ClinicalTrials.gov Protocol Registration and Results System (PRS) Receipt
Release Date: 08/31/2016

ClinicalTrials.gov ID: NCT00436163

Study Identification

Unique Protocol ID:	ML20601
Brief Title:	A Study of Peginterferon Alfa-2a (40KD) (PEGASYS®) in Participants With Hepatitis B Envelope Antigen (HBeAg) - Positive Chronic Hepatitis B
Official Title:	Baltic Post-marketing Program of PEGASYS (Peg Interferon Alpha-2a 40KD) in Patients With HBeAg-positive and HBeAg-negative Chronic Hepatitis B
Secondary IDs:	

Study Status

Record Verification:	August 2016
Overall Status:	Completed
Study Start:	March 2007
Primary Completion:	May 2010 [Actual]
Study Completion:	May 2010 [Actual]

Sponsor/Collaborators

Sponsor:	Hoffmann-La Roche
Responsible Party:	Sponsor
Collaborators:	

Oversight

FDA Regulated?:	No

IND/IDE Protocol?:	No
Review Board:	Approval Status: Approved Approval Number: 154/62 Board Name: Ethics Review Committee on Human Research of the University of Tartu Board Affiliation: Unknown Phone: 00 372 737 4350 Email: hiie.sarv@ut.ee
Data Monitoring?:	
Plan to Share Data?:	
Oversight Authorities:	Estonia: State Agency of Medicines of the Republic of Estonia Latvia: State Agency of Medicines of the Republic of Latvia Lithuania: State Medicines Control Agency of Lithuania

Study Description

Brief Summary:	This single-arm study will evaluate the efficacy and safety of peginterferon alfa-2a in treatment-naive Baltic participants with Hepatitis B envelope antigen (HBeAg)-positive chronic Hepatitis B virus (HBV). All participants will receive peginterferon alfa-2a 180 micrograms (mcg) subcutaneously once weekly. Following 48 weeks of treatment, there will be a 24 week period of treatment-free follow-up. The anticipated time on study treatment is 3-12 months, and the target sample size is less than 100 participants.
Detailed Description:	

Conditions

Conditions:	Hepatitis B, Chronic
Keywords:	

Study Design

Study Type:	Interventional
Primary Purpose:	Treatment
Study Phase:	Phase 4
Intervention Model:	Single Group Assignment
Number of Arms:	1
Masking:	Open Label

Allocation:	N/A
Endpoint Classification:	Safety/Efficacy Study
Enrollment:	39 [Actual]

Arms and Interventions

Arms	Assigned Interventions
Experimental: Peginterferon Alfa-2a Participants received peginterferon alfa-2a (Pegasys) 180 mcg subcutaneously once per week for 48 weeks.	Drug: Peginterferon alfa-2a 180 mcg subcutaneously once per week for 48 weeks. Other Names: • Pegasys®

Outcome Measures

[See Results Section.]

Eligibility

Minimum Age:	18 Years
Maximum Age:	70 Years
Gender:	Both
Accepts Healthy Volunteers?:	No
Criteria:	Inclusion Criteria:

- Adult participants, 18-70 years of age;
- HBeAg positive, Hepatitis B surface antigen (HBsAg) positive for greater than or equal to 6 months;
- anti-HBs negative;
- Hepatitis B virus deoxyribonucleic acid (HBV DNA) greater than 5,00,000 copies/milliliters.

Exclusion Criteria:

- Previous antiviral or interferon-based therapy for chronic hepatitis B;
- Evidence of decompensated liver disease;
- Chronic liver disease other than viral hepatitis;
- Co-infection with active hepatitis A, C or D virus;
- Co-infection with human immunodeficiency virus.

