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**Shanghai Henlius Biotech, Inc.**

**上海復宏漢霖生物技術股份有限公司**

*(A joint stock company incorporated in the People's Republic of China with limited liability)*

**(Stock Code: 2696)**

## **VOLUNTARY ANNOUNCEMENT**

### **CO-DEVELOPMENT AND EXCLUSIVE LICENSE AGREEMENT WITH ESSEX FOR HLX04**

#### **A. INTRODUCTION**

The board of directors of Shanghai Henlius Biotech, Inc. (the “**Company**”) is pleased to announce that on 15 October 2020, the Company entered into a co-development and exclusive license agreement (the “**Agreement**”) with Essex Bio-Investment Limited (“**Essex Investment**”) and Zhuhai Essex Bio-Pharmaceutical Company Limited\* (珠海億勝生物製藥有限公司) (“**Zhuhai Essex**”) (Essex Investment and Zhuhai Essex collectively called “**Essex**”), pursuant to which, the Company agreed to co-develop the HLX04 (a recombinant humanized anti-VEGF monoclonal antibody developed by the Company) as therapy for eye diseases such as wet age-related macular degeneration (“**wAMD**”) (the “**Licensed Product**”) with Essex and to grant an exclusive license to Essex to regulatory develop, manufacture and commercialise the Licensed Product in human ophthalmic therapeutic use and/or therapies only (the “**Field**”) globally (the “**Territory**”).

#### **B. PRINCIPAL TERMS OF THE AGREEMENT**

##### **License**

The Company will grant Essex a license under the relevant intellectual property rights in relation to the Licensed Product (a) to use and reference the dossier for any purpose, including filing marketing authorisation applications and obtaining and maintaining marketing approvals in Essex’s name, related to the Licensed Product in the Field in the Territory, and (b) for the regulatory development, manufacturing and commercialization the Licensed Product under one or more of Essex’s trademarks in the Field in the Territory.

##### **Cooperation and Development**

The Company will be mainly responsible for the pre-clinical and clinical trials of the Licensed Product, and Essex will be mainly responsible for the regulatory filing of the Licensed Product;

The Company and Essex agree to share costs and expenses associated with the Company’s development activities in relation to the Licensed Product, where the Company will be responsible for 20% and Essex will be responsible for 80% of such costs and expenses;

## **Milestone Payments and Royalties**

The Company is entitled to receive:

- (a) a signing payment of US\$10 million;
- (b) regulatory milestone payments of not more than US\$15 million, which will be received at the initiation of study 1 of the clinical trial programme and the completion of study 1 or study 2 (whichever is later) of such clinical trial programme, respectively;
- (c) commercial sales milestone payments, including US\$3 million, US\$15 million, and US\$30 million, upon Essex achieving the first US\$100 million cumulative net sales, the next US\$500 million cumulative net sales above the first US\$100 million, and every US\$1 billion above the first US\$600 million, respectively;
- (d) royalty fees based on the royalty fee rates of 6% to 10% of the annual net sales of the Licensed Product depending on the level of net sales of Licensed Product. After 10 years from the first Commercial launch of the Licensed Product in any of the four regions of the United States, Europe, Japan and China, the royalty rates will be adjusted subject to mutual agreement of the Company and Essex but will be at a maximum of 3%; and

## **Sub-license and Put Option**

Essex has the right to grant a sublicense to third parties. The Company is entitled to receive 20% of the related sublicensing revenue and Essex is entitled to receive 80% under the Agreement. Essex has the option to reduce its percentage entitlement of the sublicensing revenue by 10% to 20% (subject to a good faith negotiation between the Company and Essex) on the conditions that (1) the Phase 3 clinical trial of the Licensed Product has been completed, and (2) no sublicense has been granted by Essex in the Territory (the “**Put Option**”). For the avoidance of doubt, Essex shall have no rights to exercise the Put Option if the conditions are not fulfilled. Upon the exercise of such Put Option, the Company will have to pay a buy back amount up to US\$10.5 million to Essex in accordance with the terms of the Agreement and the Company’s percentage entitlement of the sublicensing revenue will be increased by up to 20% to 40%.

## **Term**

The Agreement is effective from date of the Agreement and will continue to be effective unless terminated in accordance with the terms of the Agreement.

### **C. INFORMATION ABOUT HLX04**

HLX04 is a monoclonal antibody biosimilar (bevacizumab biosimilar) developed by the Company independently. Currently, HLX04 has been accepted by the Center for Drug Evaluation of the National Medical Products Administration (the “NMPA”) for the treatment of metastatic colorectal cancer (mCRC) and advanced, metastatic or recurrent non-small cell lung cancer. At the same time, the Company is also actively carrying out the combination therapy study of HLX04 in combine with HLX10, the Company’s innovative monoclonal antibody product (recombinant humanised anti-PD-1 monoclonal antibody injection), and the indications cover advanced solid tumor (phase 1 clinical trial), metastatic non-squamous, non-small cell lung cancer (phase 3 clinical trial) and advanced hepatocellular carcinoma (phase 2 clinical trial).

As at the date of this announcement, the bevacizumab commercially available in mainland China (excluding Hong Kong, Macao and Taiwan, the same below) include Avastin® of Roche, Ankeda (安可達®) of Qilu Pharmaceutical Co.,Ltd., and BYVASDA® of Innovent Biologics (Suzhou), Inc. HLX04 deemed as the bio-innovative product for the treatment of wAMD and diabetic retinopathy(“DR”)since none of the aforementioned products has been approved for the treatment of the relevant indications. Currently, the investigational new drug application of HLX04 for treating of wAMD and DR has been approved by the NMPA.

### **D. REASONS AND BENEFITS OF THE COOPERATIONS**

The cooperation will fully utilize the advantages of the Company and Essex in the product development and global commercialisation of eye injury drugs, which in turn allow the articulation of the market deployment of the Licensed Product in the Territory, and strengthen the accessibility and the international influence of the Group’s products.

### **E. INFORMATION ABOUT ESSEX**

Essex Investment and Zhuhai Essex are both wholly-owned by Essex Bio-Technology Limited (“Essex Bio-tech”), the shares of which is listed and traded on the Main Board of the The Stock Exchange of Hong Kong Limited (stock code: 1061). Essex Bio-tech is principally engaged in the manufacturing, selling, marketing and distribution of biopharmaceutical products.

**WARNING STATEMENT REQUIRED BY RULE 18A.05 OF THE RULES GOVERNING THE LISTING OF SECURITIES ON THE STOCK EXCHANGE OF HONG KONG LIMITED:** The Company may not be able to develop and ultimately commercialise HLX04 successfully. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

On behalf of the Board  
**Shanghai Henlius Biotech, Inc.**  
**Qiyu CHEN**  
*Chairman*

Hong Kong, 15 October 2020

*As at the date of this announcement, the board of directors of the Company comprises Mr. Qiyu Chen as the chairman and non-executive director, Mr. Yifang Wu, Ms. Xiaohui Guan, Dr. Aimin Hui and Mr. Zihou Yan as the non-executive directors, and Mr. Tak Young So, Dr. Lik Yuen Chan, Dr. Guoping Zhao and Dr. Ruilin Song as the independent non-executive directors.*

\* *For identification purpose only*