HX044,FIH Study in Patients with Advanced Solid Tumor Malignancies

NCT06649708

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Hanx Biopharmaceuticals (Wuhan) Co., Ltd.
Enrollment	100 participants

Key Eligibility Criteria

Inclusion (11)

- Subjects must voluntarily agree to participate by providing written informed consent and agreeing to comply with protocol and scheduled visit;
- Male or female subject aged 18-75 years, inclusive;
- Eastern Cooperative Oncology Group (ECOG) performance status 0 or 1;
- Histologically confirmed advanced malignant solid tumor that is refractory/relapsed to standard therapies, or for which no effective standard therapy is available, or the subject refuses standard therapy.
- At least 1 measurable tumor (It is acceptable to allow patients with no measurable lesion but evaluable tumor lesion in the first 2 dose levels in Phase I and at least 1 measurable tumor lesion must be present in Phase IIa) according to RECIST v1.1

... and 6 more (see full listing online)

Exclusion (16)

- Prior malignancy active within the previous 5 years except for the tumor for which a subject is enrolled in the study and locally curable cancers that have been apparently cured, such as basal or squamous cell skin cancer, superficial bladder cancer or carcinoma in situ of the cervix or breast.
- Receipt of any anticancer (chemotherapy, radiation therapy, investigational drugs including small molecular inhibitors, endocrine therapy, immunotherapy) therapy within 4 weeks prior to the first dose of study treatment or 5 half-lives of the therapy, whichever is shorter.
- Severe cardiovascular disease including symptomatic congestive heart failure (New York Heart Association class III or IV), unstable angina, uncontrolled hypertension, cardiac arrhythmia, a history of myocardial infarction within 6 months or a history of arterial thromboembolic event and pulmonary embolism within 3 months of the first dose of investigational agent, as follows:
- QT/QTc interval prolongation (using Fredericia's QT correction formula) at baseline, Female \> 470 ms, Male \> 450 ms;
- Medications to prolong the QT/QTc interval are currently being taken;

... and 11 more (see full listing online)

Locations (3 total)

Blacktown Hospital, Blacktown, New South Wales, Australia
Icon Cancer Centre Wesley, Auchenflower, Queensland, Australia
Cabrini Health Limited, Malvern, Victoria, Australia