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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

CMG901 (AZD0901) CLINICAL RESULTS PRESENTED AS LBA PROFFERED PAPER AT PRESIDENTIAL SYMPOSIUM, MRG007 CLINICAL RESULTS PRESENTED AS LBA, AND ENCOURAGING DATA FOR MRG003 PRESENTED AS RAPID ORAL AT ESMO 2026

This announcement is made by the board (the “**Board**”) of directors (the “**Directors**”, each a “**Director**”) of Lepu Biopharma Co., Ltd. (the “**Company**”, together with its subsidiaries, the “**Group**”) on a voluntary basis to inform its shareholders and potential investors of: i) the Phase III clinical trial results of CMG901 (AZD0901) in second and later-line (“**2L+**”) advanced/metastatic CLDN18.2-positive gastroesophageal carcinoma (“**GEC**”); ii) the latest clinical results of MRG007 (ARR-217), a potential best-in-class CDH17-directed exatecan antibody-drug conjugate (“**ADC**”) for the treatment of colorectal cancer (“**CRC**”); and iii) the Phase II trial results of induction treatment of anti-PD-1 pucotenlimab (HX008) plus MRG003 (becotatug vedotin) in locally advanced head and neck squamous cell carcinoma (“**LA-HNSCC**”).

CMG901 (AZD0901) – LBA Proffered Paper

The Board is pleased to announce that positive high-level results from CLARITY-Gastric01 (“**CG-01**”), a global Phase III clinical trial evaluating CMG901 (AZD0901), showed a significant overall survival (“**OS**”) benefit with sonositatug vedotin (“**Sone-Ve**”) versus investigator’s choice of therapy (“**INV**”) in the third-line and later (“**3L+**”) and intention-to-treat (“**ITT**”) populations, with a manageable safety profile. These findings support Sone-Ve as a potential 2L+ treatment for a broad patient population with advanced CLDN18.2-positive GEC.

CG-01 is a randomised, open-label, global, phase III study of Sone-Ve versus INV after ≥1 prior therapy for GEC expressing CLDN18.2 in ≥25% tumour cells with membranous staining at any intensity. Patients with 2L+ unresectable, locally advanced/metastatic CLDN18.2-positive GEC (intent-to-treat population) were initially randomised 1:1:1 to Sone-Ve 1.8 mg/kg, Sone-Ve 2.2 mg/kg or INV. Post-dose selection, patients were randomised 1:1 to Sone-Ve 2.2 mg/kg or INV (2L: ramucirumab + paclitaxel, paclitaxel, or docetaxel; 3L+: irinotecan, trifluridine/tipiracil, or apatinib (China only)). Randomisation was stratified by region, prior gastrectomy and line of therapy. Dual primary endpoints are OS in 3L+ and progression-free survival (“**PFS**”) by blinded independent central review (“**BICR**”) in the ITT population. The key secondary endpoint is OS in ITT.

As at the data cut-off date of 31 May 2026, 532 of 594 total patients were randomised to Sone-Ve 2.2 mg/kg (n=267) or INV (n=265); median follow-up was 8.6 months. Sone-Ve 2.2 mg/kg significantly improved OS versus INV in 3L+ (median 10.0 versus 5.0 months, HR 0.47 (95% CI 0.36-0.62); p<0.001) and in 2L+ (ITT) (median 10.6 versus 6.4 months, HR 0.58 (95% CI 0.47-0.73); p<0.001). PFS by BICR in ITT did not meet the threshold for statistical significance. OS benefit in ITT was consistent in CLDN18.2 $\geq$ 75% (HR 0.59 (95% CI 0.45-0.78)) and $\geq$ 25–<75% (HR 0.63 (95% CI 0.42-0.94)) expression subgroups.

