

ALLIGATOR BIOSCIENCE PRESENTS NEW DATA DEMONSTRATING DURABLE RESPONSE AND ENCOURAGING ANTI-TUMOR ACTIVITY OF LEAD ASSET MITAZALIMAB

- Clinical and preclinical data from three presentations further demonstrate mitazalimab's ability to activate the immune system and enhance anti-tumor responses to chemotherapy
- Data presented at AACR Special Conference on Pancreatic Cancer 2023 and CICON 2023
- Mitazalimab OPTIMIZE-1 Phase 2 study in 1st line metastatic pancreatic cancer on track for top-line readout in early Q1 2024

Lund, Sweden – Alligator Bioscience (Nasdaq Stockholm: ATORX) today announces that new data from the ongoing OPTIMIZE-1 Phase 2 study of the company's lead asset mitazalimab, a best-in-class CD40 mAb agonist, will be presented in oral and poster presentations at the AACR (American Association for Cancer Research) Special Conference on Pancreatic Cancer, being held in Boston September 27-30, 2023. Preclinical mitazalimab data were also recently presented in a poster presentation at the International Cancer Immunotherapy Conference (CICON), held in Milan September 20-23, 2023.

*"The data reported in these three presentations add to the growing clinical evidence demonstrating that mitazalimab induces relevant activation of the immune system leading to enhanced anti-tumor responses to chemotherapy and provides durable benefits to patients with metastatic pancreatic cancer," said **Søren Bregenholt, CEO of Alligator Bioscience.** "We are very pleased to share these important developments at two of the year's most important oncology conferences, which have allowed us to update the scientific community on the great clinical progress we are making with mitazalimab in the OPTIMIZE-1 study, ahead of the topline readout in early Q1 next year."*

Oral presentation at AACR: *"CD40 agonist mitazalimab in combination with mFOLFIRINOX in patients with metastatic pancreatic ductal adenocarcinoma (mPDAC): Interim efficacy results of the OPTIMIZE phase 1b/2 study"*

Date/Time: Thursday 28 September, 2023, 2.15 - 4.40 pm EDT

Session: Plenary Session 3: Clinical Updates

Presenter: Teresa Macarulla, Vall d'Hebrón University Hospital, Barcelona, Spain

- Interim efficacy analysis of 57 evaluable patients from the OPTIMIZE-1 study (NCT04888312) **that were announced in June 2023**
- Overall response rate per RECIST v1.1 was 43.9% (25 patients with partial response); an additional 19 patients achieved stable disease, resulting in a 77.2% disease control rate
- Median time to response was 2.2 months and median duration of response was 8.7 months
- Results demonstrated encouraging anti-tumor activity in mPDAC with good durability of responses, meriting continued development, possibly in a randomized setting

The OPTIMIZE-1 study continues to progress and remains on track for top-line readout in early Q1 2024.

Poster presentation at AACR: *"Interim pharmacodynamic analyses of mitazalimab in combination with FOLFIRINOX in first-line metastatic pancreatic ductal adenocarcinoma (mPDAC) identify CD4 effector T cells as a correlate of treatment outcomes"*

Date/Time: Friday 29 September, 2023, 4.40 - 6.40 pm EDT

Session: Poster Session C

Presenter: Dr. Gregory Beatty, Abramson Cancer Center & Division of Hematology-Oncology, University of Pennsylvania

- Interim pharmacodynamic analyses and their association with outcomes from the OPTIMIZE-1 study, demonstrating that mitazalimab and mFOLFIRINOX induce distinct immune responses in pancreatic cancer patients
- Analyses demonstrated that the desired activation of the immune system after mitazalimab exposure was achieved revalidating its mechanism of action
- Analyses also demonstrated that increases in CD4 effector T cells correlate with treatment outcomes and suggest a mitazalimab-specific contribution to tumor responses in patients with metastatic pancreatic cancer

Poster presentation at CICON: *"Efficacy and pharmacodynamic biomarkers of mitazalimab in combination with chemotherapy in preclinical mouse models"*

- Details of anti-tumor efficacy of mitazalimab and FOLFIRINOX in a preclinical tumor model and pharmacodynamic biomarkers in peripheral blood, induced at early time points after treatment
- Preclinical data demonstrated that mitazalimab synergizes effectively with FOLFIRINOX, inducing long-term survival in a preclinical tumor model
- The pharmacodynamic biomarkers identified in these preclinical data are in agreement with data from a Phase 1 dose escalation study of mitazalimab in patients with advanced solid stage tumors (NCT02829099)

PRESS RELEASE

28 September 2023 08:00:00 CEST



- Together, these preclinical tumor model data support mitazalimab's mechanism of action as also observed in the ongoing OPTIMIZE-1 study

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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 New Data Demonstrating Durable Response and Encouraging Anti-Tumor Activity of Lead Asset Mitazalimab](#)