PRESS RELEASE
26 June 2023 08:30:00 CEST

ALLIGATOR BIOSCIENCE ANNOUNCES POSITIVE SECOND INTERIM EFFICACY ANALYSIS FROM MITAZALIMAB OPTIMIZE-1 PHASE 2 STUDY IN 1ST LINE PANCREATIC CANCER

- **Continued follow-up on the futility analysis cohort (23 patients) showed deepening of tumor responses and an increase in Objective Response Rate to 57% (from 52%)**
- **Interim Objective Response Rate of 44% in the full OPTIMIZE-1 cohort (57 patients) confirms benefit of mitazalimab added to mFOLFIRINOX**
- **Median Duration of Response of 8.7 months compares favorably with 5.9 months reported with FOLFIRINOX in a similar patient population**
- **Data suggest durable benefits of mitazalimab in combination with mFOLFIRINOX in patients with metastatic pancreatic cancer**

Lund, Sweden – Alligator Bioscience (Nasdaq Stockholm: ATORX) today announces positive second interim results from the ongoing OPTIMIZE-1 Phase 2 study of the company's lead asset mitazalimab in 1st line metastatic pancreatic cancer. The open-label, multi-center study is assessing the safety and efficacy of mitazalimab (CD40 mAb agonist) in combination with chemotherapy, mFOLFIRINOX, in previously untreated patients with metastatic pancreatic ductal adenocarcinoma.

The second interim analysis conducted on the 23 patients included in the interim analysis **reported in January 2023**, with a follow-up period of nine to 17 months, demonstrated the following:

- Tumor responses deepened and the Objective Response Rate (ORR) increased to 57% (from 52%), suggesting a durable benefit for patients
- Of the 13 patients achieving an objective response, seven (54%) were still ongoing in treatment for longer than 10 months with a maintained response, with the longest being 17 months

The interim analysis conducted on all 57 evaluable patients with a follow-up period of two to 17 months demonstrated the following:

- 25 patients responded to treatment resulting in an interim ORR of 44%.
- Median Duration of Response (DoR)[1] was 8.7 months compared to 5.9 reported for FOLFIRINOX alone in other studies[2], indicating an immunostimulatory effect of mitazalimab and potential Progression Free Survival (PFS) and survival benefits

- In addition, 19 patients (33%) achieved stable disease resulting in a 77% disease control rate (DCR)
- Furthermore, mitazalimab's manageable safety and tolerability profile in combination with mFOLFIRINOX was confirmed.

In both interim analyses, patients were evaluated as per the Response Evaluation Criteria in Solid Tumors (RECIST 1.1).

These data compare favorably to the ORR of 31.6%, mPFS of 6.4 months and DoR of 5.9 months reported in similar patient populations treated with standard of care FOLFIRINOX alone[2].

"Our OPTIMIZE-1 Phase 2 study has produced another set of very encouraging data to add to the growing body of compelling clinical evidence supporting our lead drug candidate mitazalimab in pancreatic cancer. Especially, we are excited to see that tumor responses continue to develop suggesting a longer benefit for the patients, and we are looking forward to seeing the data from the full cohort mature as the trial progress," said **Søren Bregenholt, CEO of Alligator Bioscience.** *" With our planned discussions with regulators and the expected top-line readout from OPTIMIZE-1 due at the beginning of next year, we continue to make excellent progress with the clinical development of mitazalimab and its route to market."*

"Several compounds have failed to show clinical benefit in pancreatic cancer. These second interim results from OPTIMIZE-1, in which mitazalimab again demonstrates a consistent response rate, together with the durable responses in several patients with extremely aggressive disease is particularly encouraging," said **Prof. Jean-Luc van Laethem, coordinating investigator, Erasmus University Hospital, Brussels (BE).** *"The consistent objective response rate together with the positive signal on duration of response of approximately 9 months gives us further crucial insight into the efficacy of mitazalimab and provides more evidence of the potential of this CD40 agonist to be further developed for becoming a therapeutic option for first line pancreatic cancer patients."*

PRESS RELEASE
26 June 2023 08:30:00 CEST

Completion of **patient enrolment in OPTIMIZE-1 was reported in April 2023**, and in May 2023, **mitazalimab was granted Orphan Drug Designation by the U. S. Food and Drug Administration for the treatment of pancreatic cancer**.

These data will form the basis of discussions with regulators in the U.S. and Europe on the optimal development and approval pathway for mitazalimab in pancreatic cancer.

OPTIMIZE-1 remains on track for top-line readout in early Q1 2024.

[1] Defined as the length of time that a tumor continues to respond to treatment without growing or spreading
[2] N Engl J Med 2011; 364:1817-1825; DOI: 10.1056/NEJMoa1011923

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

This information is information that Alligator Bioscience is obliged to make public pursuant to the EU Market Abuse Regulation. The information was submitted for publication, through the agency of the contact persons set out above, at 2023-06-26 08: 30 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 Positive Second Interim Efficacy Analysis from Mitazalimab OPTIMIZE-1 Phase 2 Study in 1st Line Pancreatic Cancer