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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 VISIT COMPLETED 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 and 20 April 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

Based on the information provided by Henlius, the first patient has recently been dosed in a phase 1 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.

As informed by Henlius, this is a single-arm phase 1 study conducted in patients with wet-AMD. As a safety run-in stage, six to twelve patients were planned to be enrolled in this study. The primary objective is to evaluate the safety and tolerability of HLX04-O in the study eye of wet-AMD patients. The secondary objective is to evaluate the systemic pharmacokinetic profiles of HLX04-O after intravitreal injection.

#### **Information about HLX04-O**

Based on the information provided by Henlius, (i) 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; (ii) 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. The primary action mechanism of HLX04-O is to inhibit VEGF's binding to its receptor Flt-1 and KDR on endothelial cells to inhibit the activation of its tyrosine kinase signaling pathway, inhibit endothelial cell proliferation and reduce angiogenesis, thereby treating eye diseases associated with angiogenesis; and (iii) HLX04-O for the treatment of wet-AMD has been approved to commence the phase 3 clinical trial in Australia, the United States, Singapore and European Union countries such as Hungary, Spain and Latvia.

#### **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.

Based on the information provided by Henlius, (i) large molecule drugs targeting wet-AMD indications that have been marketed in the PRC include Lucentis<sup>®</sup> (Ranibizumab), Langmu<sup>®</sup> (Conbercept) and Eylea<sup>®</sup> (Aflibercept); and (ii) 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 in 2020 were as follows: RMB900 million for Lucentis<sup>®</sup>, RMB880 million for Langmu<sup>®</sup> and RMB230 million for Eylea<sup>®</sup>.

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

Hong Kong, 19 July 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.