

ALLIGATOR BIOSCIENCE TO PRESENT POSITIVE PHASE 2 MITAZALIMAB DATA IN PANCREATIC CANCER AT 2024 ASCO ANNUAL MEETING

- OPTIMIZE-1 study results showed confirmed ORR of 40.4%, unconfirmed ORR of 50.9% and DCR of 79% in 57 evaluable patients with chemotherapy-naïve mPDAC
- The encouraging duration of response (median 12.5 months) and overall survival (median 14.3 months) support continued development of mitazalimab in a randomized confirmatory Phase 3 trial
- Biomarker analysis demonstrates correlation of mitazalimab-induced immune activation with clinical outcomes
- Updated results from a longer, 18-month survival follow-up in OPTIMIZE-1 expected at end of June 2024

Lund, Sweden – Alligator Bioscience (Nasdaq Stockholm: ATORX) today announced that two clinical abstracts on its lead drug candidate mitazalimab, a best-in-class CD40 agonist, in first line metastatic pancreatic cancer will be presented (abstracts 2569 and 4133) in a poster presentation session at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting, taking place in Chicago, IL and online during May 31-June 4.

Data presented at ASCO from the OPTIMIZE-1 study, of mitazalimab in combination with mFOLFIRINOX chemotherapy, showed that pharmacological analyses identified mitazalimab-induced expansion of CD4 effector T cells one week after first administration as a correlate of treatment outcomes. These data suggest the contribution of mitazalimab to tumor responses, and further supports the unique trial design of OPTIMIZE-1.

OPTIMIZE-1 achieved its primary endpoint, 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] Median Duration of Response (DoR) was 12.5 months, remarkably longer than reported so far with any other approved and investigational therapies. Median Overall Survival (OS) was 14.3 months and the survival estimate from the next planned analysis may further improve.

*“Most pancreatic cancer patients are diagnosed after the disease has already metastasized. Treatment options at this stage are rather unsatisfactory and there is a major need of novel therapies for these patients. The primary analysis results of OPTIMIZE-1 study suggest that adding mitazalimab to the modified FOLFIRINOX regimen significantly prolongs the durability of response, resulting in a meaningful extension of overall survival in this fatal disease. It is indeed encouraging to see many patients still continuing in the study, and we are very much looking forward to the 18-month survival follow-up from OPTIMIZE-1, which we expect at the end of June 2024,” said **Dr. Sumeet Ambarkhane, CMO of Alligator Bioscience.** “These results support the continued development of mitazalimab in combination with mFOLFIRINOX, in a confirmatory, phase 3, clinical trial in patients with previously untreated metastatic pancreatic ductal adenocarcinoma (mPDAC). Furthermore, the correlation of mitazalimab-induced immune activation with improved clinical outcomes suggests a potential immunological profile that could be used as a biomarker for this treatment.”*

The open-label, multi-center OPTIMIZE-1 study assessed the safety and efficacy of mitazalimab (CD40 mAb agonist) in combination with standard of care chemotherapy mFOLFIRINOX, in previously untreated, chemotherapy naïve patients. More details can be found with the clinicaltrials.gov identifier [NCT04888312](#).

Poster Presentations Details

Title: CD4 effector T cell expansion to identify objective responses to the CD40 agonist mitazalimab in combination with modified FOLFIRINOX (mFFX) as first-line therapy for metastatic pancreatic ductal adenocarcinoma (mPDAC) in the OPTIMIZE-1 study

Presenter: Peter Ellmark, PhD

Abstract: 2569

Track: Developmental Therapeutics—Immunotherapy

Location: Hall A | On Demand

Time: 1 June 2024, 09:00 – 12:00 (GMT-5)

Title: OPTIMIZE-1 primary analysis: Safety, efficacy and biomarker results of a phase 1b/2 study combining CD40 agonist mitazalimab with mFOLFIRINOX in previously untreated metastatic pancreatic ductal adenocarcinoma (mPDAC)

Presenter: Jean-Luc Van Laethem, MD, PhD

Abstract: 4133

Track: Gastrointestinal Cancer—Gastroesophageal, Pancreatic, and Hepatobiliary

Location: Hall A | On Demand

Time: 1 June 2024, 13:30 – 16:30 (GMT-5)

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

About pancreatic cancer

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

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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 Positive Phase 2 Mitazalimab Data in Pancreatic Cancer at 2024 ASCO Annual Meeting