PRESS RELEASE
06 February 2025 08:45:00 CET

ALLIGATOR BIOSCIENCE SUCCESSFULLY COMPLETES END OF PHASE 2 INTERACTION WITH FDA FOR MITAZALIMAB

- **FDA feedback validates the clinical development strategy and Phase 3 design**
- **FDA feedback confirms that the toxicology package is adequate for the BLA submission**
- **Regulatory feedback significantly reduces program risk and Company remains on track for Phase 3 initiation during 2025**

Lund, Sweden – Alligator Bioscience (Nasdaq Stockholm: ATORX) today announces the successful completion of its End of Phase 2 (EOP2) interaction with the US Food and Drug Administration (FDA), further strengthening the prospect of initiating Phase 3 in 2025 with mitazalimab, which is in development as a first-line treatment for metastatic pancreatic cancer in combination with mFOLFIRINOX.

The EOP2 meeting with the FDA provided positive feedback and alignment on the non-clinical and clinical data packages to support the Biologics License Application (BLA), including the Phase 3 trial design, thus reinforcing earlier regulatory guidance from the Paul Ehrlich Institute (PEI) of Germany in July 2024. Additionally, a recent Type C Chemistry, Manufacturing, and Controls (CMC) interaction with the FDA in December 2024 confirmed that the completed and planned CMC work through early 2025 is Phase 3-enabling.

Alligator expanded patient recruitment during 2024 in the ongoing OPTIMIZE-1 study by enrolling an additional 15 patients at the 450 µg/kg dose level as per guidance received from the FDA in December 2023. Results from this cohort, along with a 24-month follow-up on the 900 µg/kg dose group, are expected during Q1 2025. Alligator updated the FDA on this activity, and no new information emerged affecting the Phase 3 dose selection.

"*The successful outcome of our End-of-Phase 2 FDA interaction marks a critical milestone in our development program,"* said **Søren Bregenholt, CEO of Alligator Bioscience**. *" With clear regulatory alignment on our Phase 3 trial and robust CMC progress, mitazalimab is well-positioned for Phase 3 initiation during 2025. We remain committed to addressing the unmet medical need of patients with metastatic pancreatic cancer."*

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For further information, please contact:

Søren Bregenholt, CEO
E-mail: **soren.bregenholt@alligatorbioscience.com**
Phone: +46 (0) 46 540 82 00

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 18-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

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