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ESSEX BIO-TECHNOLOGY LIMITED

億勝生物科技有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 1061)

INSIDE INFORMATION

A PHASE 3 CLINICAL STUDY IN RELATION TO THE CO-DEVELOPMENT OF THE LICENSED PRODUCT WITH HENLIUS FOR THE TREATMENT OF EXUDATIVE (WET) AGE-RELATED MACULAR DEGENERATION MET THE STUDY PRIMARY ENDPOINT

This announcement is made by Essex Bio-Technology Limited (the “**Company**”) pursuant to Rule 13.09 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “**Listing Rules**”) and the Inside Information Provisions (as defined under the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong).

Reference is made to the announcement of the Company dated 15 October 2020 (“**Announcement**”) in relation to the Co-Development License Agreement entered into between the Licensee (both are wholly-owned subsidiaries of the Company) with Shanghai Henlius Biotech, Inc. (“**Henlius**”) for the co-development of, and the grant to the Licensee of the exclusive rights relating to, the Licensed Product in accordance with the terms of the Co-Development License Agreement. References are also made to various announcements of the Company published during the period from January 2021 to January 2025 in relation to certain updates thereon. The Licensed Product is a bio-pharmaceutical product that contains the recombinant anti-vascular endothelial growth factor humanised monoclonal antibody (“**anti-VEGF**”), a drug substance, which is intended for the treatment of exudative (wet) age-related macular degeneration (“**wet-AMD**”). Unless otherwise specified, capitalised terms used in this announcement shall have the same meanings as those defined in the Announcement.

FURTHER UPDATE ON THE DEVELOPMENT RELATING TO HLX04-O

The Board is pleased to announce that results of a phase 3 clinical study of the anti-VEGF ophthalmic injection bio-pharmaceutical product (referred to as “**HLX04-O**”) in Chinese patients with wet-AMD (“**AURA-1**”) have met the study primary endpoint.

AURA-1 is a multi-centre, randomised, double-blinded, active-controlled and non-inferiority phase 3 clinical trial, which aimed to compare the efficacy and safety of HLX04-O with that of ranibizumab administered by intravitreal injection (“**IVT**”) in newly diagnosed wet-AMD patients. Patients enrolled were randomised at a ratio of 1:1 to receive either HLX04-O (1.25 mg) IVT or ranibizumab (0.5 mg) IVT, administered every 4 weeks. The treatment continued for 1 year until death, withdrawal of consent, loss to follow-up or study termination by the sponsor. The primary endpoint of this study was mean change of letters in the best-corrected visual acuity (“**BCVA**”) from baseline at week 48. The secondary endpoints included other efficacy, safety, tolerability and pharmacokinetics. Results showed that the primary endpoint of this study was met, with the mean change in BCVA from baseline at week 48 in the HLX04-O group being non-inferior to that in the ranibizumab group. Additionally, HLX04-O had a good safety profile, with similar overall ocular and non-ocular safety results compared to ranibizumab in wet-AMD patients.

INFORMATION ABOUT HLX04-O

HLX04-O is a new ophthalmic preparation product developed based on HANBEITAI® (bevacizumab injection) independently developed by Henlius, through optimising the prescription, specifications and production processes of HANBEITAI® (bevacizumab injection) according to the requirements of ophthalmic drugs, without changing the active ingredients, and is intended to be used for the treatment of wet-AMD.

In addition to AURA-1 which has met its primary endpoint, an international multi-centre phase 3 clinical study of HLX04-O in patients with wet-AMD is ongoing successively in several European countries, Australia, the United States and the PRC (AURA-2) with last patient last visit completed by January 2025.

CURRENT MARKET CONDITION

As of the date of this announcement, to the best of the Directors' knowledge, there is yet an approved bevacizumab product for the treatment of wet-AMD in the PRC. According to the statistics released by IQVIA CHPA (IQVIA is the world's provider of professional information and strategic consulting services in the pharmaceutical and healthcare industry), sales of drugs approved in the PRC for the treatment of wet-AMD in 2024 were approximately RMB4.18 billion.

The Company cannot guarantee the successful development and commercialisation of HLX04-O. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

On behalf of the Board
Essex Bio-Technology Limited
Ngiam Mia Je Patrick
Chairman

Hong Kong, 2 April 2025

Executive directors of the Company as at the date of this announcement are Mr. Ngiam Mia Je Patrick, Mr. Fang Haizhou, Mr. Ngiam Hian Leng Malcolm and Ms. Yau Lai Man. Independent non-executive directors of the Company as at the date of this announcement are Mr. Fung Chi Ying, Ms. Yeow Mee Mooi and Mr. Yan Man Sing Frankie.