Contacts/Locations

Study Officials: Clinical Trials
Study Director
Hoffmann-La Roche

Locations: Latvia
Riga, Latvia, 1006

Lithuania
Vilnius, Lithuania, 08661

Vilnius, Lithuania, 08117

Kaunas, Lithuania, 50009

Klaipeda, Lithuania, 92288

Estonia
Tartu, Estonia, 51014

Tallinn, Estonia, 10138

Tallinn, Estonia, 10617

Lithuania
Kaunas, Lithuania, 47144

References

Citations:

Links:

Study Data/Documents:

Participant Flow

Reporting Groups

	Description
Peginterferon Alfa-2a	Participants received peginterferon alfa-2a (Pegasys®) 180 micrograms (mcg) subcutaneously once per week for 48 weeks.

Overall Study

	Peginterferon Alfa-2a
Started	39
Completed	36
Not Completed	3
Lost to Follow-up	2
Adverse Event	1

Baseline Characteristics

Analysis Population Description

All enrolled participants who received at least 1 dose of peginterferon alfa-2a.

Reporting Groups

	Description
Peginterferon Alfa-2a	Participants received peginterferon alfa-2a (Pegasys) 180 mcg subcutaneously once per week for 48 weeks.

Baseline Measures

	Peginterferon Alfa-2a
Number of Participants	39
Age, Continuous [units: years] Mean (Standard Deviation)	36.28 (13.141)
Gender, Male/Female [units: participants]	
Female	7

	Peginterferon Alfa-2a
Male	32

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Number of Hepatitis B Envelope Antigen (HBeAg) Positive Participants With Hepatitis B Virus Deoxyribonucleic Acid (HBV-DNA) Less Than (<) 1,00,000 Copies Per Milliliter (Copies/mL)
Measure Description	HBeAg is a soluble antigen of hepatitis B virus present in the blood during acute infection, and disappear afterward but sometimes persisting in chronic disease. HBeAg positive participants were defined as those who had HBV DNA greater than (>) 1,00,000 copies/mL at baseline. This outcome measured the number of participants with HBV-DNA levels < 1,00,000 copies/mL at Week 72, who were defined as HBeAg positive at baseline.
Time Frame	Week 72
Safety Issue?	No

Analysis Population Description

All enrolled participants who received at least 1 dose of peginterferon alfa-2a. Here, Number of participants analyzed = participants who were HBeAg positive at baseline.

Reporting Groups

	Description
Peginterferon Alfa-2a	Participants received peginterferon alfa-2a (Pegasys) 180 mcg subcutaneously once per week for 48 weeks.

Measured Values

	Peginterferon Alfa-2a
Number of Participants Analyzed	22
Number of Hepatitis B Envelope Antigen (HBeAg) Positive Participants With Hepatitis B Virus Deoxyribonucleic Acid (HBV-DNA) Less Than (<) 1,00,000 Copies Per Milliliter (Copies/mL) [units: participants]	6

2. Primary Outcome Measure:

Measure Title	Number of HBeAg Negative Participants With HBV-DNA < 10,000 Copies/mL

Measure Description	HBeAg is a soluble antigen of hepatitis B virus present in the blood during acute infection, and disappear afterward but sometimes persisting in chronic disease. HBeAg negative participants were defined as those who had HBV DNA >10,000 copies/mL at baseline. This outcome measured the number of participants with HBV DNA <10,000 copies/mL at Week 72, who were defined as HBeAg negative at baseline.
Time Frame	Week 72
Safety Issue?	No

Analysis Population Description

All enrolled participants who received at least 1 dose of peginterferon alfa-2a. Here, Number of participants analyzed = participants who were HBeAg negative at baseline.

Reporting Groups

	Description
Peginterferon Alfa-2a	Participants received peginterferon alfa-2a (Pegasys) 180 mcg subcutaneously once per week for 48 weeks.

