

ALLIGATOR BIOSCIENCE ANNOUNCES COMPLETION OF ENROLLMENT IN MITAZALIMAB OPTIMIZE-1 STUDY

- Recruitment completed for the additional cohort with 450 µg/kg of mitazalimab in combination with mFOLFIRINOX as requested by FDA ahead of Phase 3 initiation
- Alligator remains on track for mitazalimab Phase 3 initiation H1 2025

Lund, Sweden – Alligator Bioscience (Nasdaq Stockholm: ATORX) today announced an update on the on-going OPTIMIZE-1 clinical Phase 2 trial with the company's lead asset, mitazalimab. All patients in the 450 µg/kg back-fill cohort have been enrolled.

The additional cohort was enrolled in order to provide further dose characterization following advice from the FDA, to ensure mitazalimab Phase 3 readiness.

"We are pleased to see the recruitment completed in a very swift manner, a testament to the committed work by the Alligator team and the great engagement of the study investigators and their research staff involved in the OPTIMIZE-1 trial", said Søren Bregenholt, CEO of Alligator Bioscience. "We are committed to bringing mitazalimab to patients as soon as possible, and this back-fill cohort is an important step to complete the dose-characterization and ensure mitazalimab's Phase 3-readiness in accordance with the guidance from FDA."

OPTIMIZE-1, an open-label, single-arm, multicenter, Phase 1b/2 study, assessed the safety and efficacy of mitazalimab (CD40 mAb agonist) in combination with standard of care chemotherapy mFOLFIRINOX in 1st line pancreatic cancer. On June 26, the **18-month follow-up analysis** was reported, demonstrating robust data with substantial survival benefits compared to standard of care chemotherapy.

About pancreatic cancer

Pancreatic cancer is the 12th largest cancer by number of patients. It is expected to become the second leading cause of cancer death in the western world by 2030. There are about 200,000 annual cases in the U.S. and the EU, with very poor prognosis: five-year survival is about 10% and median survival about 6 months. For 80% of patients, the only option is chemotherapy that offers only marginal benefit. FOLFIRINOX is expected to be the preferred first line regimen in the U.S. and the EU for patients with good performance status.

Sources: POLARIS Market Research, KOL event

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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

Alligator Bioscience Announces Completion of Enrollment in Mitazalimab OPTIMIZE-1 Study