ClinicalTrials.gov Protocol and Results Registration System (PRS) Receipt
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A Study of PEGASYS (Peginterferon Alfa-2a (40KD)) in Patients With Hepatitis Be Antigen (HBeAg) Positive Chronic Hepatitis B (CHB).

This study has been completed.

Sponsor:	Hoffmann-La Roche
Collaborators:	
Information provided by (Responsible Party):	Hoffmann-La Roche
ClinicalTrials.gov Identifier:	NCT00435825

Purpose

This 4 arm study will compare the efficacy and safety of PEGASYS given for 24 or 48 weeks, and at doses of 90 or 180 micrograms weekly, in the treatment of HBeAg positive patients with chronic hepatitis B. Patients will be randomized to one of 4 treatment groups: a)PEGASYS 90 micrograms subcutaneous (sc) weekly for 24 weeks, b)PEGASYS 180 micrograms sc weekly for 24 weeks, c)PEGASYS 90 micrograms sc weekly for 48 weeks or d)PEGASYS 180 micrograms sc weekly for 48 weeks. Following treatment there will be a 24 week period of treatment-free follow-up in all treatment groups for the primary endpoint. The anticipated time on study treatment is 3-12 months, and the target sample size is 500+ individuals.

Condition	Intervention	Phase
Hepatitis B, Chronic	Drug: peginterferon alfa-2a [Pegasys]	Phase 4

Study Type: Interventional
Study Design: Treatment, Parallel Assignment, Double Blind (Subject, Investigator), Randomized, Safety/Efficacy Study
Official Title: A Randomized, Double-blind Study of the Effect of Treatment Duration and Dose of PEGASYS on HBeAg Seroconversion and Safety in Patients With HBeAg Positive Chronic Hepatitis B.

Further study details as provided by Hoffmann-La Roche:

Primary Outcome Measure:

- Percentage of Participants With Hepatitis Be Antigen (HBeAg) Seroconversion 24 Weeks Following End of Treatment [Time Frame: 24 Weeks following end of treatment (Week 48 for 24 Week Treatment or Week 72 for 48 Week Treatment)] [Designated as safety issue: No]
  Blood was collected for HBeAg. HBeAg seroconversion was defined as the absence of HBeAg (a negative result for HBeAg) and the presence of anti-HBe (a positive result for anti-HBe) determined at 24 weeks after the end of treatment.

Secondary Outcome Measures:

- Percentage of Participants With Hepatitis Be Antigen (HBeAg) Seroconversion at Week 72 [Time Frame: Week 72] [Designated as safety issue: No]
  Blood was collected for HBeAg. HBeAg seroconversion was defined as the absence of HBeAg (a negative result for HBeAg) and the presence of anti-HBe (a positive result for anti-HBs) determined at Week 72.
- Percentage of Participants With Loss of Hepatitis Be Antigen (HBeAg) 24 Weeks Following End of Treatment [Time Frame: 24 Weeks following end of treatment (Week 48 for 24 Week Treatment or Week 72 for 48 Week Treatment)] [Designated as safety issue: No]
  Blood was collected HBeAg 24 Weeks following the end of treatment. Loss of HBeAg is defined as the absence of HBeAg.
- Percentage of Participants With Hepatitis B Surface Antigen (HBsAg) Seroconversion 24 Weeks Following the End of Treatment [Time Frame: 24 Weeks following end of treatment (Week 48 for 24 Week Treatment or Week 72 for 48 Week Treatment)] [Designated as safety issue: No]
  HBsAg seroconversion was defined as the absence of HBsAg (a negative result for HBsAg) and the presence of anti-HBs (a positive result for anti-HBs) determined at 24 weeks after the end of treatment.
- Percentage of Participants With Loss of Hepatitis B Surface Antigen (HBsAg) 24 Weeks Following End of Treatment [Time Frame: 24 Weeks following end of treatment (Week 48 for 24 Week Treatment or Week 72 for 48 Week Treatment)] [Designated as safety issue: No]
  Blood was collected for HBsAg 24 weeks following the end of treatment. Loss of HBsAg is defined as the absence of HBsAg.
- Percentage of Participants With Normal Alanine Aminotransferase (ALT) [Time Frame: 24 Weeks following end of treatment (Week 48 for 24 Week Treatment or Week 72 for 48 Week Treatment)] [Designated as safety issue: No]
  Blood was collected 24 weeks following the end of treatment for ALT and was analyzed at a local laboratory. A normal ALT is a value within the normal range of the assay.
- Percentage of Participants With Hepatitis B Virus Deoxyribonucleic Acid (HBV-DNA) Suppression < 20,000 IU/mL 24 Weeks Following End of Treatment [Time Frame: 24 Weeks following end of treatment (Week 48 for 24 Week Treatment or Week 72 for 48 Week Treatment)] [Designated as safety issue: No]
  Blood was collected for HBV-DNA 24 weeks following the end of treatment and was analyzed at the central laboratory using the Roche approved polymerase chain reaction (PCR) methodology. Percentage of participants with a HBV-DNA suppression of < 20,000 IU/mL (Less than 100,000 copies/mL) is reported.
- Percentage of Participants With Hepatitis Deoxyribonucleic Acid (HBV-DNA) Suppression < 2,000 IU/mL 24 Weeks Following End of Treatment [Time Frame: 24 Weeks following end of treatment (Week 48 for 24 Week Treatment of Week 72 for 48 Week Treatment)] [Designated as safety issue: No]
  Blood was collected for HBV-DNA and was analyzed at the central laboratories using the Roche approved PCR methodology 24 weeks following the end of treatment. Percentage of participants with A HBV-DNA Suppression of < 2,000 IU/mL (Less than 10,000 copies/mL) is reported.
- Percentage of Participants With Combined Endpoint Response 24 Weeks Following End of Treatment [Time Frame: 24 Weeks following end of treatment (Week 48 for 24 Week Treatment or Week 72 for 48 Week Treatment)] [Designated as safety issue: No]
  Combined endpoint was defined as HBeAg seroconversion, a normal serum ALT and HBV-DNA suppression below 20,000 IU/mL.
- Percentage of Participants With Dual Endpoint Response 24 Weeks Following End of Treatment [Time Frame: 24 Weeks following end of treatment (Week 48 for 24 Week Treatment or Week 72 for 48 Week Treatment)] [Designated as safety issue: No]
  Dual endpoint was defined as the achievement of both HBeAg seroconversion and a HBV-DNA <2,000 IU/ml (Less than 10,000 copies/mL).
- Quantitative Serum Alanine Aminotransferase (ALT) 24 Weeks Following End of Treatment [Time Frame: 24 Weeks following end of treatment (Week 48 for 24 Week Treatment or Week 72 for 48 Week Treatment)] [Designated as safety issue: No]
  Blood was collected 24 weeks following the end of treatment for ALT and was analyzed at a local laboratory. A normal ALT is a value within the normal range of the assay: 0- 55 units/liter (U/L).

