Effect of Hepatic Impairment on the Pharmacokinetics of Mirdametinib

NCT06997276

Status	RECRUITING
Phase	Phase 1
Sponsor	SpringWorks Therapeutics, Inc.
Enrollment	32 participants

Key Eligibility Criteria

Inclusion (25)

- Participant understands the study procedures, is willing to comply with all study requirements and restrictions and agrees to participate in the study by providing written informed consent, prior to any study-related procedures being performed.
- Participant is between 18 and 80 years of age (inclusive) at the time of informed consent.
- Participant has a body mass index (BMI) e18 kg/m2 and d32 kg/m2 (inclusive) at Screening and Day -1 and a total body weight \>50 kg.
- Male participants that agree to the following during the treatment periods and for at least 90 days after the last dose of study treatment:
- Refrain from donating or preserving sperm; PLUS either

... and 20 more (see full listing online)

Exclusion (31)

- Participant is deemed unsuitable for this study in the opinion of the Investigator for any additional reason, condition, or prior therapy.
- Participant has clinically significant infections (e.g., coronavirus disease 2019 \[COVID-19\] or influenza) within 90 days prior to Day 1, as judged by the Investigator, or evidence of any infection with the past 14 days prior to Day 1.
- Chronic infection with Hepatitis B or C (\>180 days) may be eligible as judged by the Investigator in consultation with the Sponsor's medical monitor. If a participant tests positive for HIV at Screening, they are not eligible for participation in the study.
- Participant has a history of stomach or gastrointestinal (GI) surgery or resection that would potentially alter absorption, metabolism, and/or excretion of PO administered drugs (exceptions include participants who underwent appendectomy, cholecystectomy, or any type of hernia repair).
- Participant has a history of pre-existing condition (apart from hepatic impairment) interfering with normal GI anatomy or motility and potentially alter the absorption, metabolism, and/or excretion of orally administered drugs.

... and 26 more (see full listing online)

Locations (3 total)

Clinical Pharmacology of Miami, Miami, Florida, United States
Orlando Clinical Research Center, Orlando, Florida, United States
American Research Corporation (Texas Liver Institute), San Antonio, Texas, United States