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ESSEX BIO-TECHNOLOGY LIMITED

億勝生物科技有限公司

(Incorporated in the Cayman Islands with limited liability)

(Stock Code: 1061)

INSIDE INFORMATION

FURTHER UPDATES IN RELATION TO CO-DEVELOPMENT AGREEMENT – POSITIVE OUTCOME OF U.S. FDA SECOND PHASE 3 CLINICAL TRIAL IN DRY EYE DISEASE

This announcement is made by Essex Bio-Technology Limited (the “**Company**”, together with its subsidiaries, the “**Group**”) pursuant to Rule 13.09 of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the “**Listing Rules**”) and the Inside Information Provisions (as defined under the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong).

Reference is made to the announcements of the Company dated 16 July 2018 and 23 August 2019 (the “**2019 Announcement**”) in relation to the Co-Development Agreement entered into by Essex Bio-Investment (a wholly-owned subsidiary of the Company) with Mitotech and Russia Mitotech for the Phase 3 Clinical Trial of an ophthalmic solution containing SkQ1 for dry eye disease and the announcements of the Company dated 12 December 2019 and 22 February 2021 in relation to certain updates thereon. Unless the context otherwise requires, capitalised terms used in this announcement shall have the same meanings as those defined in the 2019 Announcement.

The Board is pleased to announce that, as informed by Mitotech, positive outcome was achieved during Second P3 Trial (“**VISTA-2**”). Importantly, the clinical trial study repeated statistically significant positive results on key predefined secondary end-point (Central Corneal Fluorescein Staining (“**CCFS**”). Both First P3 Trial (“**VISTA-1**”) and VISTA-2 demonstrated significant impact of SkQ1 on clearing of CCFS (defined as zero staining in central cornea) and improvement of Best Corrected Visual Acuity (BCVA) at day 28 ($p < 0.05$ for both endpoints in VISTA-1 and VISTA-2), providing clear guidance for primary endpoint designation in the next pivotal study for the purpose of new drug application submission with the U.S. FDA (the “**NDA Submission**”), replacing VISTA-2 nominal co-primaries (conjunctival fluorescein staining and ocular discomfort at day 56). The VISTA-2 study also continues to highlight excellent safety profile of the drug with tolerability being statistically similar to that of an artificial tear.

VISTA-2 was a multi-centre, randomised, double-blind, placebo-controlled clinical study with two treatment arms: BID SkQ1 ophthalmic solution and BID vehicle. 610 patients were enrolled in the study across more than a dozen multiple centres in the U.S. and received treatment over a 2-month period.

Based on the information provided by Mitotech, one of the study’s predetermined key secondary endpoints (change from baseline in CCFS after just 28 days of treatment) demonstrated statistically significant signal ($p < 0.05$) against vehicle group in a subgroup of patients characterised by higher Schirmer’s scores. This efficacy signal was observed in both VISTA-1 and VISTA-2 studies for that subgroup of patients, driving p-value for the combined two-study dataset to < 0.0005 .

The Board is enthusiastic about the read-out of clearing of central staining of the cornea, which reveals the potential of SkQ1 in addressing oxidative stress in dry eye diseases, and is looking forward to seeing the results of the third Phase 3 Clinical Trial (VISTA-3) on the overall regulatory pathway towards the NDA Submission targeted by Mitotech to be made in the year of 2022 to 2023.

Further announcement(s) will be made by the Company to update the shareholders and the potential investors of the Company as and when appropriate in compliance with the Listing Rules.

On behalf of the Board
Essex Bio-Technology Limited
Ngiam Mia Je Patrick
Chairman

Hong Kong, 24 February 2021

Executive directors of the Company as at the date of this announcement are Mr. Ngiam Mia Je Patrick, Mr. Fang Haizhou, Mr. Ngiam Hian Leng Malcolm and Ms. Yau Lai Man. Independent non-executive directors of the Company as at the date of this announcement are Mr. Fung Chi Ying, Mr. Mauffrey Benoit Jean Marie and Ms. Yeow Mee Mooi.