ForPatients
*by Roche*

Chronic Hepatitis BHepatitis B Virus

# A Trial To Evaluate The Efficacy And Safety Of Multiple Combination Therapies In Participants With Chronic Hepatitis B

| Trial Status | Trial Runs In | Trial Identifier |
|---|---|---|
| Completed | 14 Countries | NCT04225715 2019-002086-35 WV41073 |

*The information is taken directly from public registry websites such as ClinicalTrials.gov, EuClinicalTrials.eu, ISRCTN.com, etc., and has not been edited.*

## *Official Title:*

A Phase II, Randomised, Adaptive, Open-Label Platform Trial To Evaluate Efficacy And Safety Of Multiple Combination Therapies In Participants With Chronic Hepatitis B

## *Trial Summary:*

This is a study designed to evaluate the safety, tolerability and efficacy of New Molecular Entity (NME) combination therapies in Chronic Hepatitis B (CHB) participants with preserved liver function and without significant fibrosis/cirrhosis. The platform design allows comparison of multiple NME combination therapies against a common control, and introduction of additional treatment arms at later study time points. Each arm will consist of a screening phase (up to 8 weeks), treatment phase (up to 48 weeks) and post-treatment follow-up phase (48 weeks). The safety and efficacy will be monitored throughout the study.

**Hoffmann-La Roche**
Sponsor

**Phase 2**
Phase

**NCT04225715 2019-002086-35 WV41073**
Trial Identifiers

## *Eligibility Criteria:*

| Gender | Age | Healthy Volunteers |
|---|---|---|
| All | #18 Years & # 65 Years | No |

## *Inclusion Criteria:*

- Body mass index between 18 and 32 kg/m2 inclusive.

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- Participants with Chronic Hepatitis B (CHB) infection (HBsAg positive for >=6 months) who are on established NUC (entecavir or tenofovir alafenamide/disoproxil fumarate) monotherapy for >=12 months, having received the same NUC therapy for >=3 months prior to screening.
- HBV DNA below the lower LLOQ or < 20 IU/mL for > 6 months prior to screening and confirmed at screening.
- Alanine transaminase (ALT) <=1.5 x upper limit of normal (ULN) for > 6 months prior to screening and confirmed at screening.
- Female Participants: Eligible to participate if she is not pregnant, not breastfeeding and agrees to remain abstinent (refrain from heterosexual intercourse) or use highly effective contraceptive methods.
- Male Participants: During the treatment period and for at least 6 months after the final dose of study treatment, agrees to remain abstinent (refrain from heterosexual intercourse), use contraceptive measures and refrain from donating sperm.

## *Exclusion Criteria:*

- Pregnant or lactating women.
- Co-infection with other pathogens such as Hepatitis A, C, D and E or Human Immunodeficiency Virus (HIV).
- History of cirrhosis or current evidence of significant liver fibrosis or cirrhosis or decompensated liver disease.
- History of or suspicion of Hepatocellular Carcinoma (HCC).
- Thyroid disease poorly controlled on prescribed medications or clinically relevant abnormal thyroid function tests.
- Clinically significant disease other than CHB that, in the opinion of the Investigator, makes the participant unsuitable for the study.
- Pre-existing cardiac disease that in the opinion of the investigator would increase the risk for the participant to take part in the study.
- History of alcohol abuse and/or drug abuse within one year of randomization.
- History of having received (in the last 6 months) or currently receiving any systemic antineoplastic (including radiation) or immunosuppressive (including biologic immunosuppressors) or immune modulating treatment.
- Currently taking, or have received within 3 months of Day 1, systemic corticosteroids.
- Electrocardiogram (ECG) with clinically significant abnormalities.
- Previous treatment with an investigational agent for Hepatitis B (HBV) within 6 months prior to screening.

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