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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

CMG901 FOR THE TREATMENT OF RELAPSED/REFRACTORY GASTRIC CANCER AND GASTROESOPHAGEAL JUNCTION ADENOCARCINOMA WAS GRANTED THE FAST TRACK DESIGNATION BY THE FOOD AND DRUG ADMINISTRATION OF THE UNITED STATES

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

The Company is pleased to announce that our new drug candidate CMG901 (the “Claudin 18.2 antibody drug conjugates”) for the treatment of relapsed/refractory gastric cancer and gastroesophageal junction adenocarcinoma has been granted the Fast Track Designation (the “**FTD**”) by the Food and Drug Administration of the United States (the “**FDA**”) recently. Previously, in March 2021, we received the clinical trial application approval of CMG901 from the FDA for the clinical trial in gastric cancer and gastroesophageal junction adenocarcinoma in the United States, and received the Orphan-drug Designation from the FDA in April 2022.

The FTD is established to facilitate and expedite the clinical development and review process of drugs with a view to meeting the unmet medical demands of serious diseases. According to the regulations, the obtainment of FTD status for drug candidates would provide the opportunity to accelerate the review process in various forms, including but not limited to (1) more communications and meetings with the FDA, to obtain closer guidance in drug development, clinical trial design and so on; (2) having the qualification of priority review and accelerating approval after meeting the relevant criteria; (3) rolling review, i.e., phased submission of materials for biologic license application (BLA) or new drug application (NDA), without waiting for all information to be finalized before submitting for review.

ABOUT CMG901

CMG901 is a Claudin 18.2-targeting antibody drug conjugates comprising of a Claudin 18.2-specific antibody, a cleavable linker and a toxic payload, monomethyl auristatin E (MMAE). It is the first Claudin 18.2 antibody drug conjugates to have received both clinical trial application approval in China and the United States. The high specificity of the Claudin 18.2 is expressed in gastric cancer, pancreatic cancer and other solid tumors, which makes it an ideal tumor target for therapeutic development.

We are currently in the dose-escalation stage of CMG901 in patients with solid tumors to evaluate the safety and tolerability of CMG901. We expect to initiate the dose-expansion stage in China in the early 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, April 19, 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.