

Alebund doses first participant in global Phase IIb AP306 trial

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The study is evaluating AP306, a first-in-class oral pan-phosphate transporter inhibitor, in hyperphosphatemia patients receiving maintenance haemodialysis.



Alebund Pharmaceuticals has randomised and dosed the first participant in its global Phase IIb multi-regional clinical trial of AP306 for hyperphosphatemia in patients receiving maintenance haemodialysis.

The trial is being conducted at multiple clinical sites in the United States and China. It is co-sponsored by Alebund and R1 Therapeutics.

AP306, formerly known as EOS789, is a first-in-class oral pan-phosphate transporter inhibitor. The compound was originally discovered and developed by Chugai Pharmaceutical, and Alebund later obtained global rights to develop, manufacture and commercialise the candidate.

The therapy is designed to reduce active intestinal phosphate transport by broadly inhibiting three key intestinal phosphate transporters: NaPi-IIb, PiT-1 and PiT-2. This differs from conventional phosphate binders, which act by binding phosphate in the gut lumen.

The Phase IIb trial is a multicentre, randomised, double-blind, placebo-controlled study. It plans to enrol approximately 168 participants with hyperphosphatemia receiving maintenance haemodialysis. Participants will receive one of six fixed-dose AP306 regimens or placebo over an eight-week treatment period.

The primary endpoint is 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.

Hyperphosphatemia is a common complication in patients with chronic kidney disease receiving dialysis. Alebund noted that it affects approximately 95 per cent of dialysis-dependent CKD patients and is associated with vascular calcification, secondary hyperparathyroidism, renal osteodystrophy and increased cardiovascular and mortality risk.

Even with phosphate binders, approximately 76 per cent of dialysis patients in China fail to reach the target serum phosphate range of 3.5 to 5.5 mg/dL, compared with approximately 52 per cent in the United States and 39 per cent in Japan.

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

Alebund said the most common adverse events were gastrointestinal disorders, mainly diarrhoea. All diarrhoea events were Grade 1 or 2 and mostly resolved within two weeks. No serious adverse event was reported in the AP306 group, and discontinuation due to adverse events was below 5 per cent.

The trial has obtained approval from the Human Genetic Resources Administration of China. Peking University People's Hospital, the China leading site, has also been activated, with participant enrolment in progress.