【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 Clinical Trial of Bevacizumab EB12-20145P (HLX04-O)

Hong Kong, 19 Jul 2021

Essex Bio-Technology Ltd ("Essex" or the "Group", Stock Code: 1061.HK) today announced that the first patient was dosed in a Phase 1 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 is a single-arm Phase 1 study conducted in patients with wAMD. As a safety run-in stage, six to twelve patients were planned to be enrolled in this study. The primary objective is to evaluate the safety and tolerability of EB12-20145P (HLX04-O) in the study eye of wAMD patients. The secondary objective is to evaluate the systemic pharmacokinetic profiles of EB12-20145P (HLX04-O) after intravitreal injection. 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).

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].

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. As of now, EB12-20145P (HLX04-O) has received clinical approvals in China, Australia, the US, Singapore and EU countries including Latvia, Hungary and Spain with global multi-centre clinical trials gathering pace.

It is believed that 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 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 signaling 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 9,000 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 (NDA) 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 centers and a Shanghai-based manufacturing facility certificated by China and the EU Good Manufacturing Practice (GMP).

Henlius has pro-actively built a diversified and high-quality product pipeline covering over 20 innovative monoclonal antibodies (mAbs) and has continued to explore immuno-oncology combination therapies with proprietary serplulimab (anti-PD-1 mAb) as backbone. Apart from the launched products 汉利康® (rituximab), the first China-developed biosimilar, 汉曲优® (trastuzumab, Zercepac® in the EU), the first China-developed mAb biosimilar approved both in China and in the EU and 汉达远® (adalimumab), the Company's first product indicated for autoimmune diseases, the NDAs of HLX04 (bevacizumab) and the two innovative mAbs HLX01 (rituximab) for the treatment of rheumatoid arthritis and serplulimab indicated for MSI-H solid tumors are under review. What's more, Henlius has conducted over 20 clinical studies for 10 products and 8 combination therapies worldwide, expanding its presence in major market as well as emerging market.

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