PRESS RELEASE
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ALLIGATOR BIOSCIENCE ANNOUNCES PAEDIATRIC STUDY WAIVER FOR MITAZALIMAB GRANTED BY THE EUROPEAN MEDICINES AGENCY

Lund, Sweden, 20 May 2025 – Alligator Bioscience (Nasdaq Stockholm: ATORX), a clinical stage biotechnology company pioneering immuno-oncology therapeutics, today announced that the European Medicines Agency (EMA) has granted a waiver from conducting paediatric clinical trials for Alligator's lead asset mitazalimab.

The waiver, issued as part of the Paediatric Investigation Plan (PIP) regulatory process, exempts Alligator from the obligation to conduct pediatric studies with mitazalimab in the treatment of pancreatic cancer. This regulatory milestone removes a key requirement ahead of potential future marketing authorization submissions in the European Union.

Mitazalimab, a CD40 agonist antibody, is currently being evaluated in the OPTIMIZE-1 Phase 2 clinical trial in combination with chemotherapy for patients with previously untreated metastatic pancreatic cancer. Recent 24-month follow-up data demonstrate a survival rate of 29.4% for patients treated with mitazalimab in combination with mFOLFIRINOX, which is more than triple the estimated 8% survival rate for FOLFIRINOX alone. The median overall survival was reported at 14.9 months, and the median duration of response was 12.6 months, both indicating a favorable safety profile and encouraging survival outcomes.

> *"This decision by the EMA allows us to continue advancing mitazalimab through late-stage development with a clear regulatory path to approval,"* said **Søren Bregenholt, CEO of Alligator Bioscience**. *"While we remain committed to the highest standards of patient safety, this waiver recognizes that pancreatic cancer is extremely rare in pediatric populations and supports our focused efforts to address the significant unmet medical need in adults."*

Alligator will continue to engage with regulatory authorities in Europe and the United States as it prepares for potential registrational steps for mitazalimab.

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The information was submitted for publication, through the agency of the contact person set out above, at 2:30 p.m. CEST on 20 May 2025.

About Alligator Bioscience

Alligator is a clinical-stage biotechnology company developing tumor-directed immuno-oncology antibody drugs focused on the CD40 receptor. This validated approach promotes priming of tumor-specific T cells and reversing the immunosuppressive nature of the tumor microenvironment, with significant potential benefits for cancer patients across multiple types of cancer. The Company's lead drug candidate mitazalimab, is currently in preparation for Phase 3 development, and has previously presented unprecedented survival data at 24-months follow up in first-line metastatic pancreatic cancer patients in the Phase 2 trial OPTIMIZE-1.

Alligator is listed on Nasdaq Stockholm (ATORX) and headquartered in Lund, Sweden.

For more information, please visit **alligatorbioscience.com**.

Attachments

Alligator Bioscience announces paediatric study waiver for mitazalimab granted by the European Medicines Agency