【Press release】

ESSEX BIO-TECHNOLOGY LIMITED
億勝生物科技有限公司

(Stock Code: 1061)

Study Primary Endpoint Met in AURA-2, a Phase 3 Clinical Study of Bevacizumab EB12-20145P (HLX04-O) for the Treatment of Ophthalmic Diseases

Hong Kong, 16 June 2026

Essex Bio-Technology Limited ("Essex" or the "Group", Stock Code: 1061.HK) today announced that the multi-centre phase 3 clinical trial of EB12-20145P (HLX04-O), a recombinant anti-VEGF humanised monoclonal antibody injection jointly developed by the Group and Shanghai Henlius Biotech, Inc. ("Henlius", Stock Code: 2696.HK), in patients with wet age-related macular degeneration ("wet-AMD") ("AURA-2"), has met the study primary endpoint. Together with the global phase 3 clinical study conducted in China ("AURA-1"), these results will constitute a pivotal data package to support the Group in advancing marketing authorisation applications in overseas markets, including the United States. Previously, the Biologics License Application ("BLA") for EB12-20145P (HLX04-O) in wet-AMD has been accepted by the Centre for Drug Evaluation ("CDE") of the National Medical Products Administration ("NMPA") in China.

AURA-2 is a global multi-centre, randomised, double-blind, active-controlled, and non-inferiority phase 3 clinical trial which aimed to compare the efficacy and safety of EB12-20145P (HLX04-O) with that of ranibizumab administered by intravitreal injection ("IVT") in wet-AMD patients. Patients enrolled were randomised at a ratio of 1:1 to receive either EB12-20145P (HLX04-O) (1.25 mg) or ranibizumab (0.5 mg) IVT, administered every 4 weeks. The treatment continued for 1 year until death, withdrawal of consent, loss to follow-up, or study termination by the sponsor. The primary endpoint of this study was mean change from baseline in best-corrected visual acuity ("BCVA") at week 36. The key secondary endpoint was mean change from baseline in BCVA at week 48; secondary endpoints included other efficacy, safety, tolerability, and pharmacokinetics. Results showed that the

primary and key secondary endpoints of this study were met, with the mean change in BCVA from baseline at week 36 and week 48 in the EB12-20145P (HLX04-O) group being non-inferior to that in the ranibizumab group. Additionally, EB12-20145P (HLX04-O) had a good safety profile, with similar overall ocular and non-ocular safety results compared to ranibizumab in wet-AMD patients.

EB12-20145P (HLX04-O) is a novel ophthalmic formulation developed to address specific clinical needs in ophthalmology. According to the requirements of ophthalmic drugs, EB12-20145P (HLX04-O) is designed to optimise the prescription, specifications, and production processes of HANBEITAI (bevacizumab injection), assuming that the active ingredients remain unchanged. Developed using genetic engineering technology, EB12-20145P (HLX04-O) specifically binds to VEGF and blocks its interaction with endothelial cell receptors Flt-1 (VEGFR-1) and KDR (VEGFR-2), thereby inhibiting downstream tyrosine kinase signalling pathways. This mechanism inhibits endothelial cell proliferation and pathological neovascularisation, enabling the treatment of eye diseases associated with angiogenesis such as wet-AMD. Through a series of comparability analyses, it is proved that the changes in the production process and prescription of the preparation have no adverse impact on the quality, safety, and efficacy of the preparation. To date, no bevacizumab-based therapy marketed has been approved for the treatment of wet-AMD in Mainland China, representing a significant unmet clinical need that EB12-20145P (HLX04-O) is positioned to address.

Moving forward, Essex will continue to strive for excellence by embracing innovation to develop first-in-class and best-in-class products, providing solutions for Tomorrow's healthcare problems, Today.

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About wet-AMD

Age-related macular degeneration ("AMD") is one of the leading causes of visual impairment and blindness in the elderly worldwide [1]. According to the World Health Organization (WHO), about 30 million people have suffered from AMD globally, and about half a million people become blind due to AMD each year [2]. Wet age-related macular degeneration ("wet-AMD") is characterised by the formation of subretinal choroidal neovascularization (CNV) and is responsible for approximately 90% of cases of AMD-related blindness. Due to an aging population, wet-AMD has become a serious social medical problem and indicated a huge burden of unmet need [3]. With the development of treatment for fundus diseases, anti-VEGF drugs are becoming the first-line therapy for the management of wet-AMD [4], and the efficacy and safety of vitreous injection of bevacizumab for wet-AMD have been verified in multiple clinical studies [5-11].

About Essex

Essex is a bio-pharmaceutical company that develops, manufactures, and commercialises genetically engineered therapeutic b-bFGF, with six commercialised biologics currently marketed in China. Additionally, the Company has a diverse portfolio of commercialised preservative-free unit-dose eye drops, Shilishun(適麗順®) (Iodized Lecithin Capsules) and others, which are principally prescribed for wound healing and diseases in Ophthalmology and Dermatology.

These products are marketed and sold through approximately 14,600 hospitals, supported by the Company's 47 regional offices in China. Leveraging its in-house R&D platform in growth factor and antibody technology, Essex maintains a robust pipeline of projects in various clinical stages, covering a wide range of fields and indications.

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