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

LONG-TERM EFFICACY AND SAFETY DATA FROM A PHASE III CLINICAL TRIAL OF STAPOKIBART INJECTION AT THE EUROPEAN ACADEMY OF ALLERGY AND CLINICAL IMMUNOLOGY (EAACI) CONGRESS 2024

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 long-term efficacy and safety data of a Phase III clinical trial (NCT05265923) of stapokibart injection in patients with moderate-to-severe atopic dermatitis (AD) has been released by way of oral presentation at the European Academy of Allergy and Clinical Immunology (EAACI) Congress 2024.

This multicenter, randomized, double-blind, placebo-controlled phase III trial was designed to assess the efficacy, safety, pharmacokinetics, pharmacodynamics, and immunogenicity of stapokibart in patients with moderate-to-severe AD. During the double-blind treatment period, a total of 500 adult patients with moderate-to-severe AD were randomized 1:1 to receive stapokibart 300 mg (loading dose: 600 mg) or placebo every two weeks for 16 weeks. In the subsequent 36-week maintenance treatment period, patients in the stapokibart group continued the same dose, and patients switching from placebo to stapokibart received stapokibart 300 mg (loading dose: 600 mg) every 2 weeks. Concomitant use of topical medications for AD treatment was permitted during the maintenance treatment period. The co-primary endpoints of this trial were the proportions of patients achieving ≥75% improvement from baseline in Eczema Area and Severity Index score (EASI-75) and an Investigator's Global Assessment (IGA) score of 0/1 with a ≥2 point reduction from baseline at week 16. Other efficacy measures included EASI score, IGA score, and Peak Pruritus Numerical Rating Scale (PP-NRS), etc.

A total of 476 patients entered the maintenance treatment period, with 238 in each group. At week 52, EASI-75 was achieved in 92.5% of patients continuing stapokibart and 88.7% of those switching from placebo to stapokibart, IGA score of 0/1 with a ≥2-point reduction was achieved in 67.3% and 64.2%, respectively; a ≥4-point reduction in weekly average of daily PP-NRS was achieved in 67.3% and 60.5%, respectively. Long-term treatment with stapokibart continuously improved AD symptoms and quality of life of patients with moderate-to-severe AD. Only 1 patient (0.9%) relapsed during the maintenance period. In terms of safety, stapokibart was well-tolerated, and its safety profile over 52 weeks was consistent with the initial 16-week double-blind period, with no new safety signals identified.

Overall, long-term treatment with stapokibart demonstrated sustained efficacy and favorable safety profile in adult patients with moderate-to-severe AD, and no new safety signals were observed.

About Stapokibart

Stapokibart (R&D codename: CM310), a recombinant humanized monoclonal antibody injection targeting interleukin-4 receptor alpha subunit (IL-4Rα), is the first domestically manufactured anti-IL-4Rα antibody receiving the clinical trial application approval from the National Medical Products Administration (NMPA). By targeting IL-4Rα, stapokibart blocks both interleukin-4 (IL-4) and interleukin-13 (IL-13) signaling which are two key drivers of type 2 inflammation. A number of previous clinical studies have demonstrated favorable safety profile and encouraging efficacy of stapokibart. The new drug applications of stapokibart for the treatment of moderate-to-severe AD in adults and seasonal allergic rhinitis have been accepted by NMPA.

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 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, June 3, 2024

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.