【Press release】

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

(Stock code: 1061.HK)

The phase 1/2 clinical trial of Bevacizumab for treatment of Ophthalmic Diseases completed

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Essex Bio-Technology Ltd ("Essex" or the "Group", Stock Code: 1061.HK) today announced that a phase 1/2 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), has been completed in patients with wet age-related macular degeneration (wAMD). The results of this study demonstrated the good safety and tolerability of EB12-20145P (HLX04-O).

This single-arm, open-label, multicentre, phase I/II study aimed to evaluate the safety and preliminary efficacy of EB12-20145P (HLX04-O) via intravitreal injection (IVT) in patients with active wet age-related macular degeneration (wAMD). The study consisted of two parts. Part 1 was a safety run-in stage which enrolled 6 patients. Part 2 was a single-arm, open-label, multicentre, phase II study and 20 patients (including 6 patients from part 1) were enrolled in this part. All patients received EB12-20145P (HLX04-O) IVT (1.25 mg/0.05 mL) every four weeks until death, withdrawal of informed consent, loss to follow-up, study termination by sponsor, or completion of one-year treatment. For part 1, the primary endpoint was safety event related to EB12-20145P (HLX04-O) that occurred within four weeks after the first dose of EB12-20145P (HLX04-O); secondary endpoints were the systemic pharmacokinetic characteristics of EB12-20145P (HLX04-O) after the first and fourth IVT administration. For part 2, the primary endpoint was the mean change of letters from baseline in best corrected visual acuity (BCVA) at week 12; secondary endpoints included other efficacy measures, safety, immunogenicity, and systemic

pharmacokinetic characteristics. The results showed that EB12-20145P (HLX04-O) was safe and well tolerated in wAMD patients, and preliminary efficacy was observed.

EB12-20145P (HLX04-O) is a recombinant anti-VEGF humanized monoclonal antibody injection constructed using genetic engineering technology independently developed by Henlius. EB12-20145P (HLX04-O) can inhibit VEGF's binding to its receptor Flt-1 (VEGFR-1) and KDR(VEGFR-2) on endothelial cells to inhibit the activation of its tyrosine kinase signalling pathway, inhibit endothelial cell proliferation and reduce angiogenesis, thereby treating eye diseases associated with angiogenesis. According to the requirements of ophthalmic drugs, Henlius has developed EB12-20145P (HLX04-O) which optimizes the prescription, specifications, and production processes of HANBEITAI, assuming that the active ingredients remain unchanged. Through a series of comparability analysis, 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.

As of now, the clinical trial applications of EB12-20145P (HLX04-O) had been approved in Singapore and other countries and regions. Moreover, the first patients in the United States (US), China, the European Union (EU) and Australia were dosed in phase 3 clinical trials of EB12-20145P (HLX04-O) for the wAMD. Essex and Henlius will jointly manage progressively the global multi-centre clinical trials of EB12-20145P (HLX04-O) and apply marketing authorization in China, Australia, the EU, and the US around the globe based on the research results. EB12-20145P (HLX04-O) has the potential to be one of the first bevacizumab approved for use in ophthalmic diseases, benefiting more patients with eye diseases worldwide.

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About wAMD

Age-related macular degeneration 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 (wAMD) is characterized 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, wAMD 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 wAMD[4], and the efficacy and safety of vitreous injection of

bevacizumab for wAMD have been verified in multiple clinical studies[5-11].

About Essex (1061.HK)

Essex Bio-Technology Limited is a bio-pharmaceutical company that develops, manufactures and commercialises genetically engineered therapeutic b-bFGF (FGF-2), having six commercialised biologics marketed in China since 1998. Additionally, it has a portfolio of commercialised products of preservative-free unit-dose eye drops and Shilishun(適麗順®)(Iodized Lecithin Capsules) etc.. The products of the Company are principally prescribed for the treatment of wounds healing and diseases in Ophthalmology and Dermatology, which are marketed and sold through approximately 10,900 hospitals and managed directly by its 43 regional sales offices in China. Leveraging on its in-house R&D platform in growth factor and antibody, the Company maintains a pipeline of projects in various clinical stages, covering a wide range of fields and indications.

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