

A Study to Evaluate the Safety, Tolerability and PK of SK-09

NCT07267026

Status	RECRUITING
Phase	Phase 1
Sponsor	Consun Pharmaceutical Group
Enrollment	72 participants

Key Eligibility Criteria

Inclusion (6)

- Healthy male and female participants aged 18 to 55 years (inclusive) at the time of screening.
 - Weight and BMI for female and male participants:
 - Body weight \leq 50 kg; Body mass index (BMI) between 18.5 and 29.9 kg/m² (inclusive)
 - Participants must be in good general health.
 - Capable of understanding and voluntarily providing written informed consent prior to any study-related procedures.
- ... and 1 more (see full listing online)

Exclusion (21)

- History or current presence of clinically significant Cardiovascular; Respiratory ; Gastrointestinal; Neurological ; Hematologic/immunologic disorders.
 - Chronic GI conditions requiring daily medication; or history of bariatric surgery.
 - Live/attenuated vaccines within 4 weeks prior to dosing or planned during study.
 - Systolic blood pressure $<$ 90 mmHg or \geq 140 mmHg, or diastolic blood pressure \geq 80 mmHg.
 - History of myocardial infarction, angina, coronary artery bypass grafting, angioplasty, stenting, congestive heart failure, uncontrolled hypotension, unexplained arrhythmia, ventricular tachycardia, atrioventricular block, QT prolongation syndrome, or symptoms/family history of QT prolongation syndrome, as assessed by the investigator to be unsuitable for participation.
- ... and 16 more (see full listing online)

Locations (1 total)

Q-Pharm Pty Ltd., Herston, Queensland, Australia