- Quantitative HBV-DNA 24 Weeks Following End of Treatment [Time Frame: 24 Weeks following end of treatment (Week 48 for 24 Week Treatment or Week 72 for 48 Week Treatment)] [Designated as safety issue: No]
  Blood was collected for HBV-DNA and was analyzed at the central laboratories using the Roche approved PCR methodology 24 weeks following the end of treatment.

Enrollment: 551
Study Start Date: March 2007
Primary Completion Date: December 2010
Study Completion Date: December 2010

Arms	Assigned Interventions
Experimental: peginterferon alfa-2a 90 µg_24 Weeks Participants received 90 micrograms (µg) peginterferon alfa-2a subcutaneous once a week for 24 weeks.	Drug: peginterferon alfa-2a [Pegasys] 90 or 180 micrograms subcutaneous weekly for 24 weeks or 48 weeks.
Experimental: peginterferon alfa-2a 180 µg_24 Weeks Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 24 weeks.	Drug: peginterferon alfa-2a [Pegasys] 90 or 180 micrograms subcutaneous weekly for 24 weeks or 48 weeks.
Experimental: peginterferon alfa-2a 90 µg_48 Weeks Participants received 90 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.	Drug: peginterferon alfa-2a [Pegasys] 90 or 180 micrograms subcutaneous weekly for 24 weeks or 48 weeks.
Experimental: peginterferon alfa-2a 180 µg_48 Weeks Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.	Drug: peginterferon alfa-2a [Pegasys] 90 or 180 micrograms subcutaneous weekly for 24 weeks or 48 weeks.

Eligibility

Ages Eligible for Study: 18 Years and older
Genders Eligible for Study: Both
Accepts Healthy Volunteers: No

Criteria

Inclusion Criteria:

- adult patients, >=18 years of age;

- positive Hepatitis B surface antigen (HBsAg) for >6 months, positive HBeAg, HBV DNA >500,000 copies/mL, and anti-HBs negative;
- liver disease consistent with Chronic Hepatitis B.

Exclusion Criteria:

- antiviral therapy for CHB within previous 6 months;
- co-infection with Hepatitis A virus (HAV), Hepatitis C virus (HCV), Hepatitis D virus (HDV) or Human immuno deficiency virus (HIV);
- evidence of decompensated liver disease;
- medical condition associated with chronic liver disease.

