

*Hong Kong Exchanges and Clearing Limited and The Stock Exchange of Hong Kong Limited take no responsibility for the contents of this announcement, make no representation as to its accuracy or completeness and expressly disclaim any liability whatsoever for any loss howsoever arising from or in reliance upon the whole or any part of the contents of this announcement.*



**KeyMed Biosciences**

**Keymed Biosciences Inc.**

**康諾亞生物醫藥科技有限公司**

*(Incorporated in the Cayman Islands with limited liability)*

**(Stock Code: 2162)**

## **VOLUNTARY ANNOUNCEMENT**

### **CMG901 WAS GRANTED BREAKTHROUGH THERAPY DESIGNATION BY THE CDE FOR THE TREATMENT OF CLAUDIN 18.2-POSITIVE ADVANCED GASTRIC CANCER THAT WAS RESISTANT/REFRACTORY OR INTOLERANT TO PRIOR SYSTEMIC THERAPY**

This announcement is made by Keymed Biosciences Inc. (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis.

The Company is pleased to announce that the Center for Drug Evaluation (“**CDE**”) of the National Medical Products Administration (“**NMPA**”) has granted CMG901 (Claudin 18.2 antibody drug conjugates), a new drug candidate of the Group, breakthrough therapy designation for the treatment of Claudin 18.2-positive advanced gastric cancer that was resistant/refractory or intolerant to prior systemic therapy.

According to the Measures for the Administration of Drug Registration (《藥品註冊管理辦法》) and the announcement of the NMPA’s publication of three documents including the Working Procedures for Review of Breakthrough Therapeutics (Trial) (No. 82 of 2020) (《國家藥監局關於發佈〈突破性治療藥物審評工作程序(試行)〉等三個文件的公告》(2020年第82號)), drugs granted the breakthrough therapy designation are prioritized by the CDE in communications and guidance to promote the drug development progress.

Previously, CMG901 has been granted the Orphan Drug Designation and Fast Track Designation by the Food and Drug Administration of the United States for the treatment of relapsed/refractory gastric cancer and gastroesophageal junction adenocarcinoma. (For further details, please refer to the announcements of the Company dated April 11, 2022 and April 19, 2022).

## **ABOUT CMG901**

CMG901 is a Claudin 18.2-targeting antibody drug conjugates comprising of a Claudin 18.2-specific antibody, a cleavable linker and a toxic payload, monomethyl auristatin E (MMAE). It is the first Claudin 18.2 antibody drug conjugates to have received both clinical trial application approval in China and the United States. The high specificity of the Claudin 18.2 is expressed in gastric cancer, pancreatic cancer and other solid tumors, which makes it an ideal tumor target for therapeutic development. The Group has completed the patient enrollment of the dose-escalation stage of Phase I clinical trial of CMG901 in subjects with solid tumors in the first half of 2022. Furthermore, the Group also initiated the dose-expansion stage of Phase I clinical trial of CMG901 in subjects with solid tumors in China in the second quarter of 2022.

This announcement is made by the Company on a voluntary basis to provide information to the shareholders and potential investors of the Company. There is no assurance that the Company will ultimately develop, launch and/or commercialize the product successfully. Shareholders and potential investors of the Company are advised to exercise caution when dealing in the shares of the Company.

By order of the Board of Directors  
**Keymed Biosciences Inc.**  
**Dr. Bo CHEN**  
*Chairman*

Hong Kong, September 19, 2022

*As at the date of this announcement, the Board of Directors of the Company comprises Dr. Bo CHEN, Dr. Changyu WANG and Dr. Gang XU as executive Directors; Mr. Qi CHEN, Dr. Min Chuan WANG and Mr. Yilun LIU as non-executive Directors; Prof. Xiao-Fan WANG, Prof. Yang KE, Mr. Cheuk Kin Stephen LAW and Prof. Linqing LIU as independent non-executive Directors.*