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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)

VOLUNTARY ANNOUNCEMENT

FIRST PATIENT FIRST DOSE COMPLETED IN THE UNITED STATES 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 and 10 November 2021 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 first patient in the United States has recently been dosed in an international multi-centre phase 3 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.

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. 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. In April 2022, the first patient had been dosed in an international multi-centre phase 3 clinical study for HLX04-O in patients with wet-AMD in Latvia (a European Union country) and Australia successively.

CURRENT MARKET CONDITION

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

Large molecule drugs targeting wet-AMD indications that have been marketed globally include Eylea[®] (Aflibercept), Lucentis[®] (Ranibizumab) and BEOVU[®] (Brolucizumab). According to the statistics released by IQVIA MIDAS[™], the world's leading provider of professional information and strategic consulting services in the pharmaceutical and healthcare industry, the global sales of relevant drugs (a) in 2021 were as follows: US\$4,657 million for Eylea[®], US\$4,154 million for Lucentis[®] and US\$193 million for BEOVU[®]; and (b) in the first half of 2022 were as follows: US\$2,371 million for Eylea[®], US\$1,851 million for Lucentis[®] and US\$107 million for BEOVU[®].

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

Hong Kong, 10 February 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, Mr. Mauffrey Benoit Jean Marie and Ms. Yeow Mee Mooi.