【Press release】

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

(Stock Code: 1061)

Essex-Biotechnology Announces Bevacizumab for wAMD Has Received Clinical Trial Approval in Australia

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Essex Bio-Technology Ltd ("Essex" or the "Group", Stock Code: 1061.HK) today announced that the filing of clinical trial for EB12-20145P (HLX04-O), a recombinant anti-VEGF humanized monoclonal antibody ophthalmic injection, for the treatment of wet age-related macular degeneration (wAMD) has been approved by the Therapeutic Goods Administration, Australia. The Phase 3 clinical study of the project in Australia is intended to be initiated in the near future.

Age-related macular degeneration is one of the leading causes of 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, which indicates 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].

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 signalling pathway, inhibit endothelial cell proliferation and reduce angiogenesis, thereby treating eye diseases associated with angiogenesis. Based on the requirements for ophthalmic drugs, Henlius has developed EB12-20145P (HLX04-O) which optimizes the prescription, specifications and production

processes of HLX04, 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.

As of now, a series of studies including non-clinical pharmacodynamics, safety pharmacology, repeated administration 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). In the near future, a two-part, Phase 3, global, multicentre study of EB12-20145P (HLX04-O) will be initiated in Australia to further evaluate the efficacy and safety in treatment of wAMD.

It is believed that through the collaboration between Essex and Henlius, the global multi-centre clinical trials of EB12-20145P (HLX04-O) in China, Australia, the European Union and the United States will speed up marketing authorisation 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 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 8,880 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® (HLX01, rituximab), the first China-developed biosimilar, 汉曲优® (HLX02, trastuzumab, Zercepac® in the EU), the first China-developed mAb biosimilar approved both in China and in the EU and 汉达远® (HLX03, 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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