

A Clinical Study of YTS109 Cell in R/R Systemic Lupus Erythematosus

NCT06943937

Status	RECRUITING
Phase	Phase 1
Sponsor	China Immunotech (Beijing) Biotechnology Co., Ltd.
Enrollment	36 participants

Key Eligibility Criteria

Inclusion (14)

- Age ranges from 18 to 65 years old (including threshold), regardless of gender.
- Meet the EULAR/ACR 2019 SLE Classification Criteria:
- Cohort 1: Refractory Lupus Nephritis: Defined as failure to achieve remission after treatment with corticosteroids and e2 immunosuppressants (e.g., CTX, tacrolimus, MMF, cyclosporine) and/or biologics, with urine protein/creatinine ratio (UPCR e1.0 g/g) , and renal pathology requirement scriteria: ISN/RPS 2003 Class III/IV proliferative lupus nephritis (or combined with type V features) , with d50% glomerulosclerosis.
- Cohort 2: Refractory Immune Thrombocytopenia: Requires treatment failure with: Failed treatment with at least 1 course of MP shock (1g for 3 days) or high- dose glucocorticosteroids (1mg/kg/d equivalent dose of glucocorticosteroids) in combination with 1 or more immunosuppressive agents. At least 2 consecutive routine blood tests for platelets less than $50 \times 10^9/L$ and $>30 \times 10^9/L$ were performed prior to enrolment. other non-SLE causes of thrombocytopenia, such as infections, myelosuppression and hypersplenism, were excluded.
- \. Essential Organ Function Criteria:
... and 9 more (see full listing online)

Exclusion (14)

- Severe drug allergies or hypersensitivity.
- Uncontrolled/untreated infections (fungal, bacterial, viral, etc.).
- CNS disorders (exceptions: epilepsy, psychosis, organic brain syndrome, cerebrovascular accident, encephalitis, CNS vasculitis).
- Heart failure intolerance.
- Congenital immunoglobulin deficiency.
... and 9 more (see full listing online)

Locations (1 total)

Beijing GoBroad Hospital, Beijing, Beijing Municipality, China

<https://clinicaltrials.gov/study/NCT06943937>

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