Alebund's AP301 NDA Accepted for Review by China's NMPA

SHANGHAI, China, August 7, 2026— Alebund Pharmaceuticals (Jiangsu) Limited ("Alebund" or the "Company"; HKEX: 09637), a renal-focused biopharmaceutical company, today announced that the New Drug Application (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, is formally accepted for review by China's National Medical Products Administration (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.

AP301 is a novel fiber-iron-based phosphate binder that offers high phosphate-binding capability, does not require chewing before swallowing, does not expand in volume when exposed to gastric fluid, and is not systemically absorbed. These features contribute to a reduced pill burden, improved tolerability, and enhanced patient adherence.

AP301 China Pivotal Phase III Trial (RESPOND-1)

RESPOND-1 was a randomized, open-label, active-controlled, multicenter 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.[4]

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 [2.22 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 target attainment 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 [4].

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.[4]

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 Medical 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.[1] 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.[2] 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];[1] 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].[3] 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.[1-3]

Dr. Gavin Guoyao Xia, Co-founder, Chairman of the Board, and Chief Executive Officer of Alebund Pharmaceuticals, said: "The NMPA's acceptance of the NDA for AP301 marks a key step in advancing Alebund's proprietary products from clinical development toward commercialization, and an important milestone in our global strategy. Hyperphosphatemia requires long-term management, yet reconciling efficacy, safety and adherence remains a core challenge in clinical care today. As a potential best-in-class oral phosphate binder, AP301 can genuinely offer patients with chronic kidney disease on dialysis a long-term treatment option that brings together efficacy, tolerability and dosing convenience. Building on this acceptance, we will actively support the review process and, drawing on our manufacturing base in Yangzhou, accelerate our preparations for launch. We look forward to bringing this innovation from China to patients with kidney diseases around the world."

Jin Tian, M.D., Co-founder and Chief Medical Officer of Alebund Pharmaceuticals, commented: “Achieving the sustained serum phosphate control within the target range over the long term remains a major challenge for patients with chronic kidney disease on dialysis. Results from the AP301 China Phase III pivotal study confirmed that this novel iron-based phosphate binder effectively lowers phosphorus, is safe, and well tolerated. We will work closely throughout the review process and continue to advance the global clinical development of AP301, with the goal of making a new phosphate lowering product available to patients as soon as possible.”

References

[1] CIC, Global and Chinese Hyperphosphatemia Drug Industry Blue Book, 2023.
[2] KDIGO 2017 Clinical Practice Guideline Update. Kidney Int Suppl. 2017;7(1):1–59.
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[4] Zuo L, et al. J Am Soc Nephrol. 2025;36(10S):TH-PO1200. doi:10.1681/ASN.202556bnmcy8.

About Alebund Pharmaceuticals

Alebund Pharmaceuticals (09637.HK) is a biopharmaceutical company focused on kidney disease and related chronic conditions, aiming to bring better therapies to patients worldwide. It has one of the broadest renal-focused pipelines and an integrated platform spanning R&D, manufacturing and commercialization. Its portfolio comprises seven

investigational drug candidates and one commercialized product, Mircera®. Three of the candidates are at the clinical stage: AP301 (Phase III; China Pivotal Phase III completed, global MRCT ongoing), AP306 (Phase II) and AP303 (Phase I). Together they address chronic kidney disease (CKD) and its complications, including hyperphosphatemia, renal anemia, IgA nephropathy, diabetic kidney disease, FSGS and ADPKD. Alebund has built a manufacturing site in Yangzhou, Jiangsu to support the future commercial manufacturing of AP301 and other pipeline products and has obtained a Drug Manufacturing License (Category B) issued by the Jiangsu Provincial Drug Administration. The Company has also established a dedicated nephrology sales team responsible for the commercialization of relevant products in China. For more information, visit www.alebund.com.

礼邦医药 AP301 新药上市申请获国家药监局受理

上海，2026 年 8 月 7 日——礼邦医药（江苏）股份有限公司（以下简称“礼邦医药”或“公司”，股票代码：09637.HK），一家聚焦肾脏疾病领域的生物医药企业，今日宣布，公司管线产品 AP301 胶囊（一款新型口服含铁磷结合剂）用于治疗接受维持性透析的慢性肾脏病（CKD）患者高磷血症的新药上市申请（NDA），今日获中国国家药品监督管理局（NMPA）受理。本次 NDA 主要基于 AP301 已在中国完成的关键 III 期临床试验 RESPOND-1 的结果及其他累积临床资料。

作为一款以纤维-铁为基础的新一代口服磷结合剂，AP301 有非常高的磷结合能力，无需咀嚼，在胃液中膨胀体积小，无系统吸收等优势。这些特点有助于减少患者每日服药数量，带来更好的安全性及胃肠耐受性并提升患者依从性。

AP301 中国关键 III 期临床试验（RESPOND-1）

RESPOND-1 是一项在中国 50 家临床中心开展的随机、开放标签、阳性药物对照关键 III 期临床试验，由北京大学人民医院肾内科主任左力教授牵头。共 474 名接受维持性透析的高磷血症患者按 3:1 的比例随机分配至 AP301 组（355 名）或碳酸司维拉姆组（119 名），治疗期 52 周，两组基于同一血清磷目标值调整剂量。[4]

本研究达到预设的两项主要疗效终点。AP301 维持剂量在降低血清磷水平上，相较于无效低剂量具有临床及统计学上的显著优效性，且在整个 52 周的治疗期内，AP301 的疗效稳健且持久，达到试验设计的降低血清磷水平方面不劣于碳酸司维拉姆的终点。AP301 安全且耐受性良好。最常见的不良事件是粪便变色和腹泻。腹泻通常发生于治疗早期，无需调整治疗方案即可缓解。[4]

