PRESS RELEASE
21 August 2023 08:00:00 CEST

ALLIGATOR BIOSCIENCE RECEIVES EUROPEAN MEDICINE AGENCY ORPHAN DESIGNATION FOR MITAZALIMAB IN PANCREATIC CANCER

Lund, Sweden – Alligator Bioscience (Nasdaq Stockholm: ATORX) today announces that the European Medicines Agency (EMA) has granted Orphan Designation to its lead asset mitazalimab for the treatment of pancreatic cancer.

Mitazalimab is a monoclonal antibody targeting CD40 designed to sensitize tumors to chemotherapy and induce immune-mediated tumor killing by activating dendritic cells, B cells, and macrophages. Mitazalimab is currently being evaluated in OPTIMIZE-1, a Phase 2 open-label, multi-center study to assess its safety and efficacy in combination with chemotherapy, mFOLFIRINOX, in previously untreated patients with metastatic pancreatic ductal adenocarcinoma (**NCT04888312**).

In May 2023, **the U.S. Food and Drug Administration (FDA) granted orphan drug designation** to mitazalimab for the treatment of pancreatic cancer.

"We are very pleased that the European Medicines Agency has granted orphan designation to our lead asset mitazalimab in the treatment of pancreatic cancer," said **Søren Bregenholt, CEO of Alligator Bioscience.** *"It is our second orphan designation this year following the FDA's decision to grant us ODD in May, meaning mitazalimab now has stronger commercial protection through market exclusivity in these two key markets. This latest designation adds to the momentum we are building in our efforts to bring this promising drug candidate to market."*

To qualify for the EMA's orphan designation, a medicine must be intended for the treatment, prevention or diagnosis of rare, life-threatening or chronically debilitating diseases that affect fewer than five in 10,000 persons in the EU. Medicines that meet these criteria are eligible for financial and regulatory incentives that include 10 years of marketing exclusivity in the EU after product approval.

In June 2023, **Alligator announced a second set of strong interim results from OPTIMIZE-1**, in which mitazalimab combined with mFOLFIRINOX showed deepening of tumor response and increase in objective response rate (ORR) to 57% (from initially reported 52% ORR in 23 patients) and demonstrated an interim ORR of 44% in the full study cohort (57 patients) that is expected to further improve with longer follow up. A median duration of response (DoR) of 8.7 months , as per the Response Evaluation Criteria in Solid Tumors (RECIST 1.1), was also reported. This compares very strongly with an ORR of 31.6% and DOR of 5.9 months reported in a similar patient population treated with standard of care[1].

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

[1] N Engl J Med 2011; 364:1817-1825; DOI: 10.1056/NEJMoa1011923

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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 2023-08-21 08: 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**.

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Attachments

Alligator Bioscience Receives European Medicine Agency Orphan Designation for Mitazalimab in Pancreatic Cancer