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 PHASE III CLINICAL TRIAL OF CM310 FOR THE TREATMENT OF CHRONIC RHINOSINUSITIS WITH NASAL POLYPS ACHIEVED PRIMARY ENDPOINTS

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 Phase III clinical trial of its Class 1 innovative drug CM310 recombinant humanized monoclonal antibody (Stapokibart) injection in patients with chronic rhinosinusitis with nasal polyps (CM310-102208, registered number: CTR20221480) has completed the unblinding of data from the double-blind treatment period and the preliminary statistical analysis, which shows that the primary endpoints are achieved.

CM310-102208 is a multi-center, randomized, double-blind, placebo-controlled Phase III clinical trial to confirm the efficacy and safety of CM310 recombinant humanized monoclonal antibody injection in treatment of patients with chronic rhinosinusitis with nasal polyps. This trial enrolled 180 eligible participants, who were randomized in a 1:1 ratio to receive 300 mg CM310 or placebo, once every two weeks (Q2W), total 12 doses in the double-blind period. The co-primary endpoints were the changes from baseline in nasal polyp score (NPS) and nasal congestion score (NCS) at week 24. The results of the Phase III clinical trial are positive with co-primary endpoints both achieved: the CM310 group is superior to placebo group with statistically significant differences (P<0.0001); CM310 also demonstrates a favorable safety profile. The Company plans to submit the new drug application (NDA) of CM310 for the treatment of chronic rhinosinusitis with nasal polyps to the Center for Drug Evaluation (CDE) of the National Medical Products Administration (NMPA) of China within 2024.

About CM310 (Stapokibart)

CM310 (Stapokibart) is a high-efficient, humanized antibody targeting the interleukin-4 receptor alpha subunit (IL-4R α), the first domestically produced IL-4R α antibody receiving clinical trial approval from the NMPA. By targeting IL-4R α , CM310 can block both interleukin-4 (IL-4) and interleukin-13 (IL-13) signaling. IL-4 and IL-13 are two key cytokines that trigger type II inflammation. CM310 has shown a good safety profile and encouraging efficacy in a number of previous clinical trials. New drug application of CM310 for the treatment of moderate-to-severe atopic dermatitis in adults was accepted by the NMPA and granted priority review on December 7, 2023.

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 of Directors Keymed Biosciences Inc. Dr. Bo CHEN Chairman

Hong Kong, December 27, 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.