

Alebund advances renal pipeline as AP301 enters China regulatory review

August 28, 2026 | News

The renal-focused biopharma has completed enrolment in the global Phase III RESPOND-2 study and secured NMPA acceptance of the AP301 New Drug Application.



Alebund Pharmaceuticals has reported progress across its renal disease portfolio, including completion of enrolment in a global Phase III study of AP301 and acceptance of the candidate's New Drug Application in China.

AP301 is one of the company's lead clinical programmes and is being evaluated through the RESPOND-2 pivotal multi-regional clinical trial.

The study, conducted in China and the United States, completed patient enrolment in May 2026.

China's National Medical Products Administration has also accepted the AP301 New Drug Application for review.

The milestones form part of a broader period of clinical, regulatory and commercial development for the renal-focused biopharmaceutical company.

Alebund is building a portfolio targeting unmet needs associated with chronic kidney disease and related complications.

During the first half of 2026, the company continued to progress clinical programmes while expanding external collaborations and preparing its commercial infrastructure in China.

The company said its development strategy is centred on translating late-stage renal therapies into commercial products while continuing to build earlier-stage programmes.

Completion of RESPOND-2 enrolment is particularly significant because the trial provides the pivotal evidence base intended to support regulatory assessment of AP301.

The NMPA's acceptance of the NDA moves the programme into formal regulatory review in China.

Alebund will continue advancing its pipeline as it seeks to establish an integrated renal therapeutics business spanning clinical development and commercialisation.