Alebund Pharmaceuticals Announces Completion of Patient Enrollment in Global Phase III Pivotal Multi-Regional Clinical Trial of AP301 for Hyperphosphatemia

Shanghai, China – May 6, 2026 — Alebund Pharmaceuticals (Jiangsu) Limited ("Alebund" or the "Company"), an integrated biopharmaceutical company focusing on developing innovative therapies for the treatment of renal diseases and related chronic conditions, today announced the completion of patient enrollment in the global Phase III pivotal multi-regional clinical trial (RESPOND-2, Study AP301-HP-03) of AP301, a novel fiber-iron-based phosphate binder, for the treatment of hyperphosphatemia. The trial was conducted in the United States and China, led by Dr. Geoffrey A. Block of U.S. Renal Care, with Professor Xiaoqiang Ding, Director of the Department of Nephrology, Zhongshan Hospital, Fudan University serving as the China principal investigator, and enrolled a total of 282 chronic kidney disease ("CKD") patients on maintenance dialysis with hyperphosphatemia — 138 in the U.S. and 144 in China.

As a next-generation fiber-iron-based phosphate binder, AP301 is designed to have a higher phosphate-binding capability, favorable gastrointestinal tolerability, minimal risk of iron overload, and no requirement for chewing before swallowing, with the potential to improve treatment adherence and effectively control hyperphosphatemia.

Trial Design

RESPOND-2 is a double-blind, randomized, multi-regional Phase III clinical trial conducted in the U.S. and China. The study planned to enroll 264 CKD patients aged 12 years and above on maintenance dialysis with hyperphosphatemia, with 282 patients actually enrolled. The study comprises three treatment phases: an 8-week double-blind dose titration phase (AP301 versus AP301 ineffective low dose, 2:1 randomization), a 24-week open-label treatment phase, and a 3-week double-blind randomized withdrawal phase (AP301 maintenance dose versus AP301 ineffective low dose, 1:1 re-randomization). The primary endpoint is the change in serum phosphate levels from baseline to the end of the dose titration phase (AP301 versus AP301 ineffective low dose). The key secondary endpoint is the change in serum phosphate level from the end of the open-label treatment phase to the end of the randomized withdrawal phase (AP301 maintenance dose versus AP301 ineffective low dose).

Based on existing clinical data for AP301, the Company reached an agreement with the FDA that this global Phase III multi-regional clinical trial will serve as the single pivotal study to support U.S. registration of AP301.

Unmet Medical Need

Hyperphosphatemia is one of the most common complications in CKD patients, affecting approximately 95% of dialysis-dependent CKD patients and approximately 15% of non-dialysis CKD patients. According to KDIGO (Kidney Disease: Improving Global Outcomes) guidelines, hyperphosphatemia is defined as a serum phosphate level exceeding 4.5 mg/dL (1.45 mmol/L), with the target serum phosphate range for dialysis patients being 3.5–5.5 mg/dL (1.13–1.78 mmol/L) [1]. Chronically elevated serum phosphate is a central driver of CKD-mineral and bone disorder (CKD-MBD), leading to serious complications including vascular calcification, secondary hyperparathyroidism, and renal osteodystrophy, and is an independent risk factor for cardiovascular events and all-cause mortality in dialysis patients [2].

For CKD patients on dialysis, regular dialysis alone is insufficient to clear the accumulated phosphorus in the body, and the effect of dietary phosphorus restriction is limited. Oral phosphate binders remain the primary treatment for hyperphosphatemia. However, existing phosphate binders are commonly associated with gastrointestinal side effects, high pill burden, and systemic absorption in some agents, resulting in poor patient compliance and inadequate treatment duration. According to the Dialysis Outcomes and Practice Patterns Study (DOPPS) data, approximately 76% of dialysis patients in China, 52% in the U.S., and 39% in Japan fail to achieve target serum phosphate levels [3]. Data from the China Dialysis Calcification Study (CDCS) further showed that the serum phosphate us target attainment rate among Chinese dialysis patients within the 3.5–5.5 mg/dL range was only 40.1% [4].

