ForPatients
by Roche

Hepatitis B Virus

A Study of Pegylated Interferon Alfa-2A in Combination With Lamivudine or Entecavir Compared With Untreated Control Group in Children With Hepatitis B Envelope Antigen (HBeAg)-Positive Chronic Hepatitis B (CHB) in the Immune-Tolerant Phase

Trial Status	Trial Runs In	Trial Identifier
Completed	12 Countries	NCT02263079 2006-000977-31 NV25361

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 IIIb, Randomized, Open-Label Study of Pegylated Interferon Alfa-2A in Combination With Lamivudine or Entecavir Compared With Untreated Control Patients in Children With HBeAg Positive Chronic Hepatitis B in the Immune-Tolerant Phase

Trial Summary:

This randomized, controlled, parallel group, open-label multicenter study will evaluate the efficacy and safety of a combination of pegylated interferon alfa-2A (Pegasys) plus lamivudine or entecavir compared with an untreated control group in participants with HBeAg positive CHB in the immune tolerant phase. NOTE: STUDY RECRUITMENT HAS BEEN TERMINATED

Hoffmann-La Roche
Sponsor

Phase 3
Phase

NCT02263079 2006-000977-31 NV25361
Trial Identifiers

Eligibility Criteria:

Gender	Age	Healthy Volunteers
All	# 3 Years & # 17 Years	No

Inclusion Criteria:

- Positive for HBsAg and HBeAg for more than 6 months prior to baseline
- Detectable HBV-DNA (>20,000 IU/mL) as measured by polymerization chain reaction (PCR) or hybridization on at least 2 occasions at least one month apart with the latest determination obtained less than or equal to (</=) 42 days prior to baseline
- Compensated liver disease (Child-Pugh Class A clinical classification)
- Either Liver biopsy performed within 2 years prior to baseline showing no or minimal fibrosis (Liver Biopsy Scores and stable normal ALT levels (less than or equal to upper limit of normal [ULN]) during the 6 months leading up to baseline (including two separate occasions at least 1 month apart over the 6 months prior to baseline). Screening ALT levels must be normal (</= ULN) OR Stable normal ALT levels (</= ULN), during the 1 year leading up to baseline (including three separate occasions at least 1 month apart over the 1 year prior to baseline) and no signs of hepatocellular carcinoma (HCC), advanced fibrosis/cirrhosis, or splenomegaly on liver abdominal ultrasound at screening. Screening ALT levels must be normal (</= ULN)

Exclusion Criteria:

- Participants who have received investigational drugs or licensed treatments with anti HBV activity (Exception: Participants who have had a limited [</= 7-day] course of acyclovir for herpetic lesions more than 1 month before the study baseline visit are not excluded)
- Participants who have participated in any other clinical trial or who have received any investigational drug within 6 months prior to baseline
- Known hypersensitivity to interferon (IFN), pegylated interferon-alfa-2a or lamivudine or entecavir
- Positive test results at screening for hepatitis A virus Immunoglobulin M (IgM) antibody (Ab), anti-hepatitis C virus (HCV) Ab, anti- hepatitis D (HDV) Ab or anti-human immunodeficiency virus (HIV) Ab
- Decompensated liver disease (e.g., Child-Pugh Class B or C clinical classification or clinical evidence such as ascites or varices)
- Advanced fibrosis or cirrhosis
- Suspicion of HCC on liver abdominal ultrasound (all patients to have liver abdominal ultrasound within 6 months prior to baseline)
- History or other evidence of a medical condition associated with chronic liver disease other than CHB including metabolic liver diseases such as hemochromatosis, Wilson's disease or alpha-1 anti-trypsin deficiency
- Active substance abuse within 6 months prior to screening
- Sexually active females of childbearing potential and sexually active males who are not willing to utilize reliable contraception during treatment and for 90 days following the end of treatment
- Females who are pregnant or who are breastfeeding (females of childbearing potential who have a positive urine or serum pregnancy test result within 24 hours of baseline are excluded)