

BDB-001 Phase III Trial in ANCA-Associated Vasculitis

NCT07168161

Status	RECRUITING
Phase	Phase 3
Sponsor	Staidson (Beijing) Biopharmaceuticals Co., Ltd
Enrollment	300 participants

Key Eligibility Criteria

Inclusion (6)

- years olddAged75 years old, male or female;
- Diagnosis of granulomatosis with polyangiitis(GPA) or microscopic polyangiitis(MPA)
- Newly diagnosed or relapsed GPA or MPA that requires treatment with a full starting dose of prednisone plus cyclophosphamide/azathioprine or rituximab
- Positive test for anti-proteinase 3(PR3) or anti-myeloperoxidase (MPO)
- Estimated glomerular filtration rate e15 mL/minute/1.73 m²

... and 1 more (see full listing online)

Exclusion (11)

- Active tuberculosis infection;
- alveolar hemorrhage requiring pulmonary ventilation support
- Any other known multi-system autoimmune disease including eosinophilic granulomatosis with polyangiitis (Churg-Strauss), systemic lupus erythematosus, IgA vasculitis (Henoch-Schönlein), rheumatoid vasculitis,anti-glomerular basement membrane disease, or cryoglobulinemic vasculitis
- HBsAg positive,or HBcAb positive and HBV-DNA positive
- Received CYC within 3 months before the first administration or Received rituximab(RTX) within 12 months before the first administration

... and 6 more (see full listing online)

Locations (50 total)

Peking Union Medical College Hospital, Beijing, Beijing Municipality, China

Peking University People's Hospital, Beijing, Beijing Municipality, China

Peking University Third Hospital, Beijing, Beijing Municipality, China

... and 47 more locations