

Alebund receives FDA clearance to advance first-in-class AP308 into IgA nephropathy trial

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The engineered recombinant IgA protease is designed to directly clear pathogenic IgA and immune complexes already deposited in the kidney.



Alebund Pharmaceuticals has received clearance from the US Food and Drug Administration for the Investigational New Drug application of AP308, a first-in-class engineered recombinant IgA protease being developed for IgA nephropathy.

The clearance moves AP308 from preclinical research into clinical development, with Alebund planning to initiate the study in the near term.

AP308 is designed to directly cleave and clear pathogenic IgA and IgA immune complexes associated with IgA nephropathy.

The therapy is based on an IgA protease derived from *Thomasclavelia ramosa*, a human commensal bacterium.

According to Alebund, the engineered protease can cleave IgA1, galactose-deficient IgA1, polymeric IgA and IgA immune complexes while also clearing complement C3 already deposited in the glomeruli.

Preclinical studies indicated that AP308 could act within minutes without affecting other immunoglobulins including IgG and IgM.

IgA nephropathy is characterised by the accumulation of IgA-containing immune complexes in the kidneys, leading to inflammation and progressive renal damage.

Alebund estimates that approximately 9.5 million people were living with IgA nephropathy globally in 2025, including around 5.1 million in China.

While existing and emerging therapies often target upstream IgA production or downstream inflammatory pathways, the company is developing AP308 to directly remove pathogenic deposits already present in the kidney.

In a humanised mouse model, once-weekly subcutaneous dosing over eight weeks reduced circulating human IgA and IgA immune complexes by approximately 80% compared with controls.

Histological analysis at the end of treatment showed that glomerular IgA deposits were almost completely cleared, while proteinuria and kidney pathology improved.

A separate preclinical experiment found that a single AP308 dose completely cleared pre-existing glomerular IgA and complement C3 deposits within seven days.

The preclinical findings were published in *Kidney International* in May 2026.

The programme adds to Alebund's renal-focused pipeline, which includes clinical-stage candidates targeting complications and diseases including chronic kidney disease, renal anaemia, hyperphosphatemia and IgA nephropathy.

AP308's entry into clinical development also broadens Alebund's international development activities as the company builds an integrated nephrology portfolio spanning research, manufacturing and commercialisation.