于治疗至第 12 周，AP301 组降低血清磷（自基线计）的效果非劣于阳性对照药碳酸司维拉姆组：AP301 组血清磷较基线降幅的最小平方均值（LSM）为 0.72mmol/L（2.22 mg/dL），碳酸司维拉姆组为 0.70mmol/L（2.17 mg/dL），两组降幅差值的 95%置信区间（CI）上限（0.06 mmol/L〔0.20 mg/dL〕）低于预设非劣界值 0.19mmol/L（0.59 mg/dL），即 AP301 的降磷效果达到研究预设的非劣效标准。[4]

于低剂量对照期（第 24 周末至第 27 周末），在 AP301 治疗应答者（第 20 周末血清磷 <1.78 mmol/L〔5.5 mg/dL〕）中按 1:1 再随机分配，AP301 维持剂量组（94 名）的血清磷控制优于 AP301 无效低剂量对照组（93 名），组间差值为−0.58 mmol/L（−1.8 mg/dL）（P<0.001），兼具临床与统计学意义。[4]

于第 52 周，AP301 组血清磷较基线的平均降幅大于碳酸司维拉姆组（降幅分别为 0.76mmol/L〔2.35 mg/dL〕及 0.72 mmol/L〔2.22 mg/dL〕），血清磷应答率更高（分别为 66.7%和 58.6%），且平均每日服用剂量更低（分别为 6.52 克/天和 7.56 克/天）。[4]

AP301 于 52 周治疗中总体安全且耐受性良好；最常见的不良事件为粪便变色和腹泻；在 52 周治疗期内未观察到明显的铁过载风险信号。[4]

RESPOND-1 的研究结果已于 2025 年美国肾脏病年会（ASN）上公布。[4]

该研究的其他详情可浏览 clinicaltrials.gov 并检索登记号 NCT07030595，或浏览 www.chinadrugtrials.org.cn 并检索登记号 CTR20231624。

高磷血症与未被满足的临床需求

高磷血症是接受透析的 CKD 患者常见的并发症，约 95%接受透析的终末期肾病患者存在高磷血症。[1]血清磷水平持续升高与血管钙化、继发性甲状旁腺功能亢进、肾性骨病，以及心血管事件和全因死亡风险增加相关。[2]规律透析及饮食限磷通常不足以有效控制磷负荷，患者往往需要长期药物治疗。尽管磷结合剂已广泛使用，根据灼识咨询资料，中国仍约有 76%的透析患者血清磷水平未达到 1.13–1.78 mmol/L（3.5–5.5 mg/dL）的目标范围；[1]而据透析预后与治疗模式研究（DOPPS）2021 年资料，美国及日本分别约有 52%及 39%的血液透析患者血清磷水平高于 1.78 mmol/L（5.5 mg/dL）。[3]现有疗法仍面临胃肠道耐受性、服药负担和长期依从性等挑战，兼顾疗效、耐受性与用药便利性的创新治疗选择仍有待进一步开发。[1-3]

礼邦医药联合创始人、董事会主席兼首席执行官夏国尧博士表示：“AP301 新药上市申请获得国家药监局受理，是礼邦医药自有产品从临床开发迈向商业化的关键一步，也是我们全球战略的重要里程碑。高磷血症需要长期管理，而疗效、安全性与依从性难以兼顾仍是当今临床治疗的核心挑战。AP301 为最优的口服磷结合剂，可以真正为接受透析的慢性肾脏病患者提供兼顾疗效、耐受性与用药便利的长期治疗选择。立足此次受理，我们将积极配合审评进程，依托扬州产业化基地加速推进上市准备。我们期待让这一来自中国的创新成果，早日惠及中国乃至全球的肾病患者。”

礼邦医药联合创始人兼首席医学官田劲医生表示：“长期、稳定地将血清磷控制在目标水平，是接受透析的慢性肾脏病患者所面临的一大挑战。AP301 中国关键 III 期研究结果，证实了这款新型铁基磷酸盐结合剂降磷疗效稳定、安全且耐受性良好。我们将积极配合注册审评相关工作，并持续推进 AP301 的全球临床开发，期待能尽早为患者带来降磷治疗新的选择。”

参考文献

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关于礼邦医药

礼邦医药（09637.HK）是一家专注于肾脏疾病及相关慢性病领域的生物医药公司。围绕慢性肾脏病（CKD）不同阶段及其并发症的临床需求，公司构建了肾病适应症覆盖广泛的创新产品组合，并形成涵盖研发、生产及商业化的一体化平台，致力于为全球肾脏疾病患者带来更优的治疗方案。目前，公司已拥有 7 款在研候选产品及 1 款商业化产品（美信罗®），其中 AP301、AP306 及 AP303 三款在研产品已进入临床阶段，分别处于临床 III 期、II 期及 I 期，其中 AP301 的中国关键 III 期临床试验已完成，全球多区域临床试验（MRCT）正在进行。整体产品组合覆盖慢性肾脏病及其并发症的多个适应症，包括高磷血症、肾性贫血、IgA 肾病、糖尿病肾病、局灶节段性肾小球硬化及常染色体显性多囊肾病。公司已在江苏扬州建成生产基地，以支持 AP301 等管线产品未来的商业化生产，并已取得江苏省药品监督管理局颁发的《药品生产许可证》（B 类）；同时，公司已组建肾科专科销售团队，负责相关产品在中国的商业化推广。更多信息，请访问：www.alebund.com。