T Cell Receptor Gene-Engineered T Cell Therapy Targeting KRAS Mutations in the Treatment of Subjects With Advanced Solid Tumor

NCT06478251

Status	RECRUITING
Phase	Phase 1
Sponsor	TingBo Liang
Enrollment	9 participants

Key Eligibility Criteria

Inclusion (7)

- Age between 18-75 years
- Diagnosis of pathologically or histologically confirmed unresectable or advanced solid tumor, and have no standard treatment options available or unable to tolerate the currently available standard treatments
- HLA-A*11:01positive
- Tumor has KRAS G12V (NW-301V cohort) or G12D (NW-301D cohort) mutation
- Adequate organ function prior to apheresis and lymphodepleting chemotherapy

... and 2 more (see full listing online)

Exclusion (8)

- Received the following treatments: Cytotoxic chemotherapy within 2 weeks prior to apheresis and within 1 week prior to lymphodepletion; Treatment with antibodies (including but not limited to those with monoclonal antibodies and immune checkpoint inhibitors) or other biologic therapy within 2 weeks prior to apheresis and within 1 week prior to lymphodepletion; Immunosuppressive agents (e.g., calcineurin inhibitors, methotrexate or other chemotherapeutic agents, mycophenolate mofetil, rapamycin, thalidomide, immunosuppressive antibodies such as anti-TNF, anti-IL-6, or anti-IL-6 receptor) within 2 weeks prior to apheresis and within 1 week prior to lymphodepletion
- History of allergic reactions to cyclophosphamide, fludarabine, or any other chemical or biological components of the drugs used in this study
- History of chronic or recurrent severe autoimmune disease, or active immune disease requiring treatment with steroids or other immunosuppressive agents within 1 year prior to enrollment
- Have symptomic CNS metastases
- Have leptomeningeal disease or carcinomatous meningitis

... and 3 more (see full listing online)

Locations (1 total)

The First Affiliated Hospital of Zhejiang University school of Medicine, Hangzhou, Zhejiang, China