PRESS RELEASE
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ALLIGATOR BIOSCIENCE RECEIVES FDA ORPHAN DRUG DESIGNATION FOR MITAZALIMAB IN PANCREATIC CANCER

Lund, Sweden – Alligator Bioscience (Nasdaq Stockholm: ATORX) today announces that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to its lead asset mitazalimab for the treatment of pancreatic cancer.

Mitazalimab is a monoclonal antibody targeting CD40 with the potential 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 January 2023, **Alligator announced strong interim results from OPTIMIZE-1**, in which mitazalimab combined with mFOLFIRINOX demonstrated an objective response rate (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]. Disease control rate, the proportion of patients with objective response or stabilization of disease, was more than 90%. In April 2023, **Alligator announced that OPTIMIZE-1 had been fully enrolled**.

"This designation is a key milestone for our lead asset mitazalimab, which is producing outstanding clinical results in its Phase 2 trial in pancreatic cancer," said **Søren Bregenholt, CEO of Alligator Bioscience.** *"Orphan designation confers significant benefits in the form of cost savings during development and marketing exclusivity following approval, and we are very pleased to see the potential of mitazalimab being recognized with the award of this designation."*

Orphan designation is granted by the FDA to a drug or biological product to prevent, diagnose or treat a rare disease or condition, and it qualifies sponsors for various incentives, including seven years of market exclusivity after approval, exemption from user fees and a tax credit of qualified clinical trials.

The orphan designation for mitazalimab and the positive interim results from OPTIMIZE-1 will be a key component of discussions with regulatory authorities regarding subsequent clinical development and approval pathway for mitazalimab in pancreatic cancer. Additional interim data from OPTIMIZE-1, including Progression Free Survival, are due in mid-2023 and full top-line data are expected in the beginning of Q1 2024.

[1] Conroy et al, 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 2023-05-18 12: 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

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