Data from the Completed AP301 China Pivotal Phase III Clinical Trial

AP301 demonstrated robust and clinically meaningful efficacy in the completed China pivotal Phase III clinical trial (RESPOND-1, Study AP301-HP-02) [5]. The study was led by Professor Li Zuo, Director of the Department of Nephrology at Peking University People's Hospital, and randomized 474 participants across 50 investigational sites in China.

At Week 12, AP301 was non-inferior to sevelamer carbonate, a phosphate binder widely used in clinical practice, in reducing serum phosphate levels (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 versus sevelamer carbonate. At Week 27, participants receiving the AP301 maintenance dose achieved clinically and statistically superior serum phosphate control compared with the ineffective low dose group, with a between-group difference of -0.58 mmol/L (-1.8 mg/dL) ($P<0.001$). At the end of 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 vs. -0.72 mmol/L), a higher serum phosphate target attainment rate (66.7% vs. 58.6%), and a lower daily dose (AP301 6.52 g/day vs. sevelamer carbonate 7.56 g/day). AP301 achieved robust and sustained serum phosphate reduction, suggesting its long-term therapeutic benefit.

Overall, AP301 was safe and well-tolerated. The most common adverse events were discolored feces and diarrhea. Diarrhea typically occurred within the first 2 to 4 weeks of treatment, was predominantly mild in severity, resolved without treatment modification, and rarely led to treatment discontinuation (0.6%). In the 52-week Phase III treatment period, no safety findings related to iron accumulation were observed.

Based on the results of AP301 China pivotal phase III clinical trial and other accumulated clinical data, Alebund has obtained alignment with NMPA and plans to submit a New Drug Application (NDA).

Jin Tian, M.D., Co-founder and Chief Medical Officer of Alebund Pharmaceuticals, commented: "The on-time completion of patient enrollment in AP301's global Phase III pivotal multi-regional clinical trial reflects Alebund's ability to advance high-quality global clinical development, which is an important milestone in the global registrational development of AP301."

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About Hyperphosphatemia

Hyperphosphatemia is one of the most common complications in CKD patients. The long-term elevated serum phosphate levels could cause multiple complications such as secondary hyperparathyroidism, renal osteodystrophy, and vascular calcification. It is an independent risk factor of cardiovascular events and all-cause mortalities. Good control of serum phosphate levels could effectively improve the patients' outcome. For CKD patients undergoing dialysis treatment, regular dialysis is not sufficient to remove the excess serum phosphate in the body. Considering the limitations of low-phosphate diet which might cause dystrophia, oral use of phosphate binders is the prevailing treatment for hyperphosphatemia. However, existing phosphate binders lead to low patient compliance, with less than 50% of patients achieving good phosphate control, due to gastrointestinal side effects and high pill burden, etc.

According to the Global and Chinese Hyperphosphatemia Drug Industry Blue Book by China Insights Consultancy in 2023, the out-of-target rate of serum phosphate level in dialysis patients in Chinese mainland was significantly higher than that in other countries and regions. There remains substantial room for improvement in terms of the proportion of patients using phosphate binders and duration of their usage. According to CIC, by 2035, the market size of serum phosphorus-lowering products in China is expected to reach RMB 10 billion while the global market size is forecasted to reach USD 6 billion.

About Alebund Pharmaceuticals

Alebund was founded in Shanghai in 2018. The Company focuses on the discovery, development, manufacturing, and commercialization of novel therapies primarily for kidney diseases and their complications, as well as other chronic conditions, to bring better therapeutic options to patients in China and globally. Alebund has built a diversified and balanced pipeline of seven drug candidates and one commercialized product (Mircera®) targeting a broad range of renal indications, including chronic kidney disease (CKD) and CKD complications, such as hyperphosphatemia, renal anemia, IgA nephropathy, diabetic kidney disease, focal segmental glomerulosclerosis (FSGS), and autosomal dominant polycystic kidney disease (ADPKD). Alebund has completed the construction of its manufacturing site in Yangzhou that will supply both drug substance and drug products of our product candidates, including AP301, upon commercial launch. Alebund has also established a dedicated in-house commercialization team in China responsible for promoting our renal products.

