PRESS RELEASE
06 November 2024 08:45:00 CET

ALLIGATOR BIOSCIENCE PRESENTS AN UPDATE WITH CLINICAL AND BIOMARKER RESULTS WITH MITAZALIMAB IN PHASE 2 PANCREATIC CANCER AT SITC 2024

- The data contain efficacy results and correlative outcomes with biomarkers based on a median follow-up of 18 months in OPTIMIZE-1 trial
- Confirmed ORR of 42.1%, unprecedented median DoR of 12.6 months and a median overall survival of 14.9 months strengthen the earlier reported results
- Near doubling of overall survival estimate at 18 months *vis a vis* FOLFIRINOX
- Second presentation highlights positive preclinical data on next generation bispecific CD40/CEACAM5 antibody ATOR-4066

Lund, Sweden – Alligator Bioscience (Nasdaq Stockholm: ATORX), a company developing CD40 agonists to treat cancer, today announced the presentation of positive Phase 2 data on its lead drug candidate mitazalimab in 1st line pancreatic cancer at the 39th Annual Meeting of the Society for Immunotherapy of Cancer (SITC 2024), taking place November 6-10 in Houston, TX.

The poster presentation, entitled "CD40 agonist mitazalimab combined with mFOLFIRINOX in patients with metastatic pancreatic ductal adenocarcinoma (mPDAC): Updated efficacy and correlative biomarkers from the OPTIMIZE-1 trial", outlined updated efficacy and biomarker analysis from 57 evaluable patients treated with the 900 µg/kg dose in the OPTIMIZE-1 study.

The confirmed overall response rate (ORR) was 42.1%, with 23 partial responses (PR) and one complete response (CR). The ORR including unconfirmed responses was 54.4%. Median overall survival (OS) was 14.9 months, with a near doubling of the 18-month OS rate to 36.2%, compared to 18.6% reported with FOLFIRINOX[1] alone. Median duration of response (DoR) was 12.6 months, an unprecedented outcome in this aggressive disease, and median progression free survival (PFS) was 7.7 months. A total of 19 patients (33%) remained in the study, with nine still undergoing treatment.

Furthermore, changes in immunological profiles observed after the priming dose of mitazalimab and before the first dose of mFOLFIRINOX correlated with improved efficacy outcomes, suggesting a mitazalimab-driven response in this novel regimen. These data form the basis of a future randomized confirmatory trial of mitazalimab in combination with mFOLFIRINOX in mPDAC.

Alligator also had a poster presentation on ATOR-4066, its next-generation bispecific CD40 antibody candidate that targets CD40 and CEACAM5. The results showed that ATOR-4066 induces both myeloid cell-dependent and T-cell dependent anti-tumor activity in preclinical models. The strong *in-vivo* anti-tumor activity indicates the potential of ATOR-4066 as a monotherapy or in combination with other anticancer agents, in particular immune checkpoint inhibitors (ICI), to overcome ICI resistance in CEACAM5-expressing tumors.

> **Dr. Sumeet Ambarkhane, CMO at Alligator Bioscience,** said: "*We are proud to present these positive data, both Phase 2 on mitazalimab and preclinical on exciting bispecific CD40 antibody candidate ATOR-4066, to the scientific community at SITC 2024. The results demonstrate the potential of these candidates to significantly improve treatment options for patients, and confirm our CD40 agonists as the primary value drivers for Alligator. The OPTIMIZE-1 Phase 2 data, in particular, are very exciting as these show mitazalimab increases the chance of being alive after 18 months by 95 percent compared to the current standard of care chemotherapy, FOLFIRINOX. This clinically meaningful survival benefit shows the potential of mitazalimab to make a significant difference for pancreatic cancer patients, who still sadly have very poor prognosis*."

Mitazalimab is a stimulatory monoclonal antibody that selectively targets CD40, a receptor on dendritic cells; these specialized immune cells are capable of unveiling cancer cells to the body's immune system. In other words, CD40 stimulation enables dendritic cells to more effectively activate the immune system's weapons – specifically, T cells – and to direct them to attack the unveiled cancer cells. Data from the Phase 2 OPTIMIZE-1 clinical trial, first announced in June 2024, showed mitazalimab caused an unprecedented duration of response in first-line pancreatic cancer patients, nearly doubling 18-month survival rates. As expected based on its mechanism of action, preclinical results have shown that mitazalimab also may be effective against several additional types of cancer.

ATOR-4066, in preclinical development, is an advancement on the mechanism of mitazalimab. It is a CD40 bispecific antibody targeting both CD40 and CEA (carcinoembryonic antigen), a protein found in certain tumors but not in normal tissue. This approach is expected to improve both safety and anti-tumor efficacy.

[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 Presents an Update with Clinical and Biomarker Results with Mitazalimab in Phase 2 Pancreatic Cancer at SITC 2024