LEPU BIOPHARMA CO., LTD.
樂普生物科技股份有限公司

(A joint stock company incorporated in the People's Republic of China with limited liability)

(Stock Code: 2157)

VOLUNTARY ANNOUNCEMENT

POSITIVE TOP-LINE RESULTS ACHIEVED FROM CLARITY-GASTRIC01 GLOBAL PHASE III TRIAL OF CMG901 (AZD0901)

This announcement is made by the board of directors (the "**Board**") of Lepu Biopharma Co., Ltd. (the "**Company**", together with its subsidiaries, the "**Group**") to update its shareholders and potential investors on the Group's collaboration with AstraZeneca AB ("**AstraZeneca**", a global biopharmaceutical company) for the antibody drug conjugate ("**ADC**") candidate CMG901 (sonesitatug vedotin, also known as AZD0901).

In February 2023, KYM Biosciences Inc. ("**KYM**, a joint venture formed by us and Keymed Biosciences Inc. ("**Keymed**"),) and AstraZeneca entered into a global exclusive out-license agreement (the "**License Agreement**") to develop and commercialize CMG901, a drug candidate co-developed by us and Keymed through KYM.

As of the date of this announcement, positive high-level results from the CLARITY-Gastric01 global Phase III trial showed that sonesitatug vedotin demonstrated a statistically significant and highly clinically meaningful improvement in overall survival ("**OS**") in 2nd and later-line ("**2L+**") Claudin 18.2-positive advanced gastric cancers versus investigator's choice of therapy. The trial included patients with locally advanced or metastatic gastric cancer, gastroesophageal junction ("**GEJ**") cancer, or oesophageal adenocarcinoma ("**EAC**") with Claudin 18.2 ("**CLDN18.2**") expression on at least 25% of tumour cells at any staining intensity. Each year, there are roughly 183,500 patients in the US, EU, China and Japan treated in the 2L+ setting for advanced or metastatic CLDN18.2-positive, non-HER2-positive gastric/GEJ cancers.

The trial had dual primary endpoints of OS in the third- and later-line ("**3L+**") treatment and progression-free survival ("**PFS**") in the overall trial population. The trial met the dual primary endpoint of OS in 3L+ treatment population, and a key secondary endpoint of OS in the overall trial population of patients treated in the 2L+ setting, demonstrating a statistically significant and highly clinically meaningful improvement.

For the other dual primary endpoint of PFS as assessed by blinded independent central review ("**BICR**"), results showed a trend toward improved PFS in patients treated in the 2L+ setting, but did not reach statistical significance.

Safety Profile: CMG901 (sonesitatug vedotin, AZD0901) was well tolerated, and its profile was consistent with the known safety profile of sonesitatug vedotin with no new safety signals identified.

ABOUT CLARITY-GASTRIC01

CLARITY-Gastric01 is a randomised, open-label, sponsor-blinded, multicentre, global Phase III trial evaluating sonesitatug vedotin as a 2L+ therapy for patients with advanced or metastatic gastric cancer, GEJ cancer, or EAC with CLDN18.2 expression in 25% or more of tumour cells, with IHC+ of any intensity.

The trial is being conducted in 175 centres across 19 countries, including in North America, Europe, South America and Asia. Its dual primary endpoints are PFS as assessed by BICR in the 2L+ setting and OS in the 3rd and later-line setting. A key secondary endpoint is OS in the 2L+ setting.

ABOUT CMG901 (sonesitatug vedotin，AZD0901)

CMG901 is a Claudin 18.2-targeting ADC comprising a Claudin 18.2-specific antibody, a cleavable linker and a toxic payload, monomethyl auristatin E ("**MMAE**"). It is the first Claudin 18.2 ADC to have received IND approval in China and the U.S. Claudin 18.2 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 September 2022, CMG901 was granted a breakthrough therapy designation for the treatment of Claudin 18.2-positive advanced gastric cancer that was resistant/refractory or intolerant to prior systemic therapy by the Center for Drug Evaluation (the "**CDE**") of the National Medical Products Administration. Previously, CMG901 has been granted the Orphan Drug Designation and Fast Track Designation by the Food and Drug Administration of the United States (the "**FDA**") for the treatment of relapsed/refractory gastric cancer and gastroesophageal junction adenocarcinoma.

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, Phase III controlled study of sonesitatug vedotin (CMG901/AZD0901) in combination with capecitabine with or without rilvegostomig as first-line therapy for CLDN18.2-positive, HER2-negative advanced/metastatic gastric cancer, GEJ 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 Claudin 18.2-expressing advanced solid tumors (including gastric cancer/gastroesophageal junction adenocarcinoma, pancreatic cancer, biliary tract cancer) (CLARITY-PanTumour01).

ABOUT KYM

KYM is a joint venture formed by us and Keymed, which is held as to 30% by us and 70% by Keymed. It is primarily engaged in the development and commercialization of CMG901.

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. 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
Lepu Biopharma Co., Ltd.
Dr. Pu Zhongjie
Chairman of the Board and Executive Director

Shanghai, the PRC, July 28, 2026

As at the date of this announcement, the Board comprises Dr. Pu Zhongjie (chairman) and Dr. Sui Ziye (chief executive officer) as executive Directors; Ms. Pu Jue and Ms. Qin Yiran as non-executive Directors; and Mr. Zhou Demin, Mr. Yang Haifeng and Mr. Fengmao Hua as independent non-executive Directors.