【Press release】

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

(Stock Code: 1061)

First Patient Dosed in a Global Multi-Centre Phase 3 Clinical Study of Bevacizumab EB12-20145P (HLX04-O) for treatment of Ophthalmic Diseases in the EU

Hong Kong, 8 Apr 2022

Essex Bio-Technology Ltd ("Essex" or the "Group", Stock Code: 1061.HK) today announced that the first patient was dosed in a global 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 Latvia, a member of the European Union (EU), for the treatment of wet age-related macular degeneration (wAMD). In November 2021, the first patient has been dosed in a phase 3 clinical trial in China for EB12-20145P (HLX04-O) for the treatment of wAMD.

This two-part, multi-centre, global phase 3 study aims to compare the efficacy and safety of EB12-20145P (HLX04-O) with ranibizumab in patients with wet age-related macular degeneration (wAMD). Part 1 is an open-label safety run-in portion, of which the primary objective is to evaluate the safety and tolerability of EB12-20145P (HLX04-O). Eligible patients will receive intravitreal injection of EB12-20145P (HLX04-O) (1.25 mg) every 4 weeks for up to 1 year. Part 2 is a randomised, double-blind, active-controlled, non-inferiority study. Eligible patients will be randomised 1:1 to receive intravitreal injection of EB12-20145P (HLX04-O) (1.25 mg) or ranibizumab (0.5 mg) every 4 weeks for up to 1 year. The primary objective is to compare the efficacy of EB12-20145P (HLX04-O) with ranibizumab at Week 48 in patient's study eye with wAMD. The primary endpoint is the mean change from baseline in the best-corrected visual acuity (BCVA) at Week 48. Secondary objectives include the evaluation of other efficacy endpoints, safety, tolerability and pharmacokinetic profiles.

In addition to Latvia, the clinical trial applications of EB12-20145P (HLX04-O) had been approved in the United States, the EU (Spain, Czechia, Poland, etc.), Australia, Singapore and other countries and regions. Essex and Henlius will jointly speed up the global multi-centre clinical trials of EB12-

20145P (HLX04-O) and apply marketing authorization in China, Australia, the European Union and the United States around the globe based on the research results. EB12-20145P (HLX04-O) has the potential to be one of the first bevacizumabs approved for ophthalmic diseases, benefiting more patients with eye diseases worldwide.

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About Age-related macular degeneration (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 (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 EB12-20145P（HLX04-O）

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 signaling 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.

About Essex

Essex Bio-Technology Limited is a bio-pharmaceutical company that develops, manufactures and commercialises genetically engineered therapeutic rb-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 10,500 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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