Safety profile: The safety profile of CG-01 is summarised in the table below:

Characteristic	Sone-Ve	INV
3L+ (n)	178	177
Median OS(95% CI),months	10.0 (7.2-11.4)	5.0 (4.2-6.4)
HR(95% CI)	0.47 (0.36-0.62)	–
p-value	<0.001	–
ITT (2L+) (n)	267	265
Median OS(95% CI),months	10.6 (9.1-12.0)	6.4 (5.8-7.6)
Hazard ratio (“HR”)(95% CI)	0.58 (0.47-0.73)	–
p-value	<0.001	–
Median PFS by BICR (95% CI), months	4.2 (3.5-5.3)	3.8 (3.0-4.2)
HR(95% CI)	0.77 (0.62-0.96)	–
p-value	0.05	–
SAS* TRAE (n)	261	252
Any	224 (85.8)	205 (81.3)
Grade $\geq$ 3	95 (36.4)	113 (44.8)
Gastrointestinal toxicity	29 (11.1)	16 (6.3)
Haematological toxicity	20 (7.7)	40 (15.9)
Leading to death	3 (1.1)	2 (0.8)
Leading to discontinuation	8 (3.1)	11 (4.4)

* SAS, safety analysis set; all pts who received $\geq$ 1 dose. TRAE, treatment-related adverse event.

MRG007 (ARR-217) – LBA Rapid Oral

The Board is pleased to announce that positive, high-level preliminary results from the ongoing Phase I study of MRG007 (ARR-217) have demonstrated dose-proportional pharmacokinetics and enhanced stability with promising preliminary anti-tumour activity in patients with advanced or metastatic CRC, and a manageable safety profile supporting further development and the ongoing dose optimization for the Phase Ib study. The study included patients with locally advanced or metastatic solid tumours, including CRC and other gastrointestinal (“GI”) malignancies, who had progressed following standard therapies.

The study is a Phase I study being conducted in China and the United States. As of August 5, 2026, 123 patients were treated, including 113 with CRC. Dose escalation has been completed at 2 mg/kg, 4 mg/kg, 6 mg/kg and 8 mg/kg. Backfill is ongoing at 4-8 mg/kg, and randomised dose optimization in CRC has begun. The median prior lines of metastatic CRC were 3 (range 1-9). The primary objective in dose escalation is safety, and the primary efficacy endpoint in expansion is objective response rate (“**ORR**”). Among efficacy-evaluable CRC patients treated at 6 mg/kg the ORR was 44.8% (13/29; 95% CI, 26.4%-64.3%), and disease control rate was 93.1% (27/29). Responses were observed in both rat sarcoma (“**RAS**”) subgroups, with ORRs of 50.0% (4/8) in RAS wild-type and 42.1% (8/19) in RAS-mutant CRC. Among efficacy-evaluable CRC patients treated at 4 mg/kg or above, ORR was 34.2% (25/73; 95% CI, 23.5%-46.3%).

Safety profile: MRG007 (ARR-217) was generally well tolerated. The most common treatment-emergent adverse events (“**TEAEs**”) were cytopenias and GI toxicities, predominantly Grade 1 or Grade 2. No interstitial lung disease was reported, and one of 123 patients (0.8%) discontinued treatment due to a TEAE. Pharmacokinetics were generally dose-proportional, and the largely overlapping pharmacokinetic profiles of ADC and total antibody were consistent with conjugate stability in circulation.

MRG003 (becotatug vedotin) – Rapid Oral

The Board is also pleased to announce that the first interim safety analysis results of MRG003 (becotatug vedotin) from the GORTEC 2024-03 IDEAL trial are encouraging and showed a favourable safety profile. The trial is a randomised Phase II trial of induction treatment with (a) anti-PD-1 pucotenlimab (HX008) plus MRG003 (“**Arm A**”) versus (b) MRG003 alone (“**Arm B**”) followed by chemoradiotherapy (“**CRT**”). The trial evaluates induction becotatug vedotin ± pucotenlimab prior to definitive CRT in LA-HNSCC. Patients with LA-HNSCC (larynx, hypopharynx, oral cavity, and oropharynx p16 – and p16 +) were randomised (1:1) to 2 arms. The primary endpoint is complete response (“**CR**”) at 12 weeks post-CRT. Each arm is evaluated independently (one-stage Fleming design; H0=30%). A total of 106 patients is planned. The first interim safety analysis was conducted after completion of cycle 1 in first 20 patients.

