

【Press release】



ESSEX BIO-TECHNOLOGY LIMITED

億勝生物科技有限公司

(Stock Code: 1061.HK)

Essex and Henlius signed amendment agreement for Global Co-Development and Exclusive License Agreement for treatment of age-related macular degeneration

Hong Kong, 22 Feb 2023

Essex Bio-Technology Ltd (“Essex” or the “Group”, Stock Code: 1061.HK) today announced that two of its wholly-owned subsidiaries, Essex Bio-Investment Limited (“Essex Bio-Investment”) and Zhuhai Essex Bio-Pharmaceutical Co. Ltd (“Zhuhai Essex”), signed an amendment agreement (the “Amendment Agreement”) with Shanghai Henlius Biotech, Inc. (“Henlius”, Stock Code: 2696.HK) in relation to a global Co-Development and Exclusive license Agreement signed in October 2020 (the “Agreement”). Pursuant to the Agreement, Essex Bio-Investment and Henlius will co-develop the bevacizumab HLX04 (the “Product” or “EB12-20145P”) for treatment of ophthalmic diseases such as exudative (wet) Age-related Macular Degeneration (wAMD). Essex Bio-Investment has an exclusive global license to develop, manufacture, and commercialise the Product in the field of human ophthalmic therapeutic use and/or therapies.

Reasons for, and benefits of, the entering into the Amendment Agreement

As a result of the (i) increased cost of clinical trial operations; (ii) increased cost of patient recruitment for the clinical trial programme; (iii) general inflation in the global economy and manpower shortage in the healthcare sector during and following the COVID-19 pandemic; and (iv) increased cost associated with the establishment of new clinical trial sites in the United States and Europe to support and balance requirements imposed by various regulatory authorities for the clinical trials, the development costs of the Product have materially increased since the signing of the Agreement. Therefore, to tackle the increasing development costs and to support the continuous research and development of the Product further, Essex Bio-Investment has agreed to provide additional funding towards Henlius by entering into the Amendment Agreement.

Amended terms

(i) Payments for regulatory and commercial sales milestones

- (a) The regulatory milestone payment from Essex Bio-Investment to Henlius payable upon the completion of the clinical trial programme has been adjusted from US\$10,000,000 (equivalent to approximately HK\$78,400,000) or its Renminbi equivalent to US\$8,000,000 (equivalent to approximately HK\$62,720,000) or its Renminbi equivalent.
- (b) The amount to be paid by the Licensee to the Licensor after the commercialisation of the Licensed Products, in the event where the Licensee commercialises the Licensed Product by itself only, shall be adjusted as follows:

Commercial sales milestone payments (which shall be paid once only) of US\$1,500,000 (adjusted downwards from US\$3,000,000 in the Agreement, equivalent to approximately HK\$11,760,000), and US\$7,500,000 (adjusted downwards from US\$15,000,000 in the Agreement, equivalent to approximately HK\$58,800,000).

(ii) Development costs

The arrangement of development costs will be amended as follows:

Subject to the terms of the Agreement and the Amendment Agreement, the Licensee has agreed to share the development costs with the Licensor in the aggregate amount up to US\$55,000,000 (adjusted upwards from US\$30,000,000, equivalent to approximately HK\$431,200,000) as to 80% by the Licensee (i.e., up to US\$44,000,000 (equivalent to approximately HK\$344,960,000) ("**Amended Essex Funding**")) and as to 20% by the Licensor. The Amended Essex Funding shall be payable in accordance with the funding schedule agreed with reference to the achievement of the specified milestones.

All other principal terms of the Agreement remain unchanged.

Current status

Currently, the EB12-20145P (HLX04-O) project has completed first patient dosing in the EU, Australia, and the US, and has been licensed for clinical trials in Singapore and other countries and regions. Essex and Henlius will progressively jointly manage the global multi-centred clinical trials of EB12-20145P (HLX04-O) and apply marketing authorisation in China, Australia, the EU, the US, and ASEAN around the globe based on the research results. EB12-20145P (HLX04-O) has the potential

to be one of the first bevacizumab products approved for use in ophthalmic diseases, benefiting more patients with eye diseases worldwide.

Essex's Board believes that Essex Bio-Investment entering the Amendment Agreement with Henlius will provide assurance that the clinical trial programme under the Agreement will remain undisrupted under Essex and Essex Bio-Investment's control with the intent of moving towards progressive completion of the clinical trial programme within the scope of the clinical trial programme.

~ End ~

About Essex (1061.HK)

Essex Bio-Technology Limited is a bio-pharmaceutical company that develops, manufactures and commercialises genetically engineered therapeutic b-bFGF (FGF-2), having six commercialised biologics marketed in China since 1998. Additionally, it has a portfolio of commercialised products of preservative-free unit-dose eye drops and 适丽顺®(Iodized Lecithin Capsules) etc.. 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 10,710 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.

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