

Assessment of Quizartinib Pharmacokinetic in Subjects With Severe Hepatic Impairment

NCT06740799

Status	RECRUITING
Phase	Phase 1
Sponsor	Daiichi Sankyo
Enrollment	12 participants

Key Eligibility Criteria

Inclusion (4)

- Voluntarily consents to participate in this study and provides written informed consent before the start of any study-specific procedures.
- Male and female subjects 18 to 75 years of age (inclusive), with a body mass index (BMI) of 18 kg/m² to 37 kg/m² (inclusive) with a minimum body weight of 40 kg at Screening.
- In females, documented surgical sterilization (ie, documented hysterectomy, bilateral tubal ligation, or bilateral salpingo-oophorectomy, Essure® with hysterosalpingogram \[documentation to confirm tubal occlusion 12 weeks after procedure\]), postmenopausal status for at least 1 year (follicle stimulating hormone \[FSH\] > 40 mIU/mL serum and estradiol <40 pg/mL \[<147 pmol/L\] at Screening), or agreement to have a sterile male partner, or agreement to use 1 of the means of contraception from Screening until 7 months after the dose of quizartinib 4. In females, agreement to not retrieve eggs/ova via assisted reproductive technology (ART) either for their own use or donation while on the study or for 7 months after the last dose of study drug, whichever is later.
- \. In males, documented surgical sterilization, sexual abstinence, or agreement to use 1 of the means of contraception from Screening until 4 months after the dose of quizartinib 6. In males, agreement to avoid sperm donation for 4 months after the dose of quizartinib

Exclusion (6)

- Any serious and/or unstable pre-existing medical, psychiatric disorder, or other conditions (including lab abnormality except hepatic impairment) that could interfere with safety, obtaining informed consent, compliance to the study procedures, or the validity of the study results.
- In the opinion of the investigator, history of a clinically significant illness within 4 weeks prior to administration of quizartinib.
- Subjects with primary biliary cirrhosis or primary sclerosing cholangitis.
- Subjects with history of Gilbert's syndrome.
- Presence or history of clinically severe adverse reaction to any drug or known hypersensitivity to any of the ingredients (including inactive ingredients) of quizartinib.

... and 1 more (see full listing online)

Locations (3 total)

Clinical Pharmacology of Miami, LLC, Miami, Florida, United States
Advanced Pharma, Miami, Florida, United States
GCP Research, St. Petersburg, Florida, United States

<https://clinicaltrials.gov/study/NCT06740799>

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