Between October 23, 2025 and April 21, 2026, 49 patients were randomized. Most had oropharyngeal cancer (31 patients, including 19 p16 +). 20 patients (10 per arm) were evaluated for first safety analysis. No Grade 4 TEAEs were observed in either arm. A total of 11 Grade 3 TEAEs were observed in eight patients (Arm A: six; Arm B: two). In Arm A, these Grade 3 TEAEs included increased alanine aminotransferase (“**ALT**”) and constipation in one patient, peripheral arterial ischaemia in one patient, neutropenia in one patient, diabetes in one patient, diarrhoea in one patient and hyponatraemia in one patient. In Arm B, the Grade 3 TEAEs were myalgia, increased ALT and hypertension in one patient, and fatigue in one patient. Data on ORR (per RECIST 1.1) after induction are preliminary and not mature, the initial ORR was observed in 71%.

About CMG901 (AZD0901)

CMG901 (sonesitug 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 clearance both in China and the United States. CLDN18.2 is selectively and widely expressed in gastric cancer (“**GC**”), pancreatic cancer and other solid tumours, which makes it an ideal tumour target for therapeutic development. In July 2026, positive high-level results from the CLARITY-Gastric01 global Phase III trial showed that sonesitug vedotin demonstrated a statistically significant and highly clinically meaningful improvement in OS in 2L+ Claudin 18.2-positive advanced GCs versus investigator’s choice of therapy.

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 commercialisation of CMG901 were licensed to AstraZeneca (“**AstraZeneca**”). CLARITY-Gastric01, the Phase III trial of CMG901 (AZD0901) is sponsored by AstraZeneca and AZD0901 is owned by AstraZeneca.

About MRG007 (ARR-217)

CRC is a highly prevalent digestive tract malignancy worldwide, with approximately 1.9 million incident cases of CRC globally each year and more than 510,000 incident cases in China each year. Despite the availability of several later-line treatment options, patients with heavily pretreated metastatic CRC continue to face substantial unmet medical needs, particularly for therapies capable of achieving meaningful and durable tumour responses.

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 GI cancers, including CRC, gastric cancer and pancreatic cancer. CDH17 has a differential expression profile in tumour versus normal tissue, making it an attractive ADC target in GI cancers. In January 2025, the Company granted ArriVent BioPharma, Inc. (“**ArriVent**”) exclusive rights to develop, manufacture and commercialise MRG007 outside Greater China. The Company and ArriVent are conducting Phase Ib dose optimisation studies for CRC in China and the United States, respectively.

About MRG003 (becotatug vedotin)

MRG003 is an ADC comprising an EGFR-targeted monoclonal antibody conjugated with the potent microtubule-disrupting payload MMAE via a valine-citrulline linker. It binds specifically and with high affinity to human EGFR on the surface of tumour cells, releases the potent payload upon internalisation and lysosomal protease cleavage of the linker, and results in tumour cell death. In October 2025, MRG003 received conditional marketing approval from the National Medical Products Administration of the People’s Republic of China (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. The Group is also conducting combination trials with MRG003 and pucotenlimab in China and Europe.

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. The clinical data described in this announcement are preliminary, and further clinical trials, regulatory review and other development activities are required before any product candidate may be approved, launched and/or commercialised. There is no assurance that CMG901 (AZD0901), MRG007 (ARR-217), or any related combination therapy will ultimately be developed, approved, launched and/or commercialised successfully. There is also no assurance that therapies related to MRG003 (becotatug vedotin) or under research and development (including any related combination therapy) will ultimately be developed, approved and/or commercialised 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, October 26, 2026

As at the date of this announcement, the Board comprises Dr. Pu Zhongjie (chairman) and Dr. Sui Ziyue (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.