

ALLIGATOR BIOSCIENCE ANNOUNCES POSITIVE INTERIM RESULTS FROM MITAZALIMAB OPTIMIZE-1 PHASE 2 TRIAL IN PANCREATIC CANCER EXCEEDING 50% OBJECTIVE RESPONSE RATE

- 52% Objective Response Rate in pre-planned interim efficacy analysis of mitazalimab combined with mFOLFIRINOX in 1st line metastatic pancreatic cancer
- Data confirm the safety of mitazalimab combined with mFOLFIRINOX, as previously reported
- Alligator plans to discuss these strong results with regulators to explore potential accelerated development and approval pathway

Lund, Sweden, January 2, 2023 – Alligator Bioscience (Nasdaq Stockholm: ATORX) today announces strong interim results from the ongoing OPTIMIZE-1 Phase 2 trial of the company's lead asset mitazalimab in 1st line metastatic pancreatic cancer.

This open-label, multi-center study is assessing the safety and efficacy of mitazalimab (CD40 mAb) in combination with chemotherapy, mFOLFIRINOX, in previously untreated patients with metastatic pancreatic ductal adenocarcinoma. Within this pre-planned interim analysis for futility, data were assessed by the participating investigators and independent experts for the probability of a positive study at primary completion. The interim results demonstrate an objective response rate (ORR) of 52% in 23 evaluable patients, as per the Response Evaluation Criteria in Solid Tumors (RECIST 1.1). Disease control rate, the proportion of patients with objective response or stabilization of disease, was more than 90%. These data are noteworthy, especially in the light of an ORR of 31.6%^[1] reported with FOLFIRINOX in a similar patient population.

Safety data confirm results from the Phase 1b dose escalation phase of the trial, which showed that mitazalimab in combination with mFOLFIRINOX was safe and well tolerated at the recommended dose of 900 µg/kg.

Based on these positive results, Alligator plans to initiate discussions with regulators in the US and Europe on potential accelerated development and approval pathway for mitazalimab in pancreatic cancer, while continuing patient enrolment in this ongoing trial. Top-line data from this trial are expected in Q1 2024.

*"We are thrilled with these interim results, which demonstrate that mitazalimab combined with chemotherapy could offer a significant clinical benefit for pancreatic cancer patients over standard of care," said **Søren Bregenholt, CEO of Alligator Bioscience**. "We are very keen to progress our lead asset through the next stage of its development as quickly as we can, and we look forward to discussing with regulatory authorities the potential accelerated development and approval pathway for mitazalimab in pancreatic cancer. These strong interim data reconfirm our commitment to mitazalimab and supports broadening the mitazalimab clinical development program in additional tumor types."*

*"We are pleased with the signs of clinical activity observed in the OPTIMIZE-1 interim analysis and believe that mitazalimab in combination with chemotherapy warrants continued development for the treatment of pancreatic cancer patients, which is an area of high unmet need", said **Prof. Jean-Luc van Laethem, coordinating principal investigator, Erasmus University Hospital, Brussels (BE)**, "we will continue enrolment, treatment and follow-up of patients to further characterize the progression-free and overall survival, as the study continues".*

[1] Conroy et al, N Engl J Med 2011; 364:1817-1825; DOI: 10.1056/NEJMoa1011923

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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.

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 2023-01-02 17:30 CET.

Attachments

Alligator Bioscience Announces Positive Interim Results from Mitazalimab OPTIMIZE-1 Phase 2 Trial in Pancreatic Cancer Exceeding 50% Objective Response Rate