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 (AZD0901) CLARITY-Gastric01 GLOBAL PHASE III CLINICAL TRIAL ACHIEVES POSITIVE TOPLINE RESULTS

This announcement is made by the board of directors (the "**Board**") of Keymed Biosciences Inc. (the "**Company**", together with its subsidiaries, the "**Group**") to provide its shareholders and potential investors with the latest clinical progress of CMG901 (sonesitatug vedotin, also known as AZD0901), a collaboration between the Group and AstraZeneca AB ("**AstraZeneca**", a global biopharmaceutical company).

The positive top-line results from the CLARITY-Gastric01 global Phase III clinical trial demonstrated that, compared to the investigator-choice regimen, CMG901 (sonesitatug vedotin, AZD0901) displayed a statistically significant and highly clinically meaningful improvement in overall survival (OS) in patients with second or later-line Claudin 18.2 (CLDN18.2)-positive advanced gastric cancer. The trial enrolled patients with locally advanced or metastatic gastric cancer, gastroesophageal junction (GEJ) cancer or esophageal adenocarcinoma (EAC), with an enrollment criterion of CLDN18.2 expression in at least 25% of tumor cells at any staining intensity. It is estimated that approximately 60% of gastric cancer/GEJ cancers express CLDN18.2 in ≥25% of tumor cells. In the United States, the European Union, China and Japan, approximately 183,500 patients receive second or later-line treatments each year for CLDN18.2-positive, HER2-negative advanced or metastatic gastric cancer/GEJ cancers.

The trial featured dual primary endpoints, namely OS for the third or later-line treatment population and progression-free survival (PFS) for the overall trial population. The trial met not only the dual primary endpoint of OS for third or later-line treatments, but also the key secondary endpoint of OS in the overall trial population for second or later-line treatments, demonstrating statistically significant and highly clinically meaningful improvements in both scenarios.

As for the other dual primary endpoint of PFS as assessed by a blinded independent central review (BICR), the results demonstrated an improving trend in the PFS of patients receiving second or later-line treatments, but did not achieve statistical significance.

Safety performance: CMG901 (sonesitatug vedotin, AZD0901) demonstrated good tolerability. Its safety profile was consistent with the known profile, with no new safety signals identified.

CMG901 is the world's first CLDN18.2-targeting antibody-drug conjugate (ADC) to have obtained IND approval in China or the U.S, and is also the first CLDN18.2-targeting ADC to initiate a pivotal registrational clinical trial on a global scale and achieve an OS benefit for this indication. Based on the positive Phase III clinical results, AstraZeneca has announced that the estimated peak sales for the product will be between US$3.0 billion and US$5.0 billion.

ABOUT CLARITY-Gastric01

CLARITY-Gastric01 is a randomized, open-label, sponsor-blinded, multicenter global Phase III clinical trial designed to evaluate CMG901 (sonesitatug vedotin, AZD0901) as a second or later-line treatment for patients with advanced or metastatic gastric cancer, GEJ or EAC cancers, with an enrollment criterion of CLDN18.2 expression in at least 25% of tumor cells at any immunohistochemical staining intensity.

The trial enrolled 594 subjects and was conducted at 175 centres in 19 countries across North America, Europe, South America and Asia. Its dual primary endpoints were PFS assessed by a blinded independent central review (BICR) in the second or later-line treatment population, and OS in the third or later-line treatment population, respectively. A key secondary endpoint was OS in the second or later-line treatment population.

ABOUT CMG901 (sonesitatug vedotin, AZD0901)

CMG901 is a CLDN18.2-targeting ADC comprising a CLDN18.2-specific antibody, a cleavable linker and a toxic payload, monomethyl auristatin E (MMAE). CLDN18.2 is highly selectively and widely expressed in gastric cancer, pancreatic cancer and other solid tumors, which makes it an ideal tumor target for therapeutic development.

In February 2023, KYM Biosciences Inc. ("**KYM**", a 70% held non-wholly owned subsidiary of the Group) and AstraZeneca entered into a global exclusive out-license agreement (the "**License Agreement**") to develop and commercialize CMG901, a key product of the Group which has been co-developed with Innocube Limited, the 30% minority shareholder of KYM under the control of Lepu Biopharma Co., Ltd.

CMG901 was granted a breakthrough therapy designation for the treatment of CLDN18.2-positive advanced gastric cancer that was resistant/refractory or intolerant to prior systemic therapy by the Center for Drug Evaluation (CDE) of the National Medical Products Administration. Concurrently, CMG901 has been granted the orphan drug designation by the Food and Drug Administration of the United States (FDA) and the European Commission for the treatment of advanced gastric and GEJ cancers.

As of the date of this announcement, in addition to the above-mentioned clinical trials, AstraZeneca has also conducted multiple clinical studies regarding CMG901(sonesitatug vedotin, AZD0901)for the treatment of advanced solid tumors, targeting indications including gastric cancer, pancreatic cancer and biliary tract cancer (only trials at the highest clinical phase are presented for the same indications):

(1) A multicenter, randomized, controlled, Phase III clinical study of sonesitatug vedotin (CMG901/AZD0901) in combination with capecitabine, with or without rilvegostomig, for the first-line treatment of CLDN18.2-positive, HER2-negative advanced/metastatic gastric cancer, gastroesophageal junction cancer, or esophageal adenocarcinoma (CLARITY-Gastric 02).

(2) An open-label, multi-drug, multi-center Phase II study to evaluate the safety, tolerability, pharmacokinetics and preliminary anti-tumor activity of a novel drug or a combination therapy as a perioperative treatment of subjects with locally advanced, resectable gastroesophageal junction adenocarcinoma (GEMINI-PeriOp GC).

(3) A Phase II, open-label, multi-center clinical study to evaluate the safety, tolerability, efficacy, pharmacokinetics and immunogenicity of AZD0901 monotherapy and in combination with anti-tumor drugs for the treatment of subjects with CLDN18.2-expressing advanced solid tumors (including gastric cancer/gastroesophageal junction adenocarcinoma, pancreatic cancer, biliary tract cancer) (CLARITY-PanTumour01).

RISK WARNING

This announcement is made by the Company to provide information on a voluntary basis to the shareholders and potential investors of the Company. There is no assurance that CMG901 will be ultimately developed, launched and/or commercialized successfully by the Company or its collaborators. 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, July 28, 2026

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.