

ALLIGATOR BIOSCIENCE ANNOUNCES IND APPROVAL FOR SECOND PHASE 2 CLINICAL TRIAL OF AC101 (HLX22) IN GASTRIC CANCER DEVELOPED BY SHANGHAI HENLIUS BIOTECH IN CHINA

- Study to evaluate AC101 (HLX22) in combination with anti-PD-1 antibody serplulimab, trastuzumab and chemotherapy in gastric cancer
- Phase 2 comes in addition to ongoing study evaluating AC101 (HLX22) in 1st line gastric cancer in combo with chemo and Trastuzumab, with data expected in Q2 2023
- AC101 (HLX22) was out-licensed to Shanghai Henlius Biotech for clinical and commercial development in China on which Alligator is eligible to part of the economics

Lund, Sweden, November 8, 2022 - Alligator Bioscience (Nasdaq Stockholm: ATORX) today announces that Shanghai Henlius Biotech, Inc. has received investigational new drug (IND) approval from China's National Medical Products Administration (NMPA) for a Phase 2 clinical trial of AC101 (HLX22), a monoclonal HER2 antibody, in combination with anti-PD-1 monoclonal antibody HANSIZHUANG (serplulimab), HANQUYOU (trastuzumab) and chemotherapy as a 1st line treatment for HER2-positive locally advanced/metastatic gastric cancer patients.

Alligator out-licensed AC101 (HLX22) 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. In September 2022, Henlius announced the completion of the Phase 1 trial of AC101 (HLX22) in patients with HER2 overexpressing advanced solid tumors, in which it demonstrated a good safety and tolerability profile.

*"Henlius is making very encouraging progress in its clinical development of AC101 (HLX22) in gastric cancer," said **Søren Bregenholt, CEO of Alligator Bioscience**. "Following the good safety and tolerability results from the Phase 1 study in September, this is now the second Phase 2 study the company has initiated with this candidate in this indication. It is a further boost to the potential of our AC101 (HLX22) asset, and we are particularly looking forward to seeing what results this new combination setting yields, especially as it includes the addition of the anti-PD-1 monoclonal antibody serplulimab."*

PRESS RELEASE

08 November 2022 09:30:00 CET



Henlius initiated a prior Phase 2 clinical trial to evaluate AC101 (HLX22) in combination with HANQUYOU (trastuzumab) and chemotherapy as a first-line treatment for HER2-positive locally advanced/metastatic gastric cancer patients in September 2021. The estimated primary completion date is April 2023, and the study completion date is expected in September 2024.

The information was submitted for publication, through the agency of the contact persons set out below, at 9.30 a.m. CET on November 8, 2022.

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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 pipeline includes the two key assets mitazalimab, a CD40 agonist, and ATOR-1017, a 4- 1BB agonist. 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.

About Shanghai Henlius Biotech, Inc.

Henlius (2696.HK) is a global biopharmaceutical company with the vision to offer high-quality, affordable, and innovative biologic medicines for patients worldwide with a focus on oncology, autoimmune diseases, and ophthalmic diseases. Up to date, 3 products have been launched in China, 1 in the European Union (EU), the New Drug Applications (NDA) of 3 products accepted for review in China. Since its inception in 2010, Henlius has built an integrated biopharmaceutical platform with core capabilities of high-efficiency and innovation embedded throughout the whole product life cycle including R&D, manufacturing, and commercialization. It has established global R&D centers and a Shanghai-based manufacturing facility certificated by China and the EU Good Manufacturing Practice (GMP).

About AbClon, Inc.

AbClon, based in Seoul, South Korea, has been dedicated to the research, development of new antibody drugs. The company has established two platforms, Novel Epitope Screening Technology (NEST) and monoclonal antibody platform (AffiMab), to accelerate the discovery and development of innovative antibody therapeutics.

Attachments

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