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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)

VOLUNTARY ANNOUNCEMENT PHASE III CLINICAL TRIAL OF STAPOKIBART INJECTION FOR THE TREATMENT OF SEASONAL ALLERGIC RHINITIS ACHIEVED PRIMARY ENDPOINTS

This announcement is made by Keymed Biosciences Inc. (the "Company") on a voluntary basis.

The Company is pleased to announce that the Phase III clinical study of its Class 1 innovative drug CM310 recombinant humanized monoclonal antibody (Stapokibart) injection for the treatment of seasonal allergic rhinitis (SAR) has completed the unblinding of data from the double-blind treatment period and the statistical analysis, which shows that the primary endpoints are achieved.

This clinical trial is a multi-center, randomized, double-blind, placebo-controlled phase III study, mainly aimed at confirming the efficacy and safety of Stapokibart injection in adult patients with uncontrolled SAR by nasal glucocorticoids or other treatments. This Phase III clinical study enrolled a total of 108 subjects during the pollen season, with the research center serving as the stratification factor. The subjects were randomized in a 1:1 ratio to receive 600mg (initial dose) + 300mg of Stapokibart or placebo, once every two weeks (Q2W), total two doses in the treatment period, followed by an 8-week safety observation period. The primary endpoints of the study were the mean change from baseline in daily reflective total nasal symptom score (rTNSS) in 2 weeks.

The results of the Phase III clinical trial are positive with primary endpoints achieved. Stapokibart is significantly superior to placebo group with statistically significant differences and demonstrates a favorable safety profile.

About Stapokibart (CM310)

Stapokibart (R&D code: CM310) 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 National Medical Products Administration. By targeting IL-4R α , Stapokibart 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. Stapokibart has shown a good safety profile and encouraging efficacy in a number of previous clinical trials. New drug application of Stapokibart for the treatment of moderate-to-severe atopic dermatitis in adults was accepted by the National Medical Products Administration 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 Stapokibart (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, April 28, 2024

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; and Prof. Xiao-Fan WANG, Prof. Yang KE and Mr. Cheuk Kin Stephen LAW as independent non-executive Directors.