IL-5 CAR-T Cell Therapy for Refractory/Relapsed Eosinophilic Leukemia

NCT07257640

Status	RECRUITING
Phase	Phase 1
Sponsor	Zhejiang University
Enrollment	20 participants

Plain Language Summary

This study tests a new cell therapy called IL-5 CAR-T cells — immune cells that have been re-engineered to specifically attack a protein (IL-5 receptor) found on abnormal white blood cells — in patients with eosinophilic leukemia (a rare blood cancer involving abnormally elevated eosinophils) that has not responded to standard treatments.

You may be eligible if...
- You are 18 or older
- You have been diagnosed with eosinophilic leukemia per current diagnostic criteria
- The IL-5 receptor (CD125) is expressed on at least 50% of your leukemic cells
- Your disease has not responded to or relapsed after prior treatments

You may NOT be eligible if...
- You do not have sufficient expression of the target protein on your cancer cells
- You have significant organ damage from leukemia or other causes
- You have active serious infections or autoimmune conditions

Talk to your doctor to see if this trial is right for you.

Key Eligibility Criteria

Inclusion (13)

- • Male or female patients aged e18 years;
- • Diagnosis of eosinophilic leukemia (EL) established according to the WHO 2022 diagnostic criteria;
- • Interleukin-5 receptor ±IL-5R±ÇCD125) is expressed on e50% of leukemic blasts.
- • Meet any of the following criteria for refractory/relapsed eosinophilic leukemia:
- • a) Inadequate response to standard therapy: failure to achieve complete remission (CR) after standard treatments (e.g., imatinib, corticosteroids, interferon-±çhemotherapy, etc.);

... and 8 more (see full listing online)

Exclusion (5)

- • History of epilepsy or other central nervous system (CNS) disorders;
- • Presence of any of the following:Hepatitis B surface antigen (HBsAg)-positive; Any of HBeAg, HBeAb, or HBcAb positive and detectable hepatitis B virus (HBV) DNA in peripheral blood above the lower limit of detection; Hepatitis C virus (HCV) antibody-positive; Human immunodeficiency virus (HIV) antibody-positive; Positive serologic test for syphilis;
- • History of QT interval prolongation or severe cardiac disease;
- • Presence of uncontrolled active infection;
- • Any condition that, in the opinion of the investigator, may increase the risk to the subject or interfere with the interpretation of the study results.

Locations (1 total)

The first affiliated hospital of medical college of zhejiang university, Hangzhou, Zhejiang, China