Measured Values

	Peginterferon Alfa-2a
Number of Participants Analyzed	17
Number of HBeAg Negative Participants With HBV-DNA < 10,000 Copies/mL [units: participants]	6

3. Secondary Outcome Measure:

Measure Title	Number of Participants With HBV-DNA < 400 Copies/mL
Measure Description	
Time Frame	Week 72
Safety Issue?	No

Analysis Population Description

All enrolled participants who received at least 1 dose of peginterferon alfa-2a. Here, Number of participants analyzed = participants evaluable for this outcome measure.

Reporting Groups

	Description
Peginterferon Alfa-2a	Participants received peginterferon alfa-2a (Pegasys) 180 mcg subcutaneously once per week for 48 weeks.

Measured Values

	Peginterferon Alfa-2a
Number of Participants Analyzed	37
Number of Participants With HBV-DNA < 400 Copies/ mL [units: participants]	4

4. Secondary Outcome Measure:

Measure Title	Percentage of Hepatitis B Surface Antigen (HBsAg) Negative Participants
Measure Description	HBsAg seroconversion was defined as the absence of HBsAg (HBsAg negative) and the presence of anti-HBs (anti-HBs positive) for HBsAg participants. Percentage of HBsAg negative participants were reported.
Time Frame	Week 48 and Week 72
Safety Issue?	No

Analysis Population Description

All enrolled participants who received at least 1 dose of peginterferon alfa-2a. Here, Number of participants analyzed = participants evaluable for this outcome measure.

Reporting Groups

	Description
Peginterferon Alfa-2a	Participants received peginterferon alfa-2a (Pegasys)180 mcg subcutaneously once per week for 48 weeks.

Measured Values

	Peginterferon Alfa-2a
Number of Participants Analyzed	36
Percentage of Hepatitis B Surface Antigen (HBsAg) Negative Participants [units: percentage of participants]	
Week 48	3
Week 72	3

5. Secondary Outcome Measure:

Measure Title	Percentage of Anti-HBs Positive Participants
Measure Description	HBsAg seroconversion was defined as the absence of HBsAg (HBsAg negative) and the presence of anti-HBs (anti-HBs positive) for HbsAg participants. Percentage of Anti-HBs positive participants were reported.
Time Frame	Week 48 and Week 72
Safety Issue?	No

Analysis Population Description

All enrolled participants who received at least 1 dose of peginterferon alfa-2a. Here, Number of participants analyzed = participants evaluable for this outcome and n= participants with available data at specified time points.

Reporting Groups

	Description
Peginterferon Alfa-2a	Participants received peginterferon alfa-2a (Pegasys)180 mcg subcutaneously once per week for 48 weeks.

Measured Values

	Peginterferon Alfa-2a
Number of Participants Analyzed	36
Percentage of Anti-HBs Positive Participants [units: percentage of participants]	
Week 48 (n= 36)	8
Week 72 (n= 35)	3

6. Secondary Outcome Measure:

Measure Title	Mean Alanine Aminotransferase (ALT) Concentrations
Measure Description	
Time Frame	Week 48 and Week 72
Safety Issue?	No

Analysis Population Description

All enrolled participants who received at least 1 dose of peginterferon alfa-2a. Here, Number of participants analyzed = participants evaluable for this outcome measure.

Reporting Groups

	Description
Peginterferon Alfa-2a	Participants received peginterferon alfa-2a (Pegasys) 180 mcg subcutaneously once per week for 48 weeks.

Measured Values

	Peginterferon Alfa-2a
Number of Participants Analyzed	37
Mean Alanine Aminotransferase (ALT) Concentrations [units: international units per liter (IU/L)] Mean (Standard Deviation)	
Week 48	62.6 (5.1)
Week 72	64.5 (12.0)

7. Secondary Outcome Measure:

Measure Title	Percentage of HBeAg Negative Participants
Measure Description	HBeAg seroconversion was defined as the absence of HBeAg (HBeAg negative) and the presence of anti-HBe (anti-HBe positive) for HBeAg positive participants. Percentage of HBeAg negative participants were reported.
Time Frame	Week 48 and Week 72
Safety Issue?	No

Analysis Population Description

All enrolled participants who received at least 1 dose of peginterferon alfa-2a. Here, Number of participants analyzed = participants evaluable for this outcome and n= participants with available data at specified time points.

