PRESS RELEASE
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ALLIGATOR BIOSCIENCE'S ANNOUNCES HENLIUS BIOTECH HAS RECEIVED FDA IND CLEARANCE FOR PHASE 3 INITIATION TO EVALUATE HLX22 (AC101) IN 1ST LINE HER2+ ADVANCED GASTRIC CANCER

- **FDA IND follows promising Phase 2 results presented at 2024 ASCO GI revealing that the addition of HLX22 (AC101) to biosimilar trastuzumab and chemotherapy led to dose-dependent increase in Progression Free Survival**

Lund, Sweden – Alligator Bioscience (Nasdaq Stockholm: ATORX) today announces that Shanghai Henlius Biotech, Inc. has received Investigational New Drug (IND) clearance from the US Food and Drug Administration (FDA) to initiate a Phase 3 study to evaluate HLX22 (AC101) in combination with trastuzumab (Herceptin®) and chemotherapy in 1st line HER2-positive advanced gastric cancer patients.

Gastric/gastroesophageal junction (G/GEJ) cancer is one of the most common cancers and approximately 20% of these patients show HER2 amplification or overexpression. Despite the approval of Herceptin® (trastuzumab) in the US in 2010, the median overall survival of patients suffering from HER2+ gastric cancer remains limited.

HLX22 (AC101) is an innovative monoclonal anti-HER2-antibody, which was out-licensed by Alligator to the South Korean company AbClon, Inc. in 2016, who sub-licensed the drug candidate to Henlius Biotech for clinical and commercial development in China. Alligator retains an ownership interest entitling the company to 35% of AbClon's income from the agreement with Henlius Biotech.

In January 2024, Henlius Biotech presented promising Phase 2 results at the 2024 ASCO Gastrointestinal Cancers Symposium (ASCO GI), which were also published in the **Journal of Clinical Oncology**. The data demonstrated that the addition of HLX22 (AC101) to HLX02 (a biosimilar of trastuzumab) and XELOX (Oxaliplatin and capecitabin) in 1st line treatment of HER2-positive locally advanced or metastatic G /GEJ cancer led to a dose-dependent increase in Progression Free Survival, meeting the study's main efficacy endpoint.

"We are very pleased to see the highly encouraging progress Henlius Biotech are making with the development of HLX22 in gastric cancer," said **Søren Bregenholt, CEO of Alligator Bioscience.** *"The Phase 2 results presented at ASCO earlier this year followed by this Phase 3 IND clearance demonstrate our ability to deliver an asset like HLX22 with a highly differentiated profile and a great deal of potential to improve treatment outcomes for patients suffering from a devastating disease like gastric 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

LifeSci Advisors
Investor Relations
Guillaume van Renterghem
E-mail: **gvanrenterghem@lifesciadvisors.com**
Phone: +41 (0) 76 735 01 31

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's Announces Henlius Biotech has Received FDA IND Clearance for Phase 3 Initiation to Evaluate HLX22 (AC101) in 1st Line HER2+ Advanced Gastric Cancer