

A Clinical Study of HRS-8364 in the Treatment of Advanced Solid Tumor Subjects

NCT07446153

Status	RECRUITING
Phase	Phase 1, Phase 2
Sponsor	Jiangsu HengRui Medicine Co., Ltd.
Enrollment	282 participants

Key Eligibility Criteria

Inclusion (9)

- Voluntarily joining this study, signing an informed consent form, good compliance, and able to cooperate with follow-up.
- Age range: 18-75 years old (including boundary values), both males and females are eligible.
- Monotherapy dose escalation stage: advanced solid tumors diagnosed by cytology or histology, which have failed standard treatment or are intolerant to previous standard treatment or have no standard treatment.
- Monotherapy dose expansion stage: advanced solid tumors diagnosed by cytology or histology; with other systemic treatments during the recurrence or metastasis stage, and disease progression during or after treatment; The combined dose expansion phase allows for the inclusion of individuals who have not received prior treatment with immuno checkpoint inhibitors (ICIs).
- Efficacy expansion of monotherapy: advanced solid tumors diagnosed by histopathology or cytology; with other systemic treatments during the recurrence or metastasis stage, and disease progression during or after treatment.

... and 4 more (see full listing online)

Exclusion (12)

- Untreated brain metastases; Or accompanied by meningeal metastasis, spinal cord compression, etc.
- Large blood vessels invasion confirmed by imaging, or the subject's tumor has a high possibility of invading important blood vessels and causing fatal bleeding during treatment judged by researchers.
- Uncontrolled pleural effusion, pericardial effusion, or peritoneal effusion accompanied by clinical symptoms.
- Severe bone damage caused by tumor bone metastasis, including uncontrolled severe bone pain, pathological fractures in important areas that have occurred or are expected to occur in the past 6 months, and spinal cord compression. Subjects who require analgesic medication must have a stable analgesic treatment plan in place at the time of entry into the study.
- Other malignant tumors in the past 5 years or at the same time.

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

Locations (2 total)

The Sixth Affiliated Hospital, Sun-Yat-Sen University, Guangzhou, Guangdong, China
Liaoning Cancer Hospital & Institute, Shenyang, Liaoning, China

<https://clinicaltrials.gov/study/NCT07446153>

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