

【Press release】



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

(Stock Code: 1061)

Preservative-free Single-dose rb-bFGF Eye Drops (Single-Dose Beifushu Eye Drops) Obtained Approval from NMPA for Commercialisation in China

Hong Kong, 27 December 2019

Essex Bio-Technology Limited (“EssexBio” or the “Group”—Stock Code: 1061) is pleased to announce that Zhuhai Essex Bio-Pharmaceutical Company Limited, an indirect wholly-owned subsidiary of the Group, has obtained approval from National Medical Products Administration (NMPA) for the registration and commercialisation of the preservative-free single-dose rb-bFGF Eye Drops (Single-Dose Beifushu Eye Drops) in the People’s Republic of China (“PRC”).

As of the date of this announcement, this is the 4th preservative-free single-dose eye drops of the Group that has obtained NMPA’s approval. The other three preservative-free single-dose eye drops are Tobramycin, Levofloxacin and Sodium Hyaluronate, which were approved in April 2017 (with GMP certification in March 2018), June 2018 and July 2018 respectively.

The Board believes that the newly approved preservative-free single-dose Beifushu Eye Drops enhances the choice of patients on the range of Beifushu series products for the best treatment outcome. The addition of Single-Dose Beifushu Eye Drops will strengthen the competitiveness and leadership position of the Group in the growth factor formulated ophthalmic drugs.

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About rb-bFGF Eye Drops (Beifushu Eye Drops)

rb-bFGF Eye Drops (Beifushu Eye Drops) is a first-in-class biologics developed and commercialised by the Group since 1999. The active pharmaceutical ingredient (API) is a genetically engineered therapeutic rb-bFGF, with established mechanism of action in tissue repair and regeneration. It is widely used for the treatment of ocular surface wounds, keratitis, Dry Eye Disease (DED) and post-surgery (for eye) remedy, etc.

Beifushu series products (Beifushu Eye Drops and Beifushu Eye Gel) have been included in 2019 PRC NDRL (National Drug Reimbursement List), and the sales volume ranks among the top ophthalmic drugs. According to the latest data from MENET, market share of Beifushu series products in growth factor formulated ophthalmic drugs within sample hospitals (measured by sales revenue) is about 59.3% in 2018.

About “Blow-Fill-Seal” Single-dose Platform

As one of the key technology platforms of EssexBio, the Blow-Fill-Seal (“BFS”) platform is a state-of-the-art manufacturing plant for producing preservative-free single-dose drugs, in particular for the ophthalmic drugs. In addition to the approval of Tobramycin, Levofloxacin, Sodium Hyaluronate and rb-bFGF preservative-free single-dose eye drops, a few more preservative-free single-dose drugs are at different stages of development, which are for the treatment of ocular diseases such as ocular wounds, ocular infection, visual fatigue and dry eye, as well as respiratory diseases.

About Essex Bio-Technology

Essex Bio-Technology is a bio-pharmaceutical company that develops, manufactures and commercialises genetically engineered therapeutic rb-bFGF (FGF-2), having five 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 & Dermatology, which are marketed and sold through more than 6,900 hospitals and managed directly by its 42 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 of indication.

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