

ALLIGATOR BIOSCIENCE TO PRESENT LATEST CLINICAL DATA FROM MITAZALIMAB OPTIMIZE-1 PHASE 2 TRIAL IN PANCREATIC CANCER AT ASCO ANNUAL MEETING 2023

- Mitazalimab achieved 52% Objective Response Rate when combined with mFOLFIRINOX in 1st line pancreatic cancer and passed the futility analysis
- Well-manageable safety profile of the combination, largely reflecting mFOLFIRINOX profile
- Additional interim readout expected in Q2 2023
- Phase 2 to report top-line data in early Q1 2024

Lund, Sweden – Alligator Bioscience (Nasdaq Stockholm: ATORX) today announces that data from the ongoing OPTIMIZE-1 Phase 2 study of the company's lead asset mitazalimab in 1st line metastatic pancreatic cancer will be presented at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting, being held in Chicago, June 2-6.

The presentation, entitled "*Efficacy and Safety of mitazalimab in combination with mFOLFIRINOX in patients with metastatic pancreatic ductal adenocarcinoma (mPDAC): an interim analysis of the OPTIMIZE-1 phase 1b/2 study*", outlines comprehensive data from the interim analysis **announced in January 2023**.

The data presented at ASCO demonstrate that mitazalimab in combination with mFOLFIRINOX is a feasible treatment regimen for 1st line pancreatic cancer patients with encouraging interim efficacy and well-manageable safety profile, consistent with mFOLFIRINOX monotherapy. Combination with mFOLFIRINOX had no impact on mitazalimab pharmacokinetics and the pharmacodynamic biomarker profile in peripheral blood confirmed the immune activation profile typical of mitazalimab.

When administered at 900 µg/kg in combination with mFOLFIRINOX, mitazalimab showed robust anti-tumor activity in 23 mPDAC patients, meriting continued development. An objective response rate (ORR) of 52% was demonstrated with clinically meaningful tumor reduction in 12 of the 23 evaluable patients, which compares favorably to the 31.6%^[1] reported with FOLFIRINOX in a similar patient population. The analysis also revealed:

- 8 patients achieved stable disease resulting in a 91% disease control rate (DCR)
- 6 of the 7 patients who began treatment at least 6 months prior to the interim analysis cutoff were still on treatment, and of these, 2 patients had been receiving treatment for over 11 months.

With these encouraging results, the OPTIMIZE-1 study passed the futility analysis. Subsequently, the study has **completed its full accrual**, and top-line data are expected in early Q1 2024.

*"ASCO is the most prominent global scientific platform in the field of clinical oncology. Presentation of these strong clinical data for our lead pipeline asset mitazalimab in a very challenging indication highlight the potential of Alligator's novel immuno-oncology pipeline," said **Søren Bregenholt, CEO of Alligator Bioscience**. "Mitazalimab is a unique CD40 agonist that is demonstrating not only highly encouraging anti-tumor activity in the treatment of first-line pancreatic cancer, but also a much improved safety profile compared to the previous generations of CD40 agonists. We are truly encouraged by these data and look forward to reporting updated interim data from a larger number of patients and a longer treatment and follow-up later this month, followed by top-line results at the beginning of next year. "*

Presentation Details

Abstract Number for Publication: 4139

Abstract Title: *Efficacy and Safety of mitazalimab in combination with mFOLFIRINOX in patients with metastatic pancreatic ductal adenocarcinoma (mPDAC): an interim analysis of the OPTIMIZE-1 phase 1b/2 study*

Session Title: **Gastrointestinal Cancer - Gastroesophageal, Pancreatic, and Hepatobiliary**

Date/Time: Monday 5 June, 2023, 8.00 - 11.00 am CDT

Presenter: Hans Prenen, Head of the Oncology Department at University Hospital, Antwerp, and Investigator in the OPTIMIZE-1 Study

More information about ASCO and registration can be found [here](#).

[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.

Attachments

Alligator Bioscience to Present Latest Clinical Data from Mitazalimab OPTIMIZE-1 Phase 2 Trial in Pancreatic Cancer at ASCO Annual Meeting 2023