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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
CM310 PHASE III CLINICAL TRIAL TOPLINE DATA ACCEPTED FOR POSTER SESSION AT THE EUROPEAN ACADEMY OF DERMATOLOGY AND VENEREOLOGY (EADV) CONGRESS 2023

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 topline data from the registrational phase III clinical trial of its Class 1 new drug CM310 (generic name: Stapokibart) recombinant humanized monoclonal antibody injection for the treatment of moderate-to-severe atopic dermatitis (AD) (Protocol ID: CM310AD005) was released as a poster presentation at the European Academy of Dermatology and Venereology (EADV) Congress 2023.

CM310AD005 is a multi-center, randomized, double-blind, placebo-controlled registrational phase III clinical trial, mainly used to evaluate the efficacy, safety, PK characteristics, PD effect, and immunogenicity of CM310 in subjects with moderate-to-severe atopic dermatitis. A total of 500 eligible patients were randomized 1:1 to receive CM310 (600mg – 300mg) or placebo every two weeks (Q2W). The proportion of subjects achieving at least a 75% improvement of Eczema Area and Severity Index from baseline (EASI-75) and an Investigator's Global Assessment (IGA) score of 0/1 with a reduction of ≥ 2 points from baseline at week 16 are co-primary endpoints.

In this clinical trial, the baseline EASI scores of the CM310 and the placebo groups were 24.84 and 24.05, respectively. The proportions of subjects with baseline IGA scores of 3 in the CM310 and the placebo groups were 52.2% and 52.6%, respectively. The proportions of subjects with baseline IGA scores of 4 points in the CM310 and the placebo groups were 47.8% and 47.4%, respectively.

Efficacy results showed co-primary endpoints were met at week 16 in this trial. At week 16, the proportion of subjects achieving EASI-75 was 66.9%, and the proportion of subjects achieving an IGA score of 0 or 1 point with a reduction of ≥ 2 points from baseline (IGA 0/1, i.e. completely or substantially cleared skin lesions) was 44.2% in the CM310 group, outperforming placebo (25.8% and 16.1%, respectively), both of which were statistically significant differences (P<0.0001). Significant improvements in both pruritus control and quality of life were observed from baseline to week 16. In the CM310 group, 35.9% of subjects achieved a ≥4 point improvement from baseline in the Peak Pruritus Numerical Rating Scale (PP-NRS) at week 16. In addition, the Dermatology Life Quality Index (DLQI) showed an improvement of 8.7 points from baseline at week 16. Both the PP-NRS and DLQI in the CM310 group outperformed the placebo group (11.7% and 4.4 points, respectively) and were statistically significant (P<0.0001). In terms of safety, this trial demonstrated a favorable safety profile for CM310. The incidence of treatment-emergent adverse events (TEAEs) in the CM310 group was comparable to that in the placebo group, with most TEAEs being of mild to moderate in severity.

About CM310

CM310 is a high-affinity, humanized antibody targeting the interleukin-4 receptor alpha subunit (IL-4Rα), the first domestically produced IL-4Rα antibody to receive clinical trial approval from the NMPA. In June 2022, CM310 was granted breakthrough therapy designation for the treatment of moderate-to-severe atopic dermatitis by the CDE. By targeting IL-4Rα, CM310 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. CM310 has shown a good safety profile and encouraging efficacy in a number of previous clinical trials to date. The Group is in communication with the NMPA regarding the New Drug Application (NDA) for CM310 for the treatment of moderate-to-severe atopic dermatitis in adults, and expects to file the NDA in 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, October 11, 2023

As at the date of this announcement, the Board 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.