**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 VISIT COMPLETED IN A PHASE 3 CLINICAL STUDY IN THE PRC IN RELATION TO THE CO-DEVELOPMENT OF THE LICENSED PRODUCT WITH HENLIUS RELATING TO 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 and 19 July 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 first patient has recently been dosed in a phase 3 clinical study for recombinant anti-vascular endothelial growth factor ("**anti-VEGF**") humanised monoclonal antibody injection HLX04-O ("**HLX04-O**") for the treatment of wet-AMD in the PRC.

This is a multi-centre, randomised, double-blind and active-controlled phase 3 clinical study conducted in patients with wet-AMD, aiming 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 up to one year. The primary objective of this study is to compare the efficacy of HLX04-O with that of ranibizumab at week 48 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 48. The secondary objectives are to evaluate other efficacy endpoints, safety, tolerability and pharmacokinetic profiles.

**Information about HLX04-O**

HLX04-O is a new ophthalmic preparation product developed based on bevacizumab injection (a recombinant humanised anti-VEGF monoclonal antibody injection, original project code: HLX04) independently developed by Henlius, through optimising the prescription, specifications and production processes of bevacizumab injection HLX04 according to the requirements of ophthalmic drugs, without changing the active ingredients, and is intended to be used for the treatment of wet-AMD. By means of comparability studies, it is shown that changes in production processes and prescriptions of the preparation have no adverse impact on the quality, safety and efficacy of the pharmaceutical preparation. In July 2021, the first patient has been dosed in a phase 1 clinical study for HLX04-O for the treatment of wet-AMD in the PRC. HLX04-O for the treatment of wet-AMD has been successively approved to commence the phase 3 clinical trial in Australia, the United States, Singapore, Russia, Serbia and European Union countries such as Hungary, Spain, Latvia, the Czech Republic and Poland.

**Current Market Condition**

As of the date of this announcement, to the knowledge of the Directors, none of the bevacizumab products marketed in the PRC has shown wet-AMD indications.

Large molecule drugs targeting wet-AMD indications that have been marketed in the PRC include Lucentis® (Ranibizumab), Langmu® (Conbercept) and Eylea® (Aflibercept). According to the latest statistics released by IQVIA CHPA, being 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 (a) in 2020 were as follows: RMB990 million for Lucentis®, RMB980 million for Langmu® and RMB270 million for Eylea®; and (b) in the first half of 2021 were as follows: RMB650 million for Lucentis®, RMB600 million for Langmu® and RMB260 million for Eylea®.

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

Hong Kong, 10 November 2021

*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.*