【Press release】

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

(Stock Code: 1061)

First Patient First Visit Completed in the PRC in a Phase 3 Clinical Trial of Bevacizumab EB12-20145P (HLX04-O)

Hong Kong, 10 Nov 2021

Essex Bio-Technology Ltd ("Essex" or the "Group", Stock Code: 1061.HK) today announced that the first patient was dosed in a Phase 3 clinical trial in China for EB12-20145P (HLX04-O), a recombinant anti-VEGF humanized 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).

This multicenter, randomized, double-blind, active-controlled phase 3 study aims to compare the efficacy and safety of EB12-20145P (HLX04-O) with ranibizumab in patients with wAMD. Eligible patients will be randomised 1:1 into two groups 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 of the study 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. The secondary objectives are to evaluate other efficacy endpoints, safety, tolerability and pharmacokinetic profiles. Previously, a series of studies including non-clinical pharmacodynamics, safety pharmacology, repeat-dose toxicity, pharmacokinetics, toxicokinetics, immunotoxicity, immunogenicity, and local irritation of EB12-20145P (HLX04-O) vitreous injection in the treatment of wAMD have been carried out, providing clinical evidence on effectiveness and safety of EB12-20145P (HLX04-O).

In October 2020, Essex entered into a co-development and exclusive license agreement with Henlius. With this collaboration, Essex and Henlius plan to conduct global multi-centre clinical trials of EB12-20145P (HLX04-O) in China, Australia, the European Union (EU) and the United States (US), and apply marketing authorization in different countries and regions around the globe based on the

research results. In July 2021, the first patient had been dosed in a phase 1 clinical trial of EB12-20145P (HLX04-O) for the treatment of wAMD in mainland China. EB12-20145P (HLX04-O) for the treatment of wAMD has been successively approved to commence the phase 3 clinical trial in Australia, the United States, Singapore, Russia, Serbia and European Union countries such as Hungary, Spain, Latvia, the Czech Republic and Poland.

Through the collaboration of Essex and Henlius, 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 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 go blind due to AMD each year [2]. wAMD is characterized by the formation of subretinal choroidal neovascularization (CNV) and accounts for approximately 90% of all AMD-related blindness. Due to population aging, 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 new ophthalmic preparation product developed based on HLX04, a bevacizumab biosimilar independently developed by the Company, through optimizing the prescription, specifications and production processes of HLX04 according to the requirements of ophthalmic drugs, without changing the active ingredients, and is intended to be used for the treatment of wAMD. By means of comparability studies, it shows that changes in production processes and prescriptions of the preparation have no adverse impact on the quality, safety and efficacy of the pharmaceutical preparation. 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.

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. 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 9,760 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.

About Henlius

Henlius (2696.HK) is a global biopharmaceutical company with the vision to offer high-quality, affordable and innovative biologic medicines for patients worldwide with a focus on oncology, autoimmune diseases and ophthalmic diseases. Up to date, 3 products have been launched in China, 1 in the European Union (EU), the New Drug Applications (NDAs) of 3 products accepted for review in China. Since its inception in 2010, Henlius has built an integrated biopharmaceutical platform with core capabilities of high-efficiency and innovation embedded throughout the whole product life cycle including R&D, manufacturing and commercialisation. It has established global R&D centres and a Shanghai-based manufacturing facility certificated by China and the EU Good Manufacturing Practice (GMP).

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