Alebund Pharmaceuticals Announces First Participant Randomized and Dosed in Global Phase IIb Multi-Regional Clinical Trial of AP306 for Hyperphosphatemia

SHANGHAI, China, July 21, 2026 — Alebund Pharmaceuticals (Jiangsu) Limited ("Alebund" or the "Company"; HKEX: 09637), a renal-focused biopharmaceutical company, today announced that the first participant has been randomized and dosed in the global Phase IIb multi-regional clinical trial of AP306 in patients with hyperphosphatemia receiving maintenance hemodialysis (NCT06712654). The trial is being conducted at multiple clinical sites in the United States and China and is co-sponsored by Alebund and R1 Therapeutics, Inc. ("R1").

AP306 (formerly known as EOS789) is a first-in-class oral pan-phosphate transporter inhibitor. AP306 was originally discovered and developed by Chugai Pharmaceutical Co., Ltd. ("Chugai") and was subsequently licensed to the Company, which has obtained the global rights to develop, manufacture and commercialize AP306. Unlike conventional phosphate binders that bind phosphate in the gut lumen, AP306 broadly inhibits three key intestinal phosphate transporters — NaPi-IIb, PiT-1 and PiT-2 — to reduce active intestinal phosphate transport, offering a differentiated approach to the management of hyperphosphatemia. The randomization and dosing of the first participant marks a new stage in the multicenter clinical execution of AP306's global development program in the United States and China.

Trial Design

The Phase IIb trial is a multicenter, randomized, double-blind, placebo-controlled study that plans to enroll approximately 168 participants with hyperphosphatemia receiving maintenance hemodialysis. Participants will be randomized across six fixed-dose AP306 regimens or placebo over an eight-week treatment period. The study is designed to evaluate the safety, tolerability and serum phosphate-lowering effect of fixed-dose AP306.

The primary endpoint is the change in serum phosphate from baseline to the end of treatment. Secondary endpoints include the proportion of participants reaching the target phosphate range and the time to phosphate control. Topline results are expected in the first half of 2027.

The trial has obtained approval from the Human Genetic Resources Administration of China (HGRAC). Peking University People's Hospital, the China leading site, was recently activated, and participant enrollment is in progress.

Unmet Medical Need

Hyperphosphatemia is a common and important complication in patients with chronic kidney disease (CKD) receiving dialysis, affecting approximately 95% of dialysis-dependent CKD patients. Persistently elevated serum phosphate is associated with vascular calcification, secondary hyperparathyroidism, renal osteodystrophy, and increased risks of cardiovascular events and all-cause mortality. [1-3] Regular dialysis and dietary phosphate restriction are often insufficient to control phosphate burden, meaning patients frequently require long-term pharmacological treatment. Even with the widespread use of phosphate binders, approximately 76% of dialysis patients in China still fail to achieve the target serum phosphate range of 3.5–5.5 mg/dL, which is significantly higher than that in the U.S. (approx. 52%) and Japan (approx. 39%). [4-5] The number of dialysis patients in China is expected to grow from approximately 1.3 million in 2025 to about 3.4 million by 2035 (a CAGR of approx. 10.1%), [6] representing a continuously expanding unmet medical need. Existing therapies still face challenges such as gastrointestinal tolerability, pill burden, and long-term adherence. Innovative treatment options that balance efficacy, tolerability, and convenience remain to be further developed.

Prior Phase II Study of AP306 in China

In a completed Phase II clinical trial in China (NCT05764590), AP306 monotherapy demonstrated a mean serum phosphate reduction from baseline of 2.51 mg/dL, compared with 1.08 mg/dL for the active comparator sevelamer carbonate. At Weeks 7 to 8, nearly 95% of patients in the AP306 group had serum phosphate levels below 5.5 mg/dL, compared with approximately 50% in the sevelamer carbonate group in the trial.

The most common adverse events were gastrointestinal disorders, mainly diarrhea; all diarrhea events were Grade 1 or 2 and mostly resolved within two weeks. No serious adverse event was reported in the AP306 group, and the discontinuation rate due to adverse events was below 5%. Results were published in Kidney International Reports. [7]

Based on AP306's innovative mechanism and clinical results, the National Medical Products Administration granted Breakthrough Therapy Designation to AP306 for the treatment of hyperphosphatemia in patients with chronic kidney disease in June 2024.

