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)

VOLUNTARY ANNOUNCEMENT

UPDATE ON THE PHASE 1/2 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 and 22 February 2023 in relation to certain updates thereon. The Licensed Product is a pharmaceutical product that will contain at least HLX04-O-wAMD as 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 phase 1/2 clinical study for recombinant anti-vascular endothelial growth factor ("**anti-VEGF**") humanised monoclonal antibody ophthalmic injection HLX04-O ("**HLX04-O**") for the treatment of wet-AMD has recently shown its safety and tolerability and demonstrated preliminary efficacy.

The phase 1/2 clinical study is a single-arm, open-label and multi-centre study that consists of two parts, which aims to evaluate the safety and preliminary efficacy of HLX04-O via intravitreal injection ("**IVT**") in patients with active wet-AMD. Part 1 of the study is a safety run-in stage and 6 patients were enrolled, and part 2 of the study is a single-arm, open-label and multi-centre phase 2 study and 20 patients (including 6 patients from part 1) were enrolled. All patients received HLX04-O IVT (1.25 mg/0.05 mL) every four weeks until death, withdrawal of informed consent, loss to follow-up, termination of study by sponsor or completion of one-year treatment. For part 1, the primary endpoint is the safety event related to HLX04-O that occurred within four weeks after the first dose of HLX04-O, and secondary endpoints are the systemic pharmacokinetic characteristics of HLX04-O after the first and fourth IVT administration. For part 2, the primary endpoint is the mean change of letters from baseline in best-corrected visual acuity (BCVA) at week 12, and secondary endpoints include other efficacy measures, safety, immunogenicity and systemic pharmacokinetic characteristics. The results show that HLX04-O is safe and well tolerated in wet-AMD patients, and preliminary efficacy was observed.

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 November 2021, the first patient had been dosed in a phase 3 clinical study for HLX04-O for the treatment of wet-AMD in the PRC. So far, the first patient had been dosed in an international multi-centre phase 3 clinical study for HLX04-O in patients with wet-AMD in countries such as Latvia (a European Union country), Australia and the United States successively.

CURRENT MARKET CONDITION

As of the date of this announcement, to the knowledge of the Directors, none of the bevacizumab products marketed within the PRC has been approved for the treatment of wet-AMD.

Large molecule drugs targeting wet-AMD indications that have been marketed within the PRC include Lucentis® (Ranibizumab), Langmu® (Conbercept) and Eylea® (Aflibercept). According to the latest statistics released by IQVIA CHPA, the world's leading provider of professional information and strategic consulting services in the pharmaceutical and healthcare industry, sales of relevant drugs in the PRC in 2022 were as follows: RMB1,347 million for Lucentis®, RMB1,116 million for Langmu® and RMB644 million for Eylea®.

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

Hong Kong, 26 July 2023

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.