【Press release】

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

(Stock Code: 1061)

First Patient in the US Dosed in a Global Multicentre Phase 3 Clinical Study of Bevacizumab for treatment of Ophthalmic Diseases

Hong Kong, 10 Feb 2023

Essex Bio-Technology Ltd ("Essex" or the "Group", Stock Code: 1061.HK) today announced that the first patient in the United States (US) was dosed in a global multi-centre phase 3 clinical trial (NCT04740671) 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), for the treatment of wet age-related macular degeneration (wAMD). Previously, the first patients in the European Union (EU) and Australia were dosed in the same global multicenter phase 3 clinical trial of EB12-20145P (HLX04-O). Meanwhile, the first patient has been dosed in a parallel phase 3 clinical trial in China for EB12-20145P (HLX04-O) for the treatment of wAMD.

This randomised, double-blinded, active-controlled, 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). 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 48 weeks. The primary objective is to compare the efficacy of EB12-20145P (HLX04-O) with ranibizumab at Week 36 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 36. Secondary objectives include the evaluation of other efficacy endpoints, safety, tolerability, and pharmacokinetic profiles.

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, the Company 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.

In addition to the EU and Australia, the clinical trial applications of EB12-20145P (HLX04-O) had been approved in Singapore and other countries and regions. 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 wet age-related macular degeneration (wAMD)

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], with the efficacy and safety of vitreous injection of bevacizumab for wAMD verified in multiple clinical studies[5-11].

About Essex

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 适丽顺®(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 10,710 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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