

An Open-Label, Phase I Clinical Trial of Super CAR-T With GPC3-Positive Advanced Hepatocellular Carcinoma

NCT07493044

Status	RECRUITING
Phase	Phase 1
Sponsor	Guangzhou FinelImmune Biotechnology Co., LTD.
Enrollment	15 participants

Key Eligibility Criteria

Inclusion (13)

- Understand and voluntarily sign the informed consent form prior to participating in any trial-related activities;
- Be between 18 and 75 years of age; gender is not restricted;
- Diagnosed with hepatocellular carcinoma (HCC) based on histopathological or cytological examination: Patients classified as inoperable Stage IIa, IIb, IIIa, or IIIb according to the Chinese National Liver Cancer (CNLC) staging system, or Stage C according to the Barcelona Clinic Liver Cancer (BCLC) staging system, or Stage B patients who are inoperable or unsuitable for local treatment; Child-Pugh liver function score ≤ 7 ;
- Previous failure of or intolerance to at least two lines of standard systemic therapy;
- The subject must provide a tumor sample or biopsy specimen collected within the past 2 years that meets the requirements and tests positive for GPC3 expression via immunohistochemistry;
- ... and 8 more (see full listing online)

Exclusion (12)

- The subject has undergone major surgery within 2 weeks prior to apheresis, or is expected to undergo major surgery during the trial;
- The subject is allergic to any component of the drugs to be used in this study, including but not limited to cyclophosphamide, fludarabine, CAR-T products, or their excipients;
- Has not recovered from adverse reactions related to prior surgery or treatment to Grade ≥ 2 ; exceptions include alopecia, hyperpigmentation, and other conditions deemed by the investigator not to affect the subject's tolerability;
- Has a clinically significant central nervous system (CNS) disorder (e.g., epilepsy, severe cerebrovascular stenosis) or other diseases presenting with significant neurological symptoms (including psychiatric disorders);
- Received radiotherapy, systemic chemotherapy, or immune checkpoint inhibitors for the study disease within 2 weeks prior to apheresis; or received small-molecule targeted therapies such as sorafenib, regorafenib, or lenvatinib within 1 week prior to apheresis;
- ... and 7 more (see full listing online)

Locations (1 total)

Sun Yat-sen University Cancer Center, Guangzhou, Guangdong, China

<https://clinicaltrials.gov/study/NCT07493044>

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