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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
POSITIVE RESULT FROM PHASE II CLINICAL TRIAL OF CM310 AT
CHRONIC SINUSITIS WITH NASAL POLYPS

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 Phase II clinical study of its self-developed Class1 innovative drug CM310 recombinant humanized monoclonal antibody injection (hereinafter referred to as CM310) for the treatment of chronic sinusitis with nasal polyps (CM310NP001) has completed the analysis of unblinded data and preliminary statistics, and achieved the primary endpoints of the entire trial with positive results.

CM310NP001 is a multi-center, randomized, double-blind, placebo-controlled, multiple subcutaneous clinical trial to evaluate the efficacy, safety, pharmacokinetics, pharmacodynamics and immunogenicity of CM310 recombinant humanized monoclonal antibody injection in patients with chronic sinusitis with nasal polyps. 56 eligible subjects enrolled in this study, and were randomized in a 1:1 ratio to receive 8 doses of 300 mg CM310 (Q2W) and placebo (Q2W). The co-primary efficacy endpoints were the changes from baseline in bilateral nasal endoscopic polyp score (NPS) and nasal congestion score (NCS) at week 16 during treatment period.

Topline result of this trial are positive with co-primary efficacy endpoints fully achieved: NPS and NCS at week 16 in CM310 group reduced 2.32 and 1.23 from baseline, respectively, which were significantly superior than those in placebo (decreased by 0.19 and 0.30, respectively, both p-values <0.0001).

Meanwhile, CM310 continued to show a promising safety profile in this study. The incidence of treatment-emergent adverse events (TEAE) in CM310 group was comparable to that of placebo. No Grade 3 and above TEAE occurred and all of TEAEs were transient and the subjects recovered without any medical intervention.

Detailed data will be further presented at international academic journals or conferences in the future.

About CM310NP001

CM310NP001 study was a multi-center, randomized, double-blind, placebo-controlled, repeatedly and subcutaneously dosed phase II study to evaluate the efficacy, safety profile, PK characteristics, PD effect and immunogenicity of CM310 in patients with chronic rhinosinusitis with nasal polyposis (CRSwNP).

This study consists of 3 periods: a maximum of 4 weeks of screening period, 16 weeks of treatment period and 8 weeks of safety follow-up period. The co-primary endpoint was the changes from baseline in bilateral endoscopic nasal polyp score (NPS) and nasal congestion score (NCS) at Week 16 during treatment period. The eligible subjects will be randomized in a 1:1 ratio to CM310 group and the placebo group, and receive 8 doses of 300mg CM310 or placebo subcutaneously (SC) followed by once every 2 weeks (Q2W). During the study, subjects will continuously receive nasal glucocorticoid mometasone furoate nasal spray as background treatment.

About CM310

CM310 recombinant humanized monoclonal antibody injection 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-4R α). CM310 can selectively combine with IL-4R α to block out the combination of IL-4R α 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, March 30, 2022

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