## Alebund Pharmaceuticals Announces FDA Clearance of IND Application for AP308 for the Treatment of IgA Nephropathy

SHANGHAI, China, September 8, 2026 — Alebund Pharmaceuticals (Jiangsu) Limited ("Alebund" or the "Company"; HKEX: 09637), a renal-focused biopharmaceutical company, today announced that it has recently received clearance from the U.S. Food and Drug Administration (FDA) of its Investigational New Drug (IND) application for AP308, a first-in-class engineered recombinant IgA protease. The Company plans to initiate a first-in-human clinical trial of AP308 in the near term.

The IND clearance marks the transition of the first-in-class new drug from preclinical research into clinical development.

**About AP308**

AP308 is a first-in-class engineered recombinant IgA protease aiming for the functional cure of IgAN. The drug is developed based on an IgA protease derived from Thomasclavelia ramosa, a human commensal bacterium, and can cleave IgA1, galactose-deficient IgA1 (Gd-IgA1), polymeric IgA and IgA immune complexes, and directly clears IgA immune complexes and complement C3 already deposited in the glomeruli; in preclinical studies, it acted within minutes without affecting other immunoglobulins such as IgG and IgM.[1]

In January 2022, Alebund worked together with Peking University First Hospital ("PUFH") on developing IgA proteases into potential IgAN treatment and entered into a license agreement with PUFH. The Company has since developed and nominated AP308 as a drug candidate using its proprietary Long-Acting Protease Engineering Platform. The platform displays excellent stability and developability, extends circulating half-life, reduces renal clearance, and lowers immunogenicity while preserving the protease's potent cleavage activity against IgA1, thereby enabling long-acting, low-frequency dosing. The Company holds the global rights to develop, manufacture, and commercialize AP308.

**IgA Nephropathy and Unmet Medical Need**

IgAN is the most common primary glomerulonephritis worldwide. It is characterized by the deposition of IgA-containing immune complexes in the glomeruli, which leads to inflammation and progressive kidney damage with a poor long-term prognosis. Long-term cohort studies in China and the United Kingdom show that, under current treatment strategies, median kidney survival is approximately 11 to 12 years and most patients progress to end-stage renal disease within 10 to 15 years of diagnosis, with approximately 60% of patients in the Chinese cohort reaching end-stage renal disease within 15 years.[2][3] According to China Insights Consultancy, there were approximately 9.5 million

IgAN patients globally in 2025, including approximately 5.1 million in China, more than half of the global total and the largest IgAN patient population in the world.[4] While existing and emerging therapies mainly target IgA production or downstream inflammation, strategies to directly clear IgA immune complexes already deposited in the kidney remain to be further explored.[1] By directly cleaving and clearing pathogenic IgA and IgA immune complexes already deposited in the glomeruli, AP308 has the potential to address this unmet medical need.

**Preclinical Data**

In a humanized mouse model of IgAN, once-weekly subcutaneous dosing of AP308 over an eight-week treatment period reduced circulating human IgA and IgA immune complexes by approximately 80% relative to controls; at the end of treatment, histological examination confirmed that glomerular IgA deposits were almost completely cleared, proteinuria decreased significantly, and kidney pathology improved markedly, while repeated dosing produced no signals of liver or kidney toxicity and no significant increase in anti-drug antibody titers. In a separate paired pre- and post-treatment design, a single dose completely cleared pre-existing chronic glomerular IgA and complement C3 deposits within seven days. These preclinical results were published in May 2026 in Kidney International, the official journal of the International Society of Nephrology.[1]

**References**

[1] Shen X, Shu C, Dong Y, et al. Therapeutic efficacy and antigenicity of a novel PEGylated IgA protease in preclinical models of IgA nephropathy. Kidney Int. 2026;110(2):463–476. doi:10.1016/j.kint.2026.04.020.

[2] Shen X, Chen P, Liu M, et al. Long-term outcomes of IgA nephropathy in China. Nephrol Dial Transplant. 2025;40(6):1137–1146.

[3] Pitcher D, Braddon F, Hendry B, et al. Long-term outcomes in IgA nephropathy. Clin J Am Soc Nephrol. 2023;18(6):727–738.

[4] China Insights Consultancy (CIC).

