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

FOUR CLINICAL STUDIES SELECTED FOR PRESENTATION AT 2026 ESMO CONGRESS: CMG901 (AZD0901) CLINICAL TRIAL RESULTS SELECTED AS LBA FOR PROFFERED PAPER PRESENTATION AT PRESIDENTIAL SYMPOSIUM, MRG007 CLINICAL TRIAL RESULTS SELECTED AS LBA FOR RAPID ORAL PRESENTATION, AND TWO OTHER STUDIES SELECTED FOR RAPID ORAL PRESENTATION

This announcement is made by Lepu Biopharma Co., Ltd. (the "**Company**") on a voluntary basis.

The board of directors of the Company (the "**Board**") is pleased to announce abstracts reporting encouraging results of (1) the Phase III clinical trial of CMG901 in second or later-line (2L+) advanced/metastatic Claudin 18.2-positive gastroesophageal carcinoma ("**GEC**") has been accepted for presentation as a late-breaking abstract ("**LBA**") for Proffered Paper presentation at the Presidential Symposium; (2) the Phase I clinical study of MRG007, a potential best-in-class CDH17-targeted antibody drug conjugate ("**ADC**") candidate for the treatment of colorectal cancer ("**CRC**") has been selected as an LBA for rapid oral presentation; (3) the Phase II study in Europe for the combination therapy of MRG003 and HX008 targeting locally advanced head and neck squamous cell carcinoma ("**LA-HNSCC**") has been selected for rapid oral presentation; and (4) the Phase II study for the combination therapy of MRG003 and HX008 in epidermal growth factor receptor-positive ("**EGFR-positive**") unresectable anaplastic/poorly differentiated thyroid cancer has been selected for rapid oral presentation, at the 2026 European Society for Medical Oncology (the "**ESMO**") Congress.

OUR STUDIES SELECTED FOR PRESENTATIONS

The 2026 ESMO Congress will be held in Madrid, Spain, from October 23 to 27, 2026 (local time). As one of the world's largest, most academically prestigious and authoritative oncology conferences, the ESMO Congress brings together leading oncology experts, clinicians and clinical researchers from around the world to discuss advanced treatment concepts in global oncology care, as well as cutting-edge clinical and translational research developments.

CMG901 (AZD0901) is a CLDN18.2-targeted ADC jointly developed by the Company and Keymed Biosciences Inc. ("**Keymed**"). In February 2023, the global rights for the research, development, registration, manufacture and commercialization of CMG901 were licensed to AstraZeneca ("**AstraZeneca**"), and the detailed results of the Phase III clinical trial of CMG901 in second or later-line (2L+) advanced/metastatic Claudin 18.2-positive GEC will be disclosed for the first time as an LBA at the Presidential Symposium of the ESMO Congress. Meanwhile, the Phase I clinical study results of MRG007, a potential best-in-class, CDH17-targeted ADC for the treatment of gastrointestinal malignancies, will also be disclosed for the first time at the 2026 ESMO Congress in the form of an LBA rapid oral presentation.

1. **Study title:** CLARITY-Gastric 01 (CG-01): a Phase 3 study of sonesitatug vedotin (Sone-Ve) in second or later-line (2L+) advanced or metastatic Claudin 18.2 positive gastroesophageal carcinoma (GEC)

   Presentation type: Proffered Paper presentation as LBA at Presidential Symposium II

   Principal Investigator: Rui-Hua Xu (徐瑞華), Sun Yat-sen University Cancer Center

   Presentation time: 16:30 – 18:15, local time, October 25, 2026

2. **Study title:** First-in-human study of MRG007 (ARR-217), a CDH17-directed exatecan ADC, in patients with locally advanced or metastatic solid tumors

   Presentation type: Rapid oral presentation as LBA

   Principal Investigator: Lin Shen (沈琳), Peking University Cancer Hospital

   Presentation time: 08:30 – 10:00, local time, October 25, 2026

   In addition, the following two studies are also selected for rapid oral presentations at the 2026 ESMO Congress.

