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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

THE LATEST RESULTS FROM THE PHASE IA CLINICAL STUDY OF CMG901 AT THE 2023 ASCO GI CANCERS SYMPOSIUM

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 latest data from the Phase Ia dose-escalation trial of CMG901 (Claudin 18.2 antibody drug conjugate), a novel drug candidate, for advanced solid tumors will be presented as a poster at the 2023 Gastrointestinal Cancers Symposium of the American Society of Clinical Oncology (2023 ASCO GI).

This Phase Ia trial (NCT04805307) was designed to evaluate the safety, tolerability, pharmacokinetics, immunogenicity, and preliminary anti-tumor activity of CMG901 in patients with advanced solid tumors. During the dose-escalation phase, Claudin 18.2 expression was retrospectively tested by the central lab.

As of August 4, 2022, totally 27 patients (13 gastric/gastroesophageal junction (gastric/GEJ) cancer and 14 pancreatic cancer patients) were enrolled in the Phase Ia clinical study of CMG901. The results showed that CMG901 was well-tolerated with a favorable safety profile. Drug-related grade ≥ 3 adverse events (AEs) occurred in 3/27 (11.1%) patients. No drug-related grade ≥ 4 AEs were reported. Patients received CMG901 at dose levels up to 3.4 mg/kg, and maximum tolerated dose (MTD) was not reached. One patient in the 2.2 mg/kg cohort developed a dose-limiting toxicity.

Preliminary efficacy results demonstrated that in the 8 Claudin 18.2-positive gastric/GEJ cancer patients receiving CMG901, objective response rate (ORR) and disease control rate (DCR) were 75.0% and 100%, respectively, with ORR of 100% in the 2.6, 3.0, and 3.4 mg/kg cohorts. Median progression free survival (mPFS) and median overall survival (mOS) were not reached yet.

Efficacy of CMG901 in Claudin 18.2-positive gastric/GEJ cancer (N=8)	
ORR[#]	75.0% (6/8)
DCR[*]	100% (8/8)
Median PFS, day	NR ^{&}
Median OS, day	NR ^{&}

[#] Proportion with complete response + partial response

^{*} Proportion with complete response + partial response + stable disease

[&] mPFS and mOS were not reached.

CMG901 showed a favorable safety and tolerability profile in this trial. CMG901 at doses of ≥ 1.8 mg/kg yielded encouraging anti-tumor activity in patients with Claudin 18.2-positive gastric/GEJ cancer.

ABOUT CMG901

CMG901, a novel recombinant humanized monoclonal antibody drug conjugate targeting Claudin 18.2, has been approved for clinical trials in both China and the United States. CMG901 consists of an anti Claudin 18.2 monoclonal antibody, a protease-degradable linker, and a cytotoxic small molecule monomethyl auristatin E (MMAE). Enrollment of patients with solid tumors in Phase I dose-escalation trial of CMG901 was completed in the first half of 2022. Furthermore, Phase I dose-expansion trial of CMG901 in patients with solid tumors in China is simultaneously initiated since the second quarter of 2022.

This announcement is made by the Company on a voluntary basis to provide information to the shareholders and potential investors of the Company. There is no assurance that the Company will ultimately develop, launch and/or commercialize the product 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, January 18, 2023

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.