

ALLIGATOR BIOSCIENCE ANNOUNCES POSITIVE OUTCOME OF REGULATORY INTERACTIONS ON PHASE 3 CMC ACTIVITIES

- FDA feedback reinforces manufacturing strategy reducing regulatory risk of the program
- Feedback confirms completed and planned CMC-work as Phase 3-enabling
- Company remains on track for Phase 3 initiation during 2025

Lund, Sweden – Alligator Bioscience (Nasdaq Stockholm: ATORX) today announces the positive outcome of regulatory interactions with the Paul Ehrlich Institute (PEI) of Germany and the US Food and Drug Administration (FDA) regarding the CMC development of mitazalimab, which is in development as a first-line treatment for metastatic pancreatic cancer in combination with mFOLFIRINOX.

A recent Type C CMC interaction with the FDA in December 2024 reinforced feedback received from the PEI in July 2024, confirming that the completed and planned CMC work through early 2025 enables the Phase 3 development of mitazalimab. With this feedback, Alligator initiated manufacturing of mitazalimab to be used in the Phase 3 study, and thus remains on track for initiation of Phase 3 clinical activities during 2025.

*"This regulatory feedback from both the FDA and PEI demonstrates the robustness of our CMC development strategy and validates the significant progress we've made in advancing mitazalimab towards Phase 3" said **Søren Bregenholt, CEO of Alligator Bioscience**. "We are confident in our ability to continue to execute on our timeline and bring mitazalimab one step closer to addressing the urgent unmet need for patients with metastatic pancreatic cancer."*

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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

Alligator Bioscience Announces Positive Outcome of Regulatory Interactions on Phase 3 CMC activities