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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 LATEST DEVELOPMENT ON PHASE III CLINICAL TRIAL OF CM310 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＂）on a voluntary basis．

The Company announces that as of the date of this announcement，the data unblinding and preliminary statistical analyses for the Phase III confirmatory clinical study of its self－developed Class 1 innovative drug CM310 recombinant humanized monoclonal antibody injection in subjects with moderate to severe atopic dermatitis（AD）（trial protocol number：CM310AD005）has been completed，and both of the co－primary endpoints were achieved successfully．

In accordance with the clinical trial protocol，the Group is in the process of pushing ahead with completion of the Phase III confirmatory clinical study with collection of other long－term efficacy and safety related data，and there is no need to enroll additional patients for such data collection． The Group will continue to communicate with the Center for Drug Evaluation of the National Medical Products Administration（the＂NMPA＂）of the PRC，and proactively proceed with the marketing application for CM 310 for the treatment of moderate to severe AD．

CM310AD005 is a multi－center，randomized，double－blind，placebo－controlled Phase III confirmatory clinical study to evaluate the efficacy，safety，PK／PD and immunogenicity of CM310 in subjects with moderate to severe atopic dermatitis．The eligible subjects were randomized in a $1: 1$ ratio to receive CM310（ $600 \mathrm{mg}-300 \mathrm{mg}$ Q2W）or placebo．The co－primary endpoints are the proportion of subjects with EASI－75（Eczema Area and Severity Index（EASI）$\geq 75 \%$ improvement from baseline）and the proportion of subjects with IGA score of 0 or 1 and a reduction of $\geq 2$ points from baseline at Week 16 of treatment．

The results showed that the co－primary endpoints of CM310 were achieved successfully，and the safety profiles were well and consistent with the historical results．The Group is in communication with the NMPA regarding the new drug application（NDA）and it is expected that the NDA will be submitted in 2023.

## About CM310

CM310 is a humanized and highly potent antagonist antibody against interleukin-4 receptor $\alpha$-subunit (IL-4R $\alpha$ ). It is the first domestically-developed IL-4R $\alpha$ antibody that received IND approval from the NMPA. By targeting IL-4R $\alpha$, CM310 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. CM310 has demonstrated favorable safety and encouraging efficacy in various historical clinical trials.

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 CM310 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
Keymed Biosciences Inc.
Dr. Bo CHEN
Chairman
Hong Kong, May 30, 2023
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.

