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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)

# LAST PATIENT LAST VISIT ("LPLV") COMPLETED IN AN INTERNATIONAL MULTI-CENTRE 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

Reference is made to the announcement of Essex Bio-Technology Limited ("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 the announcements of the Company dated 29 January 2021, 19 March 2021, 20 April 2021, 19 July 2021, 10 November 2021, 10 February 2023, 22 February 2023 and 26 July 2023 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 the LPLV has recently been completed in an international multicentre phase 3 clinical study for the anti-VEGF ophthalmic injection bio-pharmaceutical product, referred to as HLX04-O, for the treatment of wet-AMD.

The phase 3 clinical study is a randomised, double-blinded, active-controlled and global study conducted in patients with wet-AMD, which aims to compare the efficacy and safety of HLX04-O with that of ranibizumab. Eligible patients will be randomly divided into two groups at a ratio of 1:1 to receive intravitreal injection of HLX04-O (1.25 mg) or ranibizumab (0.5 mg) every four weeks for 48 weeks. The primary objective of this study is to compare the efficacy of HLX04-O with that of ranibizumab at week 36 in patient's study eye with wet-AMD. The primary endpoint is the mean change from baseline in the best-corrected visual acuity (BCVA) at week 36. The secondary objectives include the evaluation of other efficacy endpoints, safety, tolerability and pharmacokinetic profiles.

### **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.

### **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.

Drugs targeting wet-AMD indications that have been approved in the PRC include Lucentis® (Ranibizumab), Langmu® (Conbercept) and Eylea® (Aflibercept).

On behalf of the Board

Essex Bio-Technology Limited

Ngiam Mia Je Patrick

Chairman

Hong Kong, 6 January 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.