

A Phase III Clinical Study to Evaluate the Efficacy, Safety, and Tolerability of Plonmarlimab in Subjects With Relapsed/Refractory Rheumatic and Immunologic Disease-associated Haemophagocytic Lymphohistiocytosis (Also Known as Macrophage Activation Syndrome [MAS])

NCT07208058

Status	RECRUITING
Phase	Phase 3
Sponsor	TJ Biopharma Co., Ltd.
Enrollment	30 participants

Key Eligibility Criteria

Inclusion (5)

- Age: 16 to 80 years (inclusive), of any gender.
- The subject is willing to participate in this study and voluntarily signs the informed consent form. For minor subjects aged 16 years (inclusive) to less than 18 years, written informed consent must be signed by both the subject and the subject's legal guardian.
- Diagnosed with a rheumatic and immunological disease.
- Diagnosed with haemophagocytic lymphohistiocytosis (HLH) according to the HLH-2004 diagnostic criteria (excluding molecular diagnosis)
- No response to/or dependence on/intolerance to/or worsening during high-dose corticosteroid therapy. High-dose corticosteroid therapy: at least 1.5-2.0 mg/kg/d of prednisone or its equivalent dose for 3 consecutive days, including methylprednisolone pulse therapy (15-30 mg/kg/d, maximum dose 1 g/d, for 3-5 days).

Exclusion (17)

- Confirmed or suspected primary haemophagocytic lymphohistiocytosis (pHLH).
 - HLH induced by infection (including but not limited to EBV-HLH) or treatment (including but not limited to drugs such as CAR-T cells, TCEs, ADCs).
 - History of other active neoplasm malignant within 5 years prior to screening, with the exception of successfully treated cutaneous basal cell or squamous cell carcinoma, or localised neoplasms that have been adequately treated with curative intent, including but not limited to, uterine carcinoma in situ, breast cancer in situ, thyroid cancer, etc.; asymptomatic, localised prostate cancer confirmed to have no metastasis and not requiring treatment, etc. Prior to receiving the investigational drug, an assessment by an oncology specialist is required to clarify the current status of the neoplasm malignant and to rule out the possibility of HLH secondary to the neoplasm malignant.
 - History of allergy to any component of the investigational drug.
 - Lung disorder: including but not limited to asthma, chronic obstructive pulmonary disease, interstitial lung disease, alveolar proteinosis, pulmonary granulomatosis, etc., and abnormal pulmonary function tests: forced vital capacity (FVC) \leq 80% of predicted value, or FEV1/FVC \leq 70%, etc.; or the investigator's comprehensive assessment concludes that the subject has a pre-existing lung disease that significantly affects pulmonary function and is unsuitable for participation in this clinical study.
- ... and 12 more (see full listing online)

Locations (15 total)

Beijing Friendship Hospital, Capital Medical University, Beijing, Beijing Municipality, China
Peking Union Medical College Hospital, Chinese Academy of Medical Sciences, Beijing, Beijing Municipality, China
Peking University People's Hospital, Beijing, Beijing Municipality, China
... and 12 more locations

<https://clinicaltrials.gov/study/NCT07208058>

DISCLAIMER: This document is for informational purposes only and does not constitute medical advice. Always consult your healthcare provider before enrolling in any clinical trial. Information may not be up to date — verify details at [ClinicalTrials.gov](https://clinicaltrials.gov). Generated by [ClinicalTrialsFinder.org](https://clinicaltrialsfinder.org).