A Phase I First-in-Human Study of GenSci128 in Patients With Solid Tumors Harboring a TP53 Y220C Mutation

NCT06908434

Status	RECRUITING
Phase	Phase 1
Sponsor	Changchun GeneScience Pharmaceutical Co., Ltd.
Enrollment	82 participants

Key Eligibility Criteria

Inclusion (7)

- Has the ability to understand and the willingness to sign a written informed consent document (prior to the initiation dose of GenSci128 and any study procedures)
- Is willing and able to comply with the scheduled visits, treatment plan, laboratory tests and other specified study procedures
- Has confirmed TP53 Y220C mutation in tumor tissue
- Has histologically or cytologically confirmed locally advanced or metastatic solid tumors and have progressed following standard therapy, or for whom, in the opinion of the investigator, no available and effective standard therapy exists.
- Has at least one measurable lesion by RECIST v1.1

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

Exclusion (12)

- Has diagnosed as primary central nervous system (CNS) tumor.
- Has CNS metastases, unless asymptomatic, neurologically stable and not requiring steroids treatment for at least 2 weeks prior to initiation dose of GenSci128.
- Has a history of leptomeningeal disease or spinal cord compression.
- Has stroke or transient ischemic attack within 6 months prior to initiation dose of GenSci128.
- Has active infection requiring intravenous (IV) antibiotics or other uncontrolled inter-current illness requiring hospitalization. Minor infections, e.g., periodontal infection or urinary tract infection (UTI), which may be treated with short term oral antibiotics are allowed.

... and 7 more (see full listing online)

Locations (1 total)

Zhongshan Hospital ,Fudan University, Shanghai, Shanghai Municipality, China

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