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## 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)

## INSIDE INFORMATION ANNOUNCEMENT

## STAPOKIBART WAS GRANTED MARKETING APPROVAL FROM NATIONAL MEDICAL PRODUCTS ADMINISTRATION FOR THE TREATMENT OF MODERATE-TO-SEVERE ATOPIC DERMATITIS IN ADULTS

This announcement is made by Keymed Biosciences Inc. (the "Company", together with its subsidiaries, the "Group") pursuant to Rule 13.09 of the Rules (the "Listing Rules") Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited (the "Stock Exchange") and the Inside Information Provisions (as defined in the Listing Rules) under Part XIVA of the Securities and Futures Ordinance (Cap. 571 of the Laws of Hong Kong).

The Board of Directors (the "**Board**") of the Company is pleased to announce that the National Medical Products Administration (the "**NMPA**") of China has recently approved the new drug application for Stapokibart (anti-IL-4Ra monoclonal antibody, trade name: Kangyueda (康悦達), R&D codename: CM310), for the indication of moderate-to-severe atopic dermatitis in adults.

The marketing approval of Stapokibart is based on a multi-center, randomized, double-blind, placebo-controlled Phase III study, with the co-primary endpoints being the achievement of at least a 75% improvement in Eczema Area and Severity Index (EASI-75) from baseline and an Investigator's Global Assessment (IGA) score of 0 or 1 with a reduction of ≥2 points from baseline at week 16. The results showed that this trial reached the co-primary endpoints at week 16 with long-term treatment achieving sustained clinical benefits with a good safety profile.

## **About Stapokibart**

Stapokibart (trade name: Kangyueda, R&D codename: CM310) is a humanized and highly potent antibody against the interleukin-4 receptor  $\alpha$ -subunit (IL-4R $\alpha$ ). It is the first domestically manufactured IL-4R $\alpha$  antibody drug granted marketing approval by the NMPA. By targeting IL-4R $\alpha$ , Stapokibart can lead to dual-blockade of interleukin-4 (IL-4) and interleukin-13 (IL-13) signaling. IL-4 and IL-13 are two critical cytokines for initiating type II inflammation. Stapokibart has demonstrated good safety and encouraging efficacy in multiple previous clinical trials. As of the date of this announcement, its new drug application for the treatments of seasonal allergic rhinitis and chronic rhinosinusitis with nasal polyposis have been accepted by the NMPA.

Cautionary Statement as required by Rule 18A.08(3) of the Listing Rules: There is no assurance that the Company will ultimately market and/or commercialize Stapokibart successfully. Shareholders and potential investors of the Company are advised to exercise caution when trading the Company's shares.

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

Hong Kong, September 12, 2024

As at the date of this announcement, the Board 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; and Prof. Xiao-Fan WANG, Prof. Yang KE and Mr. Cheuk Kin Stephen LAW as independent non-executive directors.