

*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 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**  
**NEW DRUG APPLICATION OF STAPOKIBART FOR THE TREATMENT OF**  
**MODERATE-TO-SEVERE ATOPIC DERMATITIS IN ADULTS ACCEPTED**  
**BY NATIONAL MEDICAL PRODUCTS ADMINISTRATION**

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 new drug application of Stapokibart injection (an anti-IL-4R $\alpha$  monoclonal antibody, R&D codename: CM310) was accepted by the National Medical Products Administration (“**NMPA**”) and granted priority review on December 7, 2023. The relevant information is set out below:

- Drug name: Stapokibart injection
- Dosage form: Injection
- Application matter: New drug application for registration and marketing of domestically manufactured drugs
- Registration classification: Therapeutic biologics products, Class 1
- Applicant: Chengdu Kangnuoxing Biopharma, Inc. (成都康諾行生物醫藥科技有限公司), a wholly-owned subsidiary of the Company
- Acceptance No.: CXSS2300090
- Proposed indication: For the treatment of moderate-to-severe atopic dermatitis in adults who are poorly controlled or unsuitable for topical therapy

The application is based on a multi-center, randomized, double-blind, placebo-controlled phase III study (CM310AD005), with achieving at least a 75% improvement of 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  $\geq 2$  points from baseline at week 16 as the co-primary endpoints. Results showed that the trial met its co-primary endpoints at week 16, and long-term treatment could produce sustained clinical benefits with a good safety profile.

## **About Stapokibart**

Stapokibart (R&D codename: CM310) is a high-efficient, humanized antibody targeting the interleukin-4 receptor alpha subunit (IL-4R $\alpha$ ), and is the first domestically manufactured IL-4R $\alpha$  antibody approved by the NMPA for clinical trials. By targeting IL-4R $\alpha$ , Stapokibart can dual block interleukin-4 (IL-4) and interleukin-13 (IL-13) signaling. IL-4 and IL-13 are two key cytokines that trigger type II inflammation. Stapokibart has shown a good safety profile and encouraging efficacy in a number of previous clinical trials to date.

**Cautionary Statement as required by Rule 18A.08(3) of the Rules Governing the Listing of Securities on The Stock Exchange of Hong Kong Limited:** There is no assurance that the Company will ultimately develop, market and/or commercialize Stapokibart 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, December 7, 2023

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