

ALLIGATOR BIOSCIENCE ANNOUNCES COMPLETION OF PATIENT ENROLMENT IN MITAZALIMAB OPTIMIZE-1 PHASE 2 TRIAL IN PANCREATIC CANCER AND CONFIRMS TIMELINE FOR TOP-LINE DATA IN Q1 2024

- OPTIMIZE-1 is assessing the safety and efficacy of mitazalimab in combination with mFOLFIRINOX in 1st line metastatic pancreatic cancer
- Interim efficacy results demonstrated a 52% Objective Response Rate
- Interim Progression Free Survival and survival expected mid-2023
- Top-line data expected in the beginning of Q1 2024

Lund, Sweden – Alligator Bioscience (Nasdaq Stockholm: ATORX) today announces the completion of patient enrolment in the ongoing OPTIMIZE-1 Phase 2 trial of the company's lead asset mitazalimab in 1st line metastatic pancreatic cancer. Thanks to this acceleration in patient enrolment, Alligator confirms it expects to report top-line data in the beginning of Q1 2024.

The open-label, multi-center study is assessing the safety and efficacy of mitazalimab (CD40 mAb) in combination with chemotherapy, mFOLFIRINOX, in previously untreated patients with metastatic pancreatic ductal adenocarcinoma.

*"The completion of enrolment in OPTIMIZE-1 marks another important milestone in our clinical development of mitazalimab, which has been demonstrating outstanding potential in pancreatic cancer when combined with chemotherapy," said **Søren Bregenholt, CEO of Alligator Bioscience**. "Patient enrolment has been completed earlier than initially anticipated thanks to the diligent work of the Alligator organisation, thus significantly de-risking the program. The strong interim data released earlier this year showing an objective response rate (ORR) in excess of 50%, coupled with the high unmet medical need of patients with metastatic pancreatic cancer, has spurred significant interest in mitazalimab in the medical community and with potential partners. We are confident in the potential of mitazalimab as first-line treatment and looking forward to key survival data due later this year, and ultimately to the top-line readout expected at the beginning of next year."*

PRESS RELEASE

12 April 2023 08:30:00 CEST



In January 2023, **Alligator announced strong interim results from OPTIMIZE-1**, in which mitazalimab combined with mFOLFIRINOX demonstrated an ORR of 52% in 23 evaluable patients, as per the Response Evaluation Criteria in Solid Tumors (RECIST 1.1). In comparison, a similar patient population treated only with FOLFIRINOX reported an ORR of around 32%^[1]. Mitazalimab in combination with mFOLFIRINOX also reported an interim disease control rate, the proportion of patients with objective response or stabilization of disease, of over 90%.

Alligator is planning to initiate discussions with regulators in the US and Europe on the best possible development and approval pathway for mitazalimab in pancreatic cancer later this year. Interim data from OPTIMIZE-1 on Progression Free Survival^[2] and survival are due in mid-2023 and top-line data are expected in Q1 2024.

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

^[2] Reflective of how long it take patients to have their disease progress

For further information, please contact:

Søren Bregenholt, CEO

E-mail: soren.bregenholt@alligatorbioscience.com

Phone: +46 (0) 46 540 82 00

LifeSci Advisors

Investor Relations

Guillaume van Renterghem

E-mail: gvanrenterghem@lifesciadvisors.com

Phone: +41 (0) 76 735 01 31

The information was submitted for publication, through the agency of the contact person set out above, at 8:30 a.m. CEST on April 12, 2023.

PRESS RELEASE

12 April 2023 08:30:00 CEST



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 Announces Completion of Patient Enrolment in Mitazalimab OPTIMIZE-1 Phase 2 Trial in Pancreatic Cancer and Confirms Timeline for Top-Line Data in Q1 2024