomes. At the time of the analysis, a total of 17 (30%) patients were still alive, and of these 9 (16% overall) were still on treatment. The longest ongoing treatment duration was 24 months.

The follow-up data further demonstrate:

- An additional late responding patient increased the confirmed Objective Response Rate (ORR; as per the Response Evaluation Criteria in Solid Tumors RECIST 1.1) to 42.1% from the 40.4% reported in the top-line readout, comparing favorably to the ORR of 31.6% reported in a similar patient population treated with FOLFIRINOX alone[1] and an ORR of 42% reported by NALIRIFOX[**2**]
- An increase in the unconfirmed ORR to 54.4% was reported in 57 evaluable patients
- The median Duration of Response (DoR) was 12.6 months, an unprecedented outcome in this aggressive disease and much longer compared to 5.9 months with FOLFIRINOX[**1**] and 7.3 months with NALIRIFOX[2]
- Median Progression Free Survival (PFS) was 7.7 months, and a nearly 3-fold increase in the 12-month PFS rate was reported; 35.1% in OPTIMIZE-1 against 12.1% previously reported for FOLFIRINOX[**1**].

"These latest results from the OPTIMIZE-1 study of our lead asset provide a strong validation of the clear and sustained clinical benefit produced by mitazalimab when combined with mFOLFIRINOX in the treatment of first-line pancreatic cancer. In fact, mitazalimab increases your chance of being alive at the 18-month mark by 95 percent, compared to published FOLFIRINOX data," said **Søren Bregenholt, CEO of Alligator Bioscience.** *"These highly promising outcomes warrant continued clinical development of mitazalimab in a confirmatory setting and we are committed to bringing mitazalimab to pancreatic cancer patients as fast as possible."*

"These results clearly represent a remarkable outcome in pancreatic cancer, with the robust Duration of Response indicating highly consistent clinical benefit resulting in prolonged Overall Survival," 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.** *"Particularly noteworthy is the high proportion of patients surviving at the 18-month landmark, which most patients in this disease unfortunately do not see. With such a strong immunotherapeutic contribution, mitazalimab combined with mFOLFIRINOX has the potential to become the new treatment standard in pancreatic cancer, and we are eagerly awaiting the initiation of a randomized confirmatory study."*

Top-line results from the OPTIMIZE-1 study were published in the world-leading oncology journal ***The Lancet Oncology*** and will also be presented at the upcoming ESMO Gastrointestinal Cancers Congress 2024 being held in Munich, Germany from June 26-29.

Phase 3 on track to start in first half of 2025
Alligator is continuing its preparations for the global Phase 3 registration study to evaluate mitazalimab in pancreatic cancer and the company remains on track to initiate the study in 2025. This follows Alligator's discussions with the US Food and Drug Administration (FDA) which established a clear development and approval pathway for mitazalimab in pancreatic cancer.

In 2023, mitazalimab was granted orphan drug designation in pancreatic cancer by both the **FDA** and the **European Medicines Agency (EMA).**

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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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This information is information that Alligator Bioscience is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2024-06-26 08: 00 CEST.

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 Substantial Overall Survival Benefit and Unprecedented Duration of Response in the 18-Month Analysis from Mitazalimab OPTIMIZE-1 Phase 2 Study in 1st Line Pancreatic Cancer