Reporting Groups

	Description
Peginterferon Alfa-2a	Participants received peginterferon alfa-2a (Pegasys) 180 mcg subcutaneously once per week for 48 weeks.

Measured Values

	Peginterferon Alfa-2a
Number of Participants Analyzed	21
Percentage of HBeAg Negative Participants [units: percentage of participants]	

	Peginterferon Alfa-2a
Week 48 (n= 20)	25
Week 72 (n= 21)	29

8. Secondary Outcome Measure:

Measure Title	Percentage of Anti-HBe Positive Participants
Measure Description	HBeAg seroconversion was defined as the absence of HBeAg (HBeAg negative) and the presence of anti-HBe (anti-HBe positive) for HBeAg participants. Percentage of Anti-HBe positive participants were reported.
Time Frame	Week 48 and Week 72
Safety Issue?	No

Analysis Population Description

All enrolled participants who received at least 1 dose of peginterferon alfa-2a. Here, Number of participants analyzed = participants evaluable for this outcome and n= participants with available data at specified time points.

Reporting Groups

	Description
Peginterferon Alfa-2a	Participants received peginterferon alfa-2a (Pegasys) 180 mcg subcutaneously once per week for 48 weeks.

Measured Values

	Peginterferon Alfa-2a
Number of Participants Analyzed	18
Percentage of Anti-HBe Positive Participants [units: percentage of participants]	
Week 48 (n= 17)	41
Week 72 (n= 18)	33

Reported Adverse Events

Time Frame	AEs were recorded from Screening till Week 72.
Additional Description	All enrolled participants who received at least 1 dose of peginterferon alfa-2a were included in safety analysis.

Reporting Groups

	Description
Peginterferon Alfa-2a	Participants received peginterferon alfa-2a (Pegasys) 180 mcg subcutaneously once per week for 48 weeks.

Serious Adverse Events

	Peginterferon Alfa-2a
	Affected/At Risk (%)
Total	0/39 (0%)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 0%

	Peginterferon Alfa-2a
	Affected/At Risk (%)
Total	15/39 (38.46%)
Gastrointestinal disorders	
Barrett esophagus [A] *	1/39 (2.56%)
Blood in stool [A] *	1/39 (2.56%)
Dry mouth [A] *	1/39 (2.56%)
Prostate hyperplasia [A] *	1/39 (2.56%)
Stomach ache [A] *	1/39 (2.56%)
General disorders	
Anxiety [A] *	1/39 (2.56%)
Headache [A] *	2/39 (5.13%)
Heartburn [A] *	1/39 (2.56%)

	Peginterferon Alfa-2a
	Affected/At Risk (%)
Subfebrile temperature [A] *	1/39 (2.56%)
Weakness [A] *	1/39 (2.56%)
Skin and subcutaneous tissue disorders	
Alopecia [A] *	1/39 (2.56%)
Eczema [A] *	1/39 (2.56%)
Rash [A] *	1/39 (2.56%)
Vascular disorders	
Arterial hypertension [A] *	1/39 (2.56%)

* Indicates events were collected by non-systematic methods.
A Term from vocabulary, MedDRA

Limitations and Caveats

[Not specified]

More Information

Certain Agreements:

Principal Investigators are NOT employed by the organization sponsoring the study.

There IS an agreement between the Principal Investigator and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.

The Study being conducted under this Agreement is part of the Overall Study. Investigator is free to publish in reputable journals or to present at professional conferences the results of the Study, but only after the first publication or presentation that involves the Overall Study. The Sponsor may request that Confidential Information be deleted and/or the publication be postponed in order to protect the Sponsor's intellectual property rights.

Results Point of Contact:

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