3. **Study title:** First Interim Safety analysis of GORTEC 2024-03 IDEAL: randomized phase II trial of induction treatment of anti-PD-1 pucotenlimab (HX008) plus EGFR-ADC (becotatug vedotin (MRG003)) versus EGFR-ADC alone followed by chemoradiotherapy in LA-HNSCC

   Presentation type: Rapid oral presentation

   Principal Investigator: Yungan Tao (陶運淦), Institut Gustave-Roussy, Villejuif, France

   Presentation time: 14:45 – 16:15, local time, October 25, 2026

4. **Study title:** The efficacy and safety of becotatug vedotin and pucotenlimab in EGFR-positive unresectable anaplastic/poorly differentiated thyroid cancer: preliminary results from a phase II clinical trial

   Presentation type: Rapid oral presentation

   Principal Investigator: Yu Wang (王宇), Fudan University Shanghai Cancer Center

   Presentation time: 16:15 – 17:45, local time, October 23, 2026

ABOUT THE PRODUCTS AND DRUG CANDIDATES

CMG901 (AZD0901)

CMG901 (sonesitatug vedotin, also known as AZD0901) is a CLDN18.2-targeting ADC comprising a CLDN18.2-specific antibody, a cleavable linker and a toxic payload, monomethyl auristatin E ("**MMAE**"). It is the first CLDN18.2 targeting ADC to have received investigational new drug (IND) clearance both in China and the U.S. CLDN18.2 is selectively and widely expressed in gastric cancer (GC), pancreatic cancer and other solid tumors, which makes it an ideal tumor target for therapeutic development. In July 2026, 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.

MRG007

MRG007 is a potential best-in-class, CDH17-targeted ADC for the treatment of CRC. CDH17 is a membranous cell adhesion molecule that is frequently overexpressed in gastrointestinal ("**GI**") cancers including CRC, gastric cancer, and pancreatic cancer. CDH17 has a differential expression profile in tumor versus normal tissue, making it an attractive target for ADC in GI cancers. In January 2025, the Company granted ArriVent BioPharma, Inc. ("**ArriVent**") exclusive rights to develop, manufacture and commercialize MRG007 outside Greater China. The Company and ArriVent are respectively conducting a Phase Ib dose optimization in China and the United States for CRC.

MEIYOUHENG (Becotatug Vedotin Injection) (MRG003)

MEIYOUHENG (Becotatug Vedotin Injection) is an ADC comprised of an EGFR-targeted monoclonal antibody conjugated with the potent microtubulin disrupting payload MMAE via a valine-citrulline linker. It binds specifically with high affinity to human EGFR on the surface of tumor cells, releases the potent payload upon internalization and lysosomal protease cleavage of the linker, and results in tumor cell death. In October 2025, becotatug vedotin received conditional marketing approval from the National Medical Products Administration of the PRC (中國國家藥品監督管理局) for recurrent/metastatic nasopharyngeal cancer, making it the first EGFR-targeted ADC approved in China. We are also conducting combination trials with becotatug vedotin and pucotenlimab in the PRC and in Europe.

PUYOUHENG (Pucotenlimab Injection) (HX008)

PUYOUHENG (Pucotenlimab Injection) is a humanized IgG4 mAb against human PD-1, which can antagonize the PD-1 signal to restore the capability of the immune cells to kill cancer cells through blocking PD-1 binding to its ligands PD-L1 and PD-L2, and which has been commercialized for treating microsatellite instability-high or mismatch repair-deficient ("**MSI-H/dMMR**") solid tumors and inoperable or metastatic melanoma since the second half of 2022. In April 2023, two indications were included into the 2023 CSCO Guideline, which are pucotenlimab as ≥ second-line treatment of MSI-H/dMMR CRC and solid tumors, and pucotenlimab as second-line treatment of melanoma. Moreover, Pucotenlimab for treatment of advanced and recurrent MSI-H/dMMR gynecological cancer was included into the 2023 CSCO Guideline.

Warning: There is no assurance that the CMG901, MRG007, MRG003 and/or HX008 will ultimately be successfully developed and marketed by the Company. 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,
September 23, 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.