Safety and Tolerability of CMAB017 In Patients With Advanced Solid Tumors

NCT06933069

Status	RECRUITING
Phase	Phase 1
Sponsor	Taizhou Mabtech Pharmaceutical Co.,Ltd
Enrollment	55 participants

Key Eligibility Criteria

Inclusion (10)

- fully understand and agree to sign the Informed Consent Form (ICF);
- histologically or cytologically confirmed, inoperable, locally advanced, recurrent or metastatic malignant solid tumors, including but not limited to head and neck squamous carcinoma, RAS wild-type colorectal cancer, esophageal squamous carcinoma, etc., for which the patient has failed standard treatment, does not have standard treatment, or refuses standard treatment;
- age 18\~75 years old, gender is not limited;
- Eastern Cooperative Oncology Group (ECOG) score d1;
- expected survival e 3 months;

... and 5 more (see full listing online)

Exclusion (23)

- With known active CNS metastases and/or carcinomatous meningitis. Subjects with previously treated brain metastases may be enrolled in the study provided that they have been clinically stable for at least 2 weeks, have no evidence of new or expanding brain metastases, and have discontinued steroids within 2 weeks prior to the infusion of the trial drug. Stability of brain metastases should be determined prior to the first dose of the trial drug infusion. Patients with asymptomatic brain metastases (i.e., no neurologic symptoms, no need for medication, and no lesion with a longest diameter \>1.5 cm) may be enrolled, but will be required to undergo periodic imaging;
- subjects with grade e2 corneal abnormalities present at screening;
- adverse effects of prior antineoplastic therapy that have not recovered to a CTCAE 5.0 grade rating of d grade 1 or to the level specified in the entry criteria (except for toxicities judged by the investigator to be of no safety risk, e.g., alopecia, grade 2 peripheral neurotoxicity, and hypothyroidism stabilized by hormone replacement therapy)
- other malignancies within the previous 5 years, usually with the exception of the following: a. any other aggressive malignancy (for which the subject has had adequate treatment) for which disease-free status has persisted for \>3 years and which, in the investigator's assessment, would not interfere with the assessment of oncologic efficacy; and b. cured basal cell or squamous cell skin cancers, superficial bladder cancers, and locally curable cancers such as prostate, cervical, or breast cancer in situ;
- a history of immunodeficiency, including a positive HIV antibody test, or other acquired or congenital immunodeficiency disease, or a history of organ transplantation

... and 18 more (see full listing online)

Locations (1 total)

Shanghai East Hospital, Shanghai, China