References

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Collaboration with R1

R1 is a clinical-stage biopharmaceutical company focused on developing first-in-class therapies for patients with kidney disease. In December 2025, Alebund and R1 entered into licensing and equity arrangements. Under the collaboration and license agreement forming part of these arrangements, Alebund granted R1 an exclusive license to develop, manufacture and commercialize AP306 outside Chinese Mainland, Hong Kong, Macau and Taiwan, while retaining full rights and control in those four markets. The parties are co-sponsors of the Phase IIb trial. Each party is responsible for clinical trial execution and regulatory submissions in its respective territory and provides the other party with relevant data and support required for regulatory purposes.

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 registrational Phase III trial 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.

礼邦医药宣布 AP306 全球多区域 IIb 期临床试验完成首例受试者随机入组并给药

中国·上海，2026 年 7 月 21 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，宣布其同类首创口服泛磷转运蛋白抑制剂 AP306 用于接受维持性血液透析的高磷血症患者的全球 IIb 期多区域临床试验（NCT06712654）已完成首例受试者随机入组并给药。该试验正在美国及中国的多个临床中心开展，由礼邦医药与 R1 Therapeutics, Inc.（“R1”）共同申办。

AP306 （前称 EOS789）是一款同类首创的口服泛磷转运蛋白抑制剂。 最初由中外制药股份有限公司（“日本中外制药”）发现，本公司获授权引进并取得其全球开发、生产及商业化权利。与主要结合肠道游离磷的传统磷结合剂不同，AP306 通过广泛抑制 NaPi-IIb、PiT-1 和 PiT-2 三种关键肠道磷转运蛋白，减少肠道对磷的主动转运，为高磷血症管理探索差异化治疗路径。首例受试者随机入组并给药，标志着 AP306 全球开发进入中美多中心临床实施的新阶段。

试验设计

该 IIb 期试验是一项多中心、随机、双盲、安慰剂对照研究，计划招募约 168 名接受维持性血液透析的高磷血症受试者，并将其随机分配至六个 AP306 固定剂量方案组或安慰剂组，治疗期为八周。研究旨在评估固定剂量 AP306 的安全性、耐受性及降低血清磷的效果。该试验主要终点为血清磷水平从基线至治疗结束时的变化，次要终点包括达到目标血磷范围的受试者比例及达到血磷控制的时间。该 IIb 期试验的顶线数据预计于 2027 年上半年公布。

该试验目前已获得中国人类遗传资源管理办公室（HGRAC）批准。中国牵头研究中心北京大学人民医院近期已完成启动，受试者招募正在进行中。

未被满足的临床需求

高磷血症是接受透析的慢性肾脏病患者常见且重要的并发症，约 95% 的透析依赖型慢性肾脏病患者受累。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。[1-3] 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；即便广泛使用磷结合剂，中国仍约有 76% 的透析患者血清磷水平未达到 3.5 ~ 5.5 mg/dL 的目标范围，明显高于美国（约 52%）与日本（约 39%）。[4-5] 中国透析患者规模在 2025 年约为 130 万人，预计 2035 年增至约 340 万人（复合年增长率约 10.1%），[6] 未被满足的临床需求持续扩大。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。

既往 AP306 中国 II 期临床研究

在已完成的中国 II 期临床试验（NCT05764590）中，AP306 单药治疗组的血清磷水平较基线平均降低 2.51 mg/dL，而试验中的阳性对照药碳酸司维拉姆组平均降低 1.08 mg/dL。用药第 7 至 8 周，AP306 组近 95% 的患者血清磷水平低于 5.5 mg/dL，试验中的碳酸司维拉姆组同期约 50% 的患者达到该水平。

该试验中最常见的不良事件为胃肠道症状，主要表现为腹泻；腹泻事件均为 1 至 2 级且多数于两周内缓解。AP306 组未见严重不良事件，因不良事件导致的停药率低于 5%。研究结果已于《Kidney International Reports》全文刊载。[7]

基于 AP306 的创新机制和临床结果，中国国家药品监督管理局于 2024 年 6 月授予其用于治疗慢性肾脏病患者高磷血症的突破性治疗药物认定。

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与 R1 的合作

R1 是一家临床阶段生物制药公司，专注于为肾脏疾病患者开发同类首创疗法。
2025 年 12 月，礼邦医药与 R1 订立许可及股权安排。根据其中的合作及许可协议，礼邦医药授予 R1 在中国内地、香港、澳门及台湾以外地区开发、生产及商业化 AP306 的独家许可，并保留 AP306 在上述四个地区的全部权利及控制权。双方为本项 IIb 期试验的共同申办方，各自负责其地区内的临床试验执行及监管申报，并向对方提供相关数据及监管所需的支持。

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 的中国注册性 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。