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)

INSIDE INFORMATION ANNOUNCEMENT

POSITIVE RESULTS FROM CM310 ATOPIC DERMATITIS PHASE IIB CLINICAL STUDY

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

The Company is pleased to announce that the Phase IIb clinical study of its self-developed Class 1 innovative drug CM310 recombinant humanized monoclonal antibody injection (CM310AD002) has completed the analysis of unblinded data and preliminary statistics, and obtained positive results. CM310AD002 is a multi-center, randomized, double-blind, placebo-controlled Phase IIb study to evaluate the efficacy, safety, pharmacokinetics (PK) characteristics, pharmacodynamics (PD) effects and immunogenicity of CM310 with different dosages in subjects with moderate-to-severe atopic dermatitis (AD). The subjects meeting the study eligibility requirements were randomly assigned in a 1:1:1 ratio, and received 8 treatments with high-dose (CM310 600-300mg, Q2W), low-dose (CM310 300-150mg, Q2W) and placebo. The primary endpoint is to assess the proportion of subjects with EASI-75 at week 16 (Eczema Area and Severity Index (EASI) ≥75% improvement from baseline).

The results of the Phase IIb study showed that the primary endpoint of each CM310 group was fully achieved. The proportion of subjects with EASI-75 at week 16 was 73.1% in the high-dose group and 70.6% in the low-dose group, which was significantly higher than that in the placebo group (18.2%), with both of the P values <0.0001.

In terms of Investigator's Global Assessment (IGA), the proportion of subjects with both IGA 0/1 and a reduction from baseline of ≥2 points at week 16 in the high-dose group, low-dose group and placebo group was 34.6%, 32.4% and 9.1%, respectively, with the P values of 0.023 and 0.033 respectively in comparison to placebo group. The proportion of subjects with an IGA reduction from baseline of ≥2 points at week 16 in the high-dose group, low-dose group and placebo group was 53.8%, 61.8% and 9.1%, respectively, with both of the P values <0.0001 in comparison to the placebo group.

Other efficacy endpoints such as EASI-90, EASI-50, Pruritus Numeric Rating Scale (NRS), Affected Body Surface Area (BSA) and Dermatological Life Quality Index (DLQI) were observed to be significantly better in the two CM310 groups than in the placebo group at week 16.

At the same time, it was also observed that CM310 had a promising safety profile in this study. The incidences of drug-related treatment-emergent adverse events (TEAE) in the high-dose group, low-dose group and placebo group were 20.0%, 12.5% and 12.5%, respectively, all being of grade 1 or 2 in severity.

Based on the above the Phase IIb clinical data, we will promptly advance the Phase III clinical trial of CM310 and further evaluate the role that CM310 plays in the addressing the unmet treatment need from AD patients with a hope to benefit more patients as soon as we can. In addition, we are also in the process of conducting the clinical studies of CM310 for other indications, including chronic sinusitis with nasal polyps and asthma.

About CM310AD002

CM310AD002 study was a multi-center, randomized, double-blind and placebo-controlled phase IIb study for the purpose of evaluating the efficacy, safety profile, PK characteristics, PD effect and immunogenicity of CM310 in treatment of moderate to severe atopic dermatitis (AD) subjects.

This study consisted of a maximum of 4 weeks of screening period, 16 weeks of randomized treatment period and 8 weeks of safety follow-up period and its primary endpoint was to achieve EASI-75 in subjects after 16-week treatment. The subjects eligible for enrollment were randomized in a 1:1:1 ratio to one of the following treatment groups: ① high-dose (600-300mg) CM310 group, in which subjects were given a loading dose of 600mg CM310 subcutaneously (SC) followed by 300mg every 2 weeks (Q2W); ② low-dose (300-150mg) CM310 group, in which subjects were given a loading dose of 300mg CM310 SC followed by 150mg Q2W; ③ placebo group, in which subjects were given placebo SC Q2W. Throughout the entire randomized treatment period, subjects were given study drug (CM310 or placebo) 8 times in total and applied with moisturisers as background treatment each day.

About CM310

CM310 recombinant humanized monoclonal antibody injection (referred to as CM310 herein thereafter) is an innovative humanized monoclonal antibody self-developed by Keymed Bioscience (Chengdu) Co., Ltd. (康諾亞生物醫藥科技(成都)有限公司), targeting human IL-4 receptor alpha subunit (IL-4Rα). CM310 can selectively combine with IL-4Rα to block out the combination of IL-4Rα and IL-4 as well as IL-13, thus suppressing its bioactivity.

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, November 29, 2021

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. Dong LYU, 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.