【Press release】

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

(Stock Code: 1061)

Essex-Biotechnology Announces Bevacizumab Has Received IND Approval from US FDA for the Treatment of wAMD

Hong Kong, 19 Mar 2021

Essex Bio-Technology Ltd ("Essex" or the "Group", Stock Code: 1061.HK) today announced that the Investigational New Drug (IND) application 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 U.S. Food and Drug Administration (FDA) for the treatment of wet age-related macular degeneration (wAMD).

This is the second IND approval EB12-20145P (HLX04-O) has received outside of China , after the approval from the Therapeutic Goods Administration, Australia for initiating a Phase 3 clinical trial in January 2021. The two-part, Phase 3, global and multicentre clinical study of EB12-20145P (HLX04-O) will be conducted to further evaluate the efficacy and safety of EB12-20145P (HLX04-O) in patients with wAMD in the near future. According to the protocol of the clinical study, there will be 388 patients from Chinese mainand, Australia, Singapore and several European countries including Spain, Poland and Russian Federation enroll to the study. 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).

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].

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 EB12-20145P（HLX04-O）

EB12-20145P（HLX04-O） is a recombinant anti-VEGF humanized monoclonal antibody ophthalmic 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, the Company has developed EB12-20145P （ HLX04-O ） which optimizes the prescription, specifications and production processes of HLX04-O, assuming that the active ingredients remain unchanged.

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. 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 European Union (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. Up to date, Henlius has launched three mAbs developed independently: 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. In addition, the New Drug Applications of HLX04 (bevacizumab) and HLX01 (rituximab) for the treatment of rheumatoid arthritis are under review, and 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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