礼邦医药宣布 AP301 全球 III 期关键性多区域临床试验完成全部患者入组

中国上海，2026 年 5 月 6 日—礼邦医药（江苏）股份有限公司（“礼邦医药”或“公司”），一家专注于开发治疗肾脏疾病及相关慢性病创新药物的综合性生物制药公司，今日宣布其新型口服含铁磷结合剂 AP301 的全球 III 期关键性多区域临床试验（RESPOND-2，试验编号 AP301-HP-03）已完成全部患者入组。该试验在美国和中国同步开展，由美国 U.S. Renal Care 的 Geoffrey A. Block 医生牵头，复旦大学附属中山医院肾内科主任丁小强教授担任中国主要研究者，共计入组 282 名慢性肾脏病（“CKD”）维持性透析伴高磷血症患者，其中美国入组 138 名、中国入组 144 名。

作为一款以纤维-铁为基础的新一代口服磷结合剂，AP301 设计定位为具有较强的磷酸盐结合力、良好胃肠耐受性、极低铁过载风险，且无需在吞服前咀嚼，预期可提高患者治疗依从性，有效控制高磷血症。

试验设计

RESPOND-2 是一项在美国和中国开展的双盲、随机、多区域 III 期临床试验，计划入组 264 名 12 岁及以上 CKD 维持性透析伴高磷血症患者，实际入组 282 名。研究包含三个治疗阶段：8 周双盲剂量滴定期（AP301 对比 AP301 无效低剂量，2:1 随机）、24 周开放标签治疗期以及 3 周双盲随机撤药期（AP301 维持剂量对比 AP301 无效低剂量，1:1 再随机）。主要终点为滴定期结束时血清磷水平相对基线的变化（AP301 组对比 AP301 无效低剂量组）。关键次要终点为开放标签治疗期结束至随机撤药期结束期间的血清磷水平变化（AP301 维持剂量组对比 AP301 无效低剂量组）。

基于 AP301 已有的临床研究数据，公司已与 FDA 达成一致，该项全球 III 期关键性多区域临床试验将作为支持 AP301 在美国注册上市的单一关键性研究。

未被满足的临床需求

高磷血症是 CKD 患者最常见的并发症之一，影响约 95% 的透析依赖性 CKD 患者及约 15% 的非透析 CKD 患者。根据 KDIGO（改善全球肾脏病预后组织）指南，血清磷酸盐浓度超过 4.5 mg/dL（1.45 mmol/L）即定义为高磷血症，透析患者的血清磷目标范围为 3.5–5.5 mg/dL（1.13–1.78 mmol/L）[1]。血磷水平长期过高是 CKD 矿物质和骨异常（CKD-MBD）的核心驱动因素，可导致血管钙化、甲状旁腺功能亢进及肾性骨病等多种严重并发症，是透析患者心血管事件和全因死亡的独立危险因素 [2]。

对于 CKD 透析患者，即使规律透析也无法充分清除体内蓄积的磷酸盐，而饮食限磷作用有限，口服磷结合剂是目前治疗高磷血症的主要方法。然而，现有磷结合剂普遍存在胃肠道副作用明显、药片负担高、部分药物存在系统性吸收等问题，导致患者依从性差、治疗

持续时间不足。根据透析结局与实践模式研究（DOPPS）数据，中国约 76%、美国约 52%、日本约 39% 的透析患者血磷控制未达标 [3]；来自中国透析钙化研究（CDCS）的数据进一步显示，我国透析患者在 3.5–5.5 mg/dL 范围内的血磷达标率仅为 40.1% [4]。

已完成的 AP301 中国关键 III 期临床试验数据

AP301 在已完成的中国关键 III 期临床研究（RESPOND-1，试验编号 AP301-HP-02）中展现出稳健且具有临床意义的疗效 [5]。该研究由北京大学人民医院肾内科主任左力教授担任牵头研究者，在中国 50 家研究中心共随机入组 474 名参与者。

