

# CAR T-cell Therapy Targeting CD19 and BCMA(QT-019C) in Patients With Relapse/Refractory Autoimmune Diseases

NCT07315087

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Status	RECRUITING
Phase	Phase 1
Sponsor	Institute of Hematology & Blood Diseases Hospital, China
Enrollment	12 participants

## Key Eligibility Criteria

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### Inclusion (31)

- Age e 18 years old (inclusive), regardless of gender.
- Functional requirements for major organs are as follows Except for abnormalities related to autoimmune disease activity : 1) Bone marrow function must meet: A. Neutrophil count e  $1 \times 10^9/L$  (no colony-stimulating factor treatment within 2 weeks before examination); B. Hemoglobin e 60g/L; 2) Liver function: Alanine aminotransferase (ALT) d  $3 \times ULN$  (excluding ALT elevation due to inflammatory myopathy), aspartate aminotransferase (AST)d $3 \times$ Upper limit of normal (ULN) (excluding AST elevation due to inflammatory myopathy), TBILd $2 \times ULN$  (or d  $3.0 \times ULN$  for subjects with Gilbert syndrome); 3) Renal function: creatinine clearance rate (CrCl) e 30mL/minute (calculated by Cockcroft/Gault formula, acute CrCl decrease due to the target disease is excluded; LN is excluded).
- Female subjects of childbearing potential and male subjects with partners of childbearing potential must use medically approved contraception or abstinence during the study treatment period and for at least 6 months after the end of the study treatment; Female subjects of childbearing potential must have a negative human chorionic gonadotropin (hCG) test within 7 days before study enrollment and not be lactating.
- Willing to participate in this clinical study, sign an informed consent form, have good compliance, and cooperate with follow-up.
- Refractory/Relapsed Systemic Lupus Erythematosus:  
... and 26 more (see full listing online)

### Exclusion (13)

- Subjects with a history of severe drug allergies or allergic tendencies.
- Presence or suspicion of uncontrolled or treatment-required fungal, bacterial, viral, or other infections.
- Subjects with central nervous system diseases caused by autoimmune diseases or non-autoimmune diseases (including epilepsy, psychosis, organic brain syndrome, cerebral vascular accidents, encephalitis, central nervous system vasculitis).
- Subjects with insufficient cardiac function.
- Subjects with congenital immunoglobulin deficiencies.  
... and 8 more (see full listing online)

## Locations (1 total)

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Institute of Hematology & Blood Diseases Hospital, Tianjin, China