PRESS RELEASE
20 June 2024 08:00:00 CEST

ALLIGATOR BIOSCIENCE TO PRESENT POSITIVE PHASE 2 DATA ON MITAZALIMAB IN PANCREATIC CANCER AT ESMO GI 2024

- **Primary endpoint of OPTIMIZE-1 trial was met, with Objective Response Rate (ORR) of 40.4% in 57 evaluable patients**
- **Unprecedented Duration of Response (DoR) and a prolonged Overall Survival (OS)**
- **Further validation of data, following recent ASCO presentations and publication in *The Lancet Oncology***
- **18-month survival follow-up data from OPTIMIZE-1 expected in late June 2024**

Lund, Sweden – Alligator Bioscience (Nasdaq Stockholm: ATORX) today announced it will present positive Phase 2 data on its lead drug candidate mitazalimab in first line metastatic pancreatic cancer at the European Society for Medical Oncology Gastrointestinal Cancers Congress 2024 (ESMO GI 2024), taking place in Munich, Germany from June 26-29.

The oral presentation outlines **OPTIMIZE-1**, an open-label, multicenter, Phase 1b/2 study, assessing the safety and efficacy of mitazalimab (CD40 mAb agonist) in combination with standard of care chemotherapy mFOLFIRINOX. The trial study **met its primary endpoint**, with mitazalimab showing a manageable safety profile and promising DoR associated with a clinically meaningful survival benefit.

Furthermore, there was a significant correlation between treatment-induced increases in natural killer T (NKT) cells and T cells expressing CD38 and depth of response, strongly suggestive of a mitazalimab-dependent contribution to deep anti-tumor responses.

The 5-year overall survival rate for metastatic pancreatic ductal adenocarcinoma (mPDAC) is less than 5%, and current systemic therapies are associated with poor outcomes. The OPTIMIZE-1 data have also recently been published in the peer-reviewed ***The Lancet Oncology*** and presented in two posters at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting.

Alligator expects to report 18-month survival follow-up data from OPTIMIZE-1 at the end of June 2024, and that these will provide further insights into the potential of mitazalimab.

"We are pleased to present these exciting results with mitazalimab to the scientific community at ESMO GI. It is an important validation of the potential of our product candidate to make a meaningful difference to pancreatic cancer patients, who currently have a very poor prognosis and limited treatment options," said **Dr. Sumeet Ambarkhane, CMO of Alligator Bioscience.** *"In particular, the long-lasting responses and related biomarker associations reported in OPTIMIZE-1 demonstrate a critical immunomodulatory contribution of mitazalimab. The increase in ORR and PFS, compared to FOLFIRINOX alone, are superior outcomes and mitazalimab also showed a favorable safety profile. Taken as a whole, these are very encouraging data which form the basis of planning mitazalimab's development in a randomized Phase 3 study."*

About the OPTIMIZE-1 data
Results from the OPTIMIZE-1 trial showed mitazalimab in combination with mFOLFIRINOX had a confirmed ORR of 40.4% in 57 evaluable patients (unconfirmed ORR was 50.9%). Median DoR was 12.5 months and the median OS was 14.3 months. Median Progression Free Survival (PFS) was 7.7 months. These data compare favorably to the historically reported outcomes with FOLFIRINOX (ORR 31.6%, mDoR 5.9 months, mOS 11.1 months and mPFS 6.4 months)[1]. The recently approved new treatment regimen of NALIRIFOX was associated with an ORR of 42%, mDoR of 7.3 months, mPFS 7.4 months and a mOS of 11.1 months[2].

Details of the presentation:
Title: CD40 agonist mitazalimab combined with mFOLFIRINOX (mFFX) in patients with metastatic pancreatic ductal adenocarcinoma (mPDAC): Primary analysis of the OPTIMIZE-1 phase 1b/2 study

Type: Oral presentation

Time: Saturday, June 29, 8:45am CET

Location: Room 13a

Presenter: Prof. Teresa Macarulla Mercade, MD, PhD, Vall d'Hebron, Barcelona

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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

[1] Conroy et al., N Engl J Med 2011; 364:1817-1825; DOI: 10.1056/NEJMoa1011923
[2] Wainberg et al., Lancet 2023; 402(10409):1272-1281; DOI: 10.1016/S0140-6736(23)01366-1

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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**.

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Attachments

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