**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 (China pivotal Phase III trial completed, NDA

accepted for review by the NMPA, global MRCT ongoing), AP306 (Phase II) and AP303 (Phase I), and the IND application for AP308 has also been cleared by the U.S. FDA. 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 AP308 治疗 IgA 肾病的新药临床试验申请获美国 FDA 批准

上海，2026 年 9 月 8 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，AP308（一款同类首创的工程化重组 IgA 蛋白酶）用于治疗 IgA 肾病的新药临床试验（IND）申请近日获美国食品药品监督管理局（FDA）批准，公司计划于近期启动 AP308 的首次人体临床试验。

AP308 的 IND 获批标志着这一首创新药由临床前研究迈入临床开发阶段。

**关于 AP308**

AP308 是一款旨在实现 IgA 肾病功能性治愈的同类首创工程化重组 IgA 蛋白酶。该药物基于源自人体共生菌 Thomasclavelia ramosa 的 IgA 蛋白酶开发，可切割 IgA1、半乳糖缺陷型 IgA1（Gd-IgA1）、多聚 IgA 及 IgA 免疫复合物，并可直接清除于肾小球的 IgA 免疫复合物及补体 C3 沉积；在临床前研究中可于数分钟内起效，且不影响 IgG、IgM 等其他免疫球蛋白。[1]

2022 年 1 月，礼邦医药与北京大学第一医院（"北大医院"）就相关 IgA 蛋白酶开发为 IgA 肾病潜在疗法展开合作，并与北大医院订立授权协议。公司其后依托自主研发的长效蛋白酶工程平台开发并确定 AP308 为候选药物。该平台具有优异的稳定性及成药性，并可在保留蛋白酶对 IgA1 高效切割活性的同时，显著延长药物体内半衰期、降低肾脏清除并减弱免疫原性，为长效、低频次给药奠定基础。公司持有 AP308 的全球开发、生产及商业化权利。

**IgA 肾病与未被满足的临床需求**

gA 肾病是全球最常见的原发性肾小球肾炎，以含 IgA 的免疫复合物沉积于肾小球为特征，可引致炎症及进行性肾脏损伤，长期预后不佳。中国及英国的长期队列研究显示，在现行治疗策略下，患者中位肾存活期约 11 至 12 年，大多数患者于确诊后 10 至 15 年内进展至终末期肾病，中国队列中 60%的患者于确诊后 15 年内进展至终末期肾病。[2][3] 根据灼识咨询的资料，2025 年全球 IgA 肾病患者约 950 万人，其中中国约 510 万人，占全球逾半，为全球最大的 IgA 肾病患者群体。[4] 现有及在研疗法多着眼于减少致病性 IgA 的生成或应对下游炎症，直接清除已沉积于肾脏的 IgA 免疫复合物的治疗策略仍有待进一步探索。[1] AP308 通过直接切割并清除已沉积于肾小球的致病性 IgA 及 IgA 免疫复合物，有望应对这一未被满足的临床需求。

**临床前研究数据**

在人源化 IgA 肾病小鼠模型中，以每周一次皮下给药持续八周后，AP308 使循环中人源 IgA 及 IgA 免疫复合物水平较对照组降低约 80%；治疗结束时，组织学检查显示肾小球 IgA 沉积近乎完全清除，蛋白尿显著下降，肾脏病理显著改善，重复给药未见肝肾毒性信号，抗药抗体滴度亦无显著升高。在另一项治疗前后配对设计中，单次给药后七天内即完全清除已形成的肾小球 IgA 及补体 C3 沉积。上述临床前研究结果已于 2026 年 5 月在国际肾脏病学会（ISN）官方期刊《Kidney International》全文刊载。[1]

**参考文献**

[1] Shen X, Shu C, Dong Y, et al. Therapeutic efficacy and antigenicity of a novel PEGylated IgA protease in preclinical models of IgA nephropathy. Kidney Int. 2026;110(2):463–476. doi:10.1016/j.kint.2026.04.020.

[2] Shen X, Chen P, Liu M, et al. Long-term outcomes of IgA nephropathy in China. Nephrol Dial Transplant. 2025;40(6):1137–1146.

[3] Pitcher D, Braddon F, Hendry B, et al. Long-term outcomes in IgA nephropathy. Clin J Am Soc Nephrol. 2023;18(6):727–738.

[4] 灼识咨询（CIC）资料

**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，AP308 的新药临床试验申请亦已获美国 FDA 批准；其中 AP301 的中国关键性 III 期临床试验已完成，新药上市申请已获国家药品监督管理局受理，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。