

An Exploratory Study of CD19/CD22/BCMA CAR-T Cells (BZE2204) in Subjects With Relapsed or Refractory Autoimmune Diseases

NCT07174843

Status	RECRUITING
Phase	Early Phase 1
Sponsor	Shanghai Cell Therapy Group Co.,Ltd
Enrollment	20 participants

Key Eligibility Criteria

Inclusion (29)

- Males or females, aged 18-70 years old
 - Adequate bone marrow, hepatic, renal, coagulation and pulmonary function defined as:
 - Bone marrow reservation: absolute neutrophil count (ANC) $\geq 1 \times 10^9/L$; absolute lymphocyte count (ALC) $\geq 0.5 \times 10^9/L$; hemoglobin ≥ 80 g/L; platelets $\geq 50 \times 10^9/L$ (except for ITP);
 - Hepatic function: i: Serum alanine aminotransferase (ALT)/aspartate aminotransferase (AST) ≤ 5 upper limit of normal (ULN) (except for elevations are evaluated to be related to autoimmune disease by investigators) and ii: total bilirubin ≤ 2 ULN, (except for Gilbert's syndrome patients, those with total bilirubin ≤ 3 ULN and direct bilirubin ≤ 1.5 ULN can be enrolled).
 - Renal function: serum creatinine ≤ 1.5 ULN, or estimated glomerular filtration rate (eGFR) ≥ 60 mL/min/1.73m² [eGFR = $186 \times \text{age}^{-0.203} \times \text{SCr}^{-1.154}$ mg/dl, female $\times 0.742$]
- ... and 24 more (see full listing online)

Exclusion (21)

- A history of severe hypersensitivity or allergic reactions, or contraindications or hypersensitivity to any component of the investigational drug
 - Presence of any serious heart diseases defined in the protocol
 - A medical history of severe central nervous system or symptoms within 6 months
 - Any concurrent malignancy or a history of malignancy with exceptions indicated in the protocol
 - Clinically significant hemorrhage symptoms or definite bleeding tendencies (except for events caused by ITP) within 6 months prior to screening; arteriovenous thrombosis events within 6 months prior to screening
- ... and 16 more (see full listing online)

Locations (1 total)

Shanghai Mengchao Cancer Hospital, Shanghai, Shanghai Municipality, China