治疗至第 12 周，AP301 在降低血清磷水平方面非劣于临床广泛使用的磷结合剂碳酸司维拉姆（两组自基线降幅分别为 -0.72 mmol/L [-2.22 mg/dL] vs. -0.70 mmol/L [-2.17 mg/dL]），组间差异的 95% 置信区间（CI）上限为 0.06 mmol/L（0.20 mg/dL），低于预设非劣界值 0.19 mmol/L（0.59 mg/dL），即 AP301 的降磷效果达到了与碳酸司维拉姆比较的研究预设非劣效标准；在第 27 周，接受维持剂量 AP301 的受试者与无效低剂量组相比，两组差异为 -0.58 mmol/L（-1.8 mg/dL），实现了统计学及临床意义上更优的血磷控制（P<0.001）。在第 52 周治疗结束时，AP301 血清磷水平较基线下降均值大于碳酸司维拉姆组（-0.76 mmol/L vs. -0.72 mmol/L），血清磷达标率高于碳酸司维拉姆组（66.7% vs. 58.6%），且日服用剂量更低（AP301 6.52 g/天，碳酸司维拉姆 7.56 g/天）。AP301 展现了稳健且持久的降磷效果，表明其能带来长期治疗获益。

总体而言，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；腹泻通常发生在治疗的前 2 至 4 周内，严重程度多为轻度，无需调整治疗方案即可缓解，且很少导致治疗终止（0.6%）。AP301 在长达 52 周的 III 期治疗中未发现与铁累积相关的安全性问题。

基于该中国关键临床的结果和其他已获得临床数据，礼邦医药和 NMPA 已达成一致，将于近期递交 AP301 在中国的上市申请。

田劲医生，礼邦医药联合创始人兼首席医学官表示：“AP301 全球 III 期关键性多区域临床试验按计划完成全部患者入组，体现了礼邦医药在全球范围内推进高质量临床开发的执行能力，是 AP301 全球注册开发进程中的重要里程碑。”

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关于高磷血症

高磷血症是慢性肾脏病患者的重要并发症之一。血磷水平长期过高可导致甲状旁腺功能亢进、肾性骨病、血管钙化等多种并发症，是增加患者心血管事件和全因死亡的独立危险因素。控制血磷水平达标可有效改善慢性肾脏病患者的预后。对于慢性肾脏病接受透析治疗的高磷血症患者，即使规律透析也无法清除每日摄入磷酸盐在体内的蓄积量。由于饮食限磷的作用有限、且会影响患者的营养状况，口服磷结合剂是目前治疗高磷血症的主要方法， 但超过一半的患者血磷控制不佳，其中一个主要原因是现有磷结合剂的胃肠道副作用明显且服用药片数量过多，导致患者治疗依从性差。根据灼识咨询 2023 年《全球及中国高磷血症药物行业蓝皮书》，中国在透患者血磷水平不达标率显著高于其他国家及地区，磷结合剂使用比例以及磷结合剂使用患者的用药时长方面均仍有较高提升空间。据 CIC，随着新一代降磷产品的上市，预计 2035 年中国降磷药物市场规模将达到超百亿元人民币规模、全球市场规模预期达到 60 亿美元。

关于礼邦医药

2018 年初，礼邦医药创建于中国上海。作为一家生物制药公司，礼邦主要致力于肾脏病及其相关慢性疾病创新药物的发现，开发，生产和商业化，为全球慢性肾脏病及相关疾病患者提供更佳临床治疗方案。礼邦医药已经建立起了丰富且均衡的肾脏病新药产品管线，包括七个在研药物及一个已上市产品（美信罗®）。公司产品管线包括针对慢性肾病（CKD）及其并发症，如高磷血症，肾性贫血、IgA 肾病、糖尿病肾病、局灶阶段性肾小球硬化（FSGS）、常染色体显性多囊肾病（ADPKD）等的产品。礼邦医药已在扬州建成并

启用药物生产基地，以支持礼邦管线产品包括 AP301 未来的商业化。同时，礼邦亦搭建了肾科专科销售团队负责相关产品的中国商业化推广。