PRESS RELEASE
20 March 2025 15:00:00 CET

ALLIGATOR BIOSCIENCE ANNOUNCES FDA ORPHAN DRUG DESIGNATION FOR HLX22/AC101 IN GASTRIC CANCER

Lund, Sweden – 20 March 2025 – Alligator Bioscience (Nasdaq Stockholm: ATORX) today announces that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation (ODD) to HLX22 (AC101), 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 .
The FDA's ODD provides incentives such as tax credits for clinical trials, waiver of certain regulatory fees, and market exclusivity upon approval, supporting the continued development of HLX22 as a potential treatment for HER2-positive metastatic gastric and gastroesophageal junction (GEJ) cancer.

Henlius is conducting a Phase 3 clinical trial (HLX22-GC-301) to evaluate HLX22 /AC101 in combination with trastuzumab and chemotherapy as a first-line treatment for HER2-positive metastatic gastric and GEJ cancer. The global study is enrolling patients across the U.S., China, Japan, and Australia.

> Søren Bregenholt, CEO of Alligator, commented: *"The FDA's recognition of HLX22 /AC101's potential with Orphan Drug Designation is a notable recognition. While Alligator's is not directly involved in the development of HLX22/AC101, we continue to follow its progress as it potentially represents future income to Alligator."*

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

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The information was submitted for publication, through the agency of the contact person set out above, at 3:00 p.m. CET on 20 March 2025.

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Attachments

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