

A Study to Assess the Safety, Tolerability, and Pharmacokinetics of GIGA-2339 in Participants With Chronic Hepatitis B Virus Infection

NCT07024641

Status	RECRUITING
Phase	Phase 1
Sponsor	GigaGen, Inc.
Enrollment	48 participants

Key Eligibility Criteria

Inclusion (6)

- Hepatitis B envelope antigen (HBeAg) negative chronic HBV infection for e 6 months, defined as presence of Hepatitis B surface antigen (HBsAg) in serum for e 6 months.
- Serum HBsAg concentration between e 100 international units per milliliter (IU/mL) and 2000 IU/mL at screening.
- Currently on stable dose of nucleot(s)ide analogues (NAs) (e 6 months) and expected to continue while participating in the study, or are not received NAs.
- Have serum HBV deoxyribonucleic acid (DNA) concentration d 50 IU/mL at screening (for those who are on NAs); or have serum HBV DNA concentration d 2000 IU/mL at screening (for those who are NOT on NAs).
- Male participants must refrain from donating spermatozoa and agree to use highly effective contraception.

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

Exclusion (16)

- Positive for co-infection with hepatitis C virus (HCV), human immunodeficiency virus (HIV), and/or hepatitis D virus (HDV) at screening.
- Participants that weigh less than 50 kilograms (kg) and/or have a body mass index (BMI) less than 18.5.
- History of documented liver cirrhosis at screening. Patients under liver cirrhosis evaluation at screening will not be eligible until cirrhosis is ruled out.
- Liver stiffness \gt 8 kilopascal (kPa) at screening.
- History of chronic liver disease from another cause, immune complex disease, or autoimmune diseases that in the opinion of the investigator would preclude participation.

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

Locations (16 total)

Grifols Investigative site, Chandler, Arizona, United States
Grifols Investigative site, Huntington Beach, California, United States
Grifols Investigative site, Lake Forest, California, United States
... and 13 more locations

<https://clinicaltrials.gov/study/NCT07024641>

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