【Press release】

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

(Stock Code: 1061)

Application for Clinical Trial of Bevacizumab Has Been Approved for the Treatment of wAMD in Latvia

Hong Kong, 20 Apr 2021

Essex Bio-Technology Ltd ("Essex" or the "Group", Stock Code: 1061.HK) today announced that the application for clinical trial of EB12-20145P (HLX04-O), a recombinant anti-VEGF humanized monoclonal antibody ophthalmic injection jointly developed by the Group and Shanghai Henlius Biotech, Inc. ("Henlius", Stock Code: 2696.HK) has been approved by the State Agency of Medicines of Latvia, for the treatment of wet age-related macular degeneration (wAMD). This is the third clinical trial approval EB12-20145P (HLX04-O) has received outside of China, after the approvals of clinical trial from the Therapeutic Goods Administration (TGA), Australia and U.S. Food and Drug Administration (FDA), and also the first clinical trial approval for EB12-20145P (HLX04-O) in European Union(EU) countries. Besides, Henlius has successively submitted applications for clinical trial of EB12-20145P (HLX04-O) in Hungary, Spain, Czech Republic and other EU countries, which are expected to be approved in the near future.

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 and the United States, and apply marketing authorization in different countries and regions around the globe based on the research results. 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, initially proving the efficacy and safety of EB12-20145P (HLX04-O). A phase 3, global and multi-centre clinical study of EB12-20145P (HLX04-O) is intended to commence in China, Australia, Russian Federation, Singapore, Spain and Poland in the near future to further evaluate the efficacy and safety of EB12-20145P (HLX04-O) for the treatment of wAMD.

Essex and Henlius will speed up the global multicentre clinical trials of EB12-20145P (HLX04-O) and apply marketing authorization in different countries and regions 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 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 EB12-20145P（HLX04-O）

EB12-20145P（HLX04-O） is a new ophthalmic preparation product developed based on HLX04, a bevacizumab biosimilar independently developed by Henlius, 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. In January and March 2021, EB12-20145P（HLX04-O）for the treatment of wAMD has been approved to commence clinical trials in Australia and the United States.

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 2 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 HLX10 (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 NDA of HLX04 (bevacizumab) and HLX01 (rituximab) for the treatment of rheumatoid arthritis 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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Essex Contact:
Investor Relations: Investors@essex.com.cn
Media: Media@essex.com.cn