【Press release】

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

(Stock Code: 1061)

NMPA Accepted Essex's Biologics License Application for EB12-20145P (HLX04-O) for the Treatment of Wet Age-Related Macular Degeneration.

Hong Kong, 13 August 2025

Essex Bio-Technology Limited ("Essex" or the "Group", Stock Code: 1061.HK) is pleased to announce that a Biologics License Application ("BLA") for EB12-20145P (HLX04-O), a recombinant anti-VEGF humanized monoclonal antibody injection, has recently been accepted by the Centre for Drug Evaluation ("CDE") of the National Medical Products Administration ("NMPA") in China. The product is jointly developed by the Group and Shanghai Henlius Biotech, Inc. ("Henlius", Stock Code: 2696.HK) for the treatment of wet age-related macular degeneration ("wet-AMD") in China.

The phase 3 clinical trial of EB12-20145P (HLX04-O) among Chinese patients ("AURA-1") has successfully reached the primary endpoint in April this year. AURA-1 is a 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 newly diagnosed wet-AMD patients.

In addition to AURA-1, the BLA of which has been validated by the NMPA, an international, multi-centre phase 3 clinical study of EB12-20145P (HLX04-O) in patients with wet-AMD is ongoing successively in several European countries, Australia, the United States, and China ("AURA-2") with last patient last visit completed by January 2025. 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 14,000 hospitals, supported by the Company's 44 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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