PRESS RELEASE
26 May 2025 15:00:00 CEST

ALLIGATOR BIOSCIENCE ANNOUNCES EUROPEAN ORPHAN DRUG DESIGNATION FOR HLX22 IN GASTRIC CANCER

Lund, Sweden – 26 May 2025 – Alligator Bioscience (Nasdaq Stockholm: ATORX) today announces that the European Commission has granted orphan drug designation (ODD) to HLX22, an anti-HER2 monoclonal antibody, for the treatment of gastric cancer. HLX22 is being developed by Shanghai Henlius Biotech, Inc. under a sublicense from AbClon, Inc., which had previously licensed the antibody from Alligator.

This designation follows the ODD granted by the U.S. Food and Drug Administration (FDA) in March 2025, further highlighting HLX22's potential as a treatment for HER2-positive gastric cancer.

Henlius is conducting a global Phase 3 clinical trial (NCT06532006) to evaluate HLX22 in combination with trastuzumab and chemotherapy as a first-line treatment for HER2-positive metastatic gastric and gastroesophageal junction (GEJ) cancer.

Søren Bregenholt, CEO of Alligator Bioscience, commented:
"The orphan designation to HLX22 in Europe represents another important regulatory milestone for this program. Following the earlier FDA designation, this reinforces the potential clinical and commercial value of the antibody. While Alligator is not directly involved in the development, we look forward to following its progress as it may contribute future revenue to Alligator."

Under the terms of the license agreement, Alligator is entitled to 35% of AbClon's revenue from its sublicense agreement with Henlius.

For further information, please contact:

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

The information was submitted for publication, through the agency of the contact person set out above, at 3:00 p.m. CEST on 26 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**.

About the European Orphan Drug Designation

The European Orphan Drug Designation is granted to medicines intended for the treatment, prevention or diagnosis of life-threatening or chronically debilitating conditions affecting no more than five in 10,000 people in the EU. The designation provides a range of incentives, including protocol assistance, fee reductions, and ten years of market exclusivity following regulatory approval.

Attachments

Alligator Bioscience announces European orphan drug designation for HLX22 in gastric cancer