Alebund Pharmaceuticals (Jiangsu) Limited
禮邦醫藥(江蘇)股份有限公司
(A joint stock company incorporated in the People's Republic of China with limited liability)
(Stock Code: 09637)

VOLUNTARY ANNOUNCEMENT NEW DRUG APPLICATION FOR AP301 CAPSULES FOR THE TREATMENT OF HYPERPHOSPHATEMIA IN PATIENTS WITH CHRONIC KIDNEY DISEASE RECEIVING DIALYSIS ACCEPTED FOR REVIEW BY THE NATIONAL MEDICAL PRODUCTS ADMINISTRATION OF CHINA

This announcement is made by Alebund Pharmaceuticals (Jiangsu) Limited (the "**Company**", together with its subsidiaries, the "**Group**") on a voluntary basis to inform the shareholders and potential investors of the Company about the latest business development of the Group.

The board of directors of the Company (the "**Board**") is pleased to announce that the New Drug Application (the "**NDA**") for AP301 capsules, a novel oral iron-based phosphate binder, for the treatment of hyperphosphatemia in patients with chronic kidney disease ("**CKD**") receiving maintenance dialysis, has been formally accepted for review by the National Medical Products Administration of China (the "**NMPA**") today. The NDA is supported primarily by the results of RESPOND-1, the pivotal Phase III clinical trial of AP301 completed in China, together with other accumulated clinical data.

THE CHINA PIVOTAL PHASE III CLINICAL TRIAL (RESPOND-1)

RESPOND-1 was a randomized, open-label, active-controlled, pivotal Phase III clinical trial conducted at 50 sites in China and led by Professor Li Zuo, Director of the Department of Nephrology at Peking University People's Hospital. A total of 474 patients with hyperphosphatemia receiving maintenance dialysis were randomized in a 3:1 ratio to AP301 (355 patients) or sevelamer carbonate (119 patients) for a 52-week treatment period, with doses in both groups titrated to the same serum phosphate target.

The trial met both of its pre-specified primary efficacy endpoints. The AP301 maintenance dose demonstrated clinically and statistically significant superiority over the ineffective low dose in reducing serum phosphate levels, and the efficacy of AP301 was robust and sustained throughout the entire 52-week treatment period, meeting the endpoint of non-inferiority to sevelamer carbonate in reducing serum phosphate levels as designed in the trial. AP301 was safe and well tolerated. The most common adverse events were discolored feces and diarrhea. Diarrhea generally occurred early in treatment and resolved without any change to treatment.

At Week 12, the AP301 group was non-inferior to the active comparator sevelamer carbonate group in reducing serum phosphate levels (least-squares mean reductions from baseline of 0.72 mmol/L [2.22 mg/dL] vs. 0.70 mmol/L [2.17 mg/dL], respectively); the upper bound of the 95% confidence interval (CI) for the between-group difference (0.06 mmol/L [0.20 mg/dL]) was below the pre-defined non-inferiority margin of 0.19 mmol/L (0.59 mg/dL), demonstrating that AP301 met the pre-specified non-inferiority criterion.

During the low-dose control period (from the end of Week 24 to the end of Week 27), among AP301 responders (serum phosphate <1.78 mmol/L [5.5 mg/dL] at the end of Week 20) who were re-randomized 1:1, serum phosphate control in the AP301 maintenance-dose group (94 patients) was superior to that in the AP301 ineffective low-dose control group (93 patients), with a between-group difference of -0.58 mmol/L (-1.8 mg/dL) (P <0.001), which was both clinically and statistically meaningful.

At Week 52, the AP301 group showed a greater mean reduction in serum phosphate level from baseline than the sevelamer carbonate group (0.76 mmol/L [2.35 mg/dL] vs. 0.72 mmol/L [2.22 mg/dL]), a higher serum phosphate response rate (66.7% vs. 58.6%), and a lower mean daily dose exposure (AP301 6.52 g/day vs. sevelamer carbonate 7.56 g/day). AP301 achieved a robust and sustained reduction in serum phosphate levels throughout the 52-week treatment period.

AP301 was generally safe and well tolerated over the 52-week treatment period. The most common adverse events were discolored feces and diarrhea. Diarrhea generally occurred early in treatment and resolved without any change to treatment. In addition, no notable iron-overload risk signal was observed during the 52-week treatment period.

Results from RESPOND-1 were presented at the American Society of Nephrology (ASN) Kidney Week 2025.

Further details of the trial are available at clinicaltrials.gov under identifier NCT07030595, or at www.chinadrugtrials.org.cn under registration number CTR20231624.

HYPERPHOSPHATEMIA AND UNMET CLINICAL NEED

Hyperphosphatemia is a common complication in patients with CKD receiving dialysis, affecting approximately 95% of patients with end-stage renal disease ("**ESRD**") on dialysis. Chronically elevated serum phosphate is associated with vascular calcification, secondary hyperparathyroidism and renal osteodystrophy, as well as increased risks of cardiovascular events and all-cause mortality. Regular dialysis and dietary phosphorus restriction are generally insufficient to adequately control the phosphate burden, and patients often require long-term pharmacological treatment. Despite the widespread use of phosphate binders, according to data from China Insights Consultancy, approximately 76% of dialysis patients in China fail to achieve the target serum phosphate range of 1.13-1.78 mmol/L [3.5-5.5 mg/dL]; separately, according to 2021 data from the Dialysis Outcomes and Practice Patterns Study (DOPPS), approximately 52% and 39% of hemodialysis patients in the United States and Japan, respectively, had serum phosphate levels above 1.78 mmol/L [5.5 mg/dL]. Existing therapies continue to face challenges in gastrointestinal tolerability, pill burden and long-term treatment adherence, and innovative treatment options that combine efficacy, tolerability and dosing convenience remain to be further developed.

Warning statement required by Rule 18A.08(3) of the Listing Rules: The Company cannot guarantee that it will be able to develop, or ultimately market, AP301 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
Alebund Pharmaceuticals (Jiangsu) Limited
Dr. Gavin Guoyao Xia
Chairman of the Board, executive Director and Chief Executive Officer

Hong Kong, August 7, 2026

As of the date of this announcement, the Board comprises (i) Dr. Gavin Guoyao Xia, Jin Tian, M.D., Ms. Wang Yun and Dr. Zhang Huading as executive Directors; (ii) Dr. Lu An as a non-executive Director; and (iii) Dr. Xu Runhong, Dr. Zhui Chen and Mr. Leung Chi Wai as independent non-executive Director