

# Anti CD19/BCMA CAR Gene Therapy for Relapsed/Refractory Immune Thrombocytopenia

NCT06973356

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Status	RECRUITING
Phase	Not Applicable
Sponsor	Anhui Provincial Hospital
Enrollment	18 participants

## Key Eligibility Criteria

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### Inclusion (3)

- 1. Age ≥ 18 years old, regardless of gender.
- 2. Clinical diagnosis of primary immune thrombocytopenia for at least 6 months, platelet count  $< 30 \times 10^9/L$  within 48 hours before participating in the study.
- 3. Positive anti-platelet glycoprotein autoantibodies (such as GPIIb/IIIa).
- 4. Prior second-line ITP therapy (first-line treatment includes: corticosteroids or immunoglobulins; Second-line therapies include thrombopoietin receptor agonists (eg, eltrombopag, romiplostim) and/or rituximab, but are ineffective (platelet count  $< 30 \times 10^9/L$  after treatment, or platelet count does not increase twice as much as baseline, or there is bleeding), or relapse after effective treatment (platelet count falls below  $30 \times 10^9/L$  after effective treatment, or falls below baseline, or bleeding symptoms) or is difficult to maintain after discontinuation of TPO agonists.
- 5. Bone marrow examination shows megakaryocytosis or normal.
- 6. Basic normal functions of important organs: Echocardiography shows an ejection fraction of  $\geq 50\%$  and no significant abnormalities on ECG. Creatinine clearance (CrCl) (Cockcroft-Gault formula)  $\geq 30$  mL/min. Alanine aminotransferase (ALT) and aspartate aminotransferase (AST)  $\leq 3.0 \times$  upper limit of normal (ULN). Total bilirubin (TBIL) and alkaline phosphatase (AKP or ALP)  $\leq 2.0 \times$  ULN (Gilbert's syndrome  $\leq 3.0 \times$  ULN). Absolute lymphocyte count (ALC)  $\geq 0.5 \times 10^9/L$ ; Absolute neutrophil count (ANC)  $\geq 1 \times 10^9/L$ ; Hemoglobin (Hb)  $\geq 60$  g/L; Platelet count  $\geq 10 \times 10^9/L$ . Oxygen saturation  $\geq 92\%$ . ECOG performance status  $\leq 2$ .
- 7. Males and women of childbearing potential must agree to use effective contraception from the time of signing the informed consent form until 1 year after the use of the study drug. Women of childbearing potential must have a negative blood pregnancy test at screening and prior to drug infusion and must not be breastfeeding.

### Exclusion (9)

- 1. Thrombocytopenia caused by myelodysplastic syndrome, early aplastic anemia, atypical aplastic anemia, thrombotic thrombocytopenic purpura, etc.
- 2. During the screening period, bone marrow examination showed myelofibrosis MFe2 (European consensus scoring standard Thieleja 2005) or bone marrow examination showed the presence of a primary disease other than ITP that can lead to thrombocytopenia.
- 3. History of hypersensitivity to any component of the therapeutic medication.
- 4. Major organs: NYHA class III to IV congestive heart failure. Myocardial infarction or coronary artery bypass grafting (CABG) or coronary artery stent implantation within 6 months. Ventricular arrhythmias, or history of unexplained syncope (excluding vasovagal syncope or dehydration). History of severe non-ischemic cardiomyopathy.
- 5. Malignant disease within 3 years prior to screening, except for the following: malignant disease that has been curatively treated before enrollment and has no known active disease for 3 years; or well-treated non-melanoma skin cancer with no evidence of disease.
- 6. Symptomatic deep vein thrombosis or pulmonary embolism within the past 6 months or currently requiring anticoagulation.
- ... and 4 more (see full listing online)

## Locations (1 total)

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Hunan Siweikang Therapeutic Co.Ltd, Changsha, Hunan, China

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<https://clinicaltrials.gov/study/NCT06973356>

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