

ALLIGATOR BIOSCIENCE PRESENTS ADDITIONAL DATA FROM MITAZALIMAB OPTIMIZE-1 PHASE 1B/2 TRIAL AT AACR SPECIAL CONFERENCE ON PANCREATIC CANCER 2022

- Data from Phase 1b dose escalation part of the study shows that mitazalimab combined with mFOLFIRINOX is safe and well tolerated
- 900 µg/kg dose of mitazalimab selected as the recommended dose for Phase 2 study
- Pharmacodynamic markers in peripheral blood confirm immune activation and pharmacologic activity, in accordance with mitazalimab mode of action
- Patient enrollment is ongoing at sites in Europe; interim efficacy read-out expected in Q4 2022
- Phase 2 primary endpoint is RECIST-defined overall response rate (ORR)

Lund, Sweden, September 14, 2022 - Alligator Bioscience (Nasdaq Stockholm: ATORX) today announces a poster presentation on the OPTIMIZE-1 Phase 1b/2 trial of mitazalimab in combination with modified FOLFIRINOX in first-line metastatic pancreatic cancer with the company's lead asset mitazalimab (CD40 mAb) at the 2022 AACR (American Association for Cancer Research) Special Conference on Pancreatic Cancer, being held in Boston September 13-16.

The presentation, entitled "*Mitazalimab (CD40 agonist) in combination with mFOLFIRINOX in patients with metastatic pancreatic ductal adenocarcinoma (mPDAC); Safety data and recommended dose of phase 2 (RP2D) from OPTIMIZE-1, a phase 1b/2 study*", outlines additional results from the Phase 1b dose escalation part of the study that were announced in March, 2022 ([press release](#)).

The results presented at AACR, demonstrate that mitazalimab is safe and tolerable at 900 µg/kg, the highest dose tested in OPTIMIZE-1. Most of the mitazalimab related AEs at both dose levels (fever, muscle pain, loss of appetite and fatigue) were mild to moderate (grade 1 or 2) severity and manageable. Only one patient out of the 6 patients in the 900 µg/kg cohort experienced a grade 3 treatment-related adverse event (TRAE) of headache. There were no grade 4 TRAEs or treatment related death reported. Pharmacodynamic markers in peripheral blood confirmed immune activation, in accordance with mitazalimab's mode of action.

Overall, the data showed that mitazalimab combined with mFOLFIRINOX is safe and well tolerated. The 900 µg/kg dose of mitazalimab was selected as the recommended dose for the Phase 2 study. Enrollment for the Phase 2 is ongoing at sites in Europe with an interim efficacy and safety read-out expected in Q4 2022.

PRESS RELEASE

14 September 2022 08:30:00 CEST



*"The AACR Special Conference on Pancreatic Cancer is an extremely well-regarded scientific forum for Alligator to be presenting additional data from our OPTIMIZE-1 trial," said **Søren Bregenholt, PhD, CEO of Alligator Bioscience**. "Mitazalimab's differentiated efficacy and tolerability profile allows for the higher and more frequent doses which, when combined with chemotherapy like mFOLFIRINOX, increases the chances of demonstrating clinical benefit in the treatment of metastatic pancreatic cancer. We are very pleased with the successful completion of the Phase 1b section of the trial and we continue to make great progress with the enrollment for Phase 2."*

The information was submitted for publication, through the agency of the contact person set out below, at 08:30 a.m. CEST on September 14, 2022.

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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 pipeline includes the two key assets mitazalimab, a CD40 agonist, and ATOR-1017, a 4- 1BB agonist. 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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About OPTIMIZE-1

OPTIMIZE-1 is an open-label, multi-center Phase 1b/2 study assessing the safety and efficacy of mitazalimab in combination with chemotherapy, mFOLFIRINOX, in patients with metastatic pancreatic ductal adenocarcinoma (NCT04888312). The primary endpoint for the Phase 2 part of the study is RECIST-defined overall response rate. Progression-free survival and overall survival will be assessed as secondary endpoints.

Attachments

Alligator Bioscience Presents Additional Data from mitazalimab OPTIMIZE-1 Phase 1b/2 Trial at AACR Special Conference on Pancreatic Cancer 2022