Contacts and Locations

Locations

United States, California
Los Angeles, California, United States, 90095
Palo Alto, California, United States, 94304-1509
San Diego, California, United States, 92105
San Francisco, California, United States, 94115
San Jose, California, United States, 95116

United States, Georgia
Atlanta, Georgia, United States, 30306

United States, New York
Flushing, New York, United States, 11355

United States, Oregon
Portland, Oregon, United States, 97227

United States, Pennsylvania
Philadelphia, Pennsylvania, United States, 19141

United States, Virginia
Richmond, Virginia, United States, 23249

Australia
Fitzroy, Australia, 3065
Greenslopes, Australia, 4120
Woolloongabba, Australia, 4102

Brazil
Campinas, Brazil, 13081-970
Ribeirão Preto, Brazil, 14049-900
Salvador, Brazil, 40150-130
Santo Andre, Brazil, 09060-650
Sao Paulo, Brazil, 05403-000

China
Beijing, China, 100050
Beijing, China, 100054
Guangzhou, China, 510630
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Shanghai, China, 201508

Shanghai, China, 200025

France

Clichy, France, 92118
Montpellier, France, 34295
Nice, France, 06202
Strasbourg, France, 67091
Toulouse, France, 31078
Villejuif, France, 94804

Germany

Berlin, Germany, 13353
Frankfurt Am Main, Germany, 60590
Freiburg, Germany, 79106
Hannover, Germany, 30625
Köln, Germany, 50937

Hong Kong

Hong Kong, Hong Kong, 852
Hong Kong, Hong Kong

Korea, Republic of

Seoul, Korea, Republic of, 110-744
Seoul, Korea, Republic of, 138-736
Seoul, Korea, Republic of, 120-752

New Zealand

Auckland, New Zealand, 100
Hamilton, New Zealand

Russian Federation

Samara, Russian Federation, 443021
Smolensk, Russian Federation, 214006
St Petersburg, Russian Federation, 190103
Stavropol, Russian Federation, 355017

Singapore

Singapore, Singapore, 169608

Taiwan

Kaohsiung, Taiwan, 807
Taipei, Taiwan, 100
Taoyuan, Taiwan, 333

Thailand

Bangkok, Thailand, 10400
Bangkok, Thailand, 10400
Bangkok, Thailand, 10700
Chiang Mai, Thailand, 50202
Khon Kaen, Thailand, 40002
Songkhla, Thailand, 90112

Investigators

Study Director:	Clinical Trials	Hoffmann-La Roche

More Information

Responsible Party: Hoffmann-La Roche
Study ID Numbers: WV19432
Health Authority: United States: Food and Drug Administration

Study Results

Participant Flow

Reporting Groups

	Description
Peginterferon Alfa-2a 90 µg_24 Weeks	Participants received 90 micrograms (µg) peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 180 µg_24 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 90 µg_48 Weeks	Participants received 90 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.
Peginterferon Alfa-2a 180 µg_48 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.

Overall Study

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
Started	141	136	138	136
Received Study Drug	140	136	136	136
Entered Follow-up	140	132	135	133
Completed 24 Weeks Treatment	128	126	134	131
Completed 48 Weeks Treatment	0	0	124	117
Completed	123 [1]	124	127	120
Not Completed	18	12	11	16
Abnormality of Laboratory Test	0	1	0	0
Insufficient Therapeutic Response	3	1	0	3

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
Other Protocol Violation	1	0	0	0
Refused treatment	2	0	0	5
Failure to return	5	0	4	0
Did not receive study drug	1	0	2	0
Did not enter follow-up	0	4	1	3
Did not complete full follow-up period	6	6	4	5

[1] Completed is the number of participants who received study treatment and completed follow-up.

Baseline Characteristics

Analysis Population Description

Baseline Measures are based on participants from the Intent-to-treat population who received study drug.

Reporting Groups

	Description
Peginterferon Alfa-2a 90 µg_24 Weeks	Participants received 90 micrograms (µg) peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 180 µg_24 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 90 µg_48 Weeks	Participants received 90 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.
Peginterferon Alfa-2a 180 µg_48 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.

Baseline Measures

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks	Total
Number of Participants	140	136	136	136	548
Age, Customized [units: Years] Mean (Full Range)	31.8 (18 to 56)	33.0 (18 to 66)	33.8 (16 to 62)	33.3 (18 to 69)	32.98 (16 to 69)
Gender, Male/Female					

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks	Total
[units: participants]					
Female	44	39	40	48	171
Male	96	97	96	88	377

Outcome Measures

1. Primary Outcome Measure:

Measure Title	Percentage of Participants With Hepatitis Be Antigen (HBeAg) Seroconversion 24 Weeks Following End of Treatment
Measure Description	Blood was collected for HBeAg. HBeAg seroconversion was defined as the absence of HBeAg (a negative result for HBeAg) and the presence of anti-HBe (a positive result for anti-HBe) determined at 24 weeks after the end of treatment.
Time Frame	24 Weeks following end of treatment (Week 48 for 24 Week Treatment or Week 72 for 48 Week Treatment)
Safety Issue?	No

Analysis Population Description

Per-protocol population defined as all participants who received study drug and who did not have any major protocol deviation. Patients were analyzed according to the treatment received, rather than the randomized treatment. 10 patients in the per-protocol population switched treatment groups for the analysis.

Reporting Groups

	Description
Peginterferon Alfa-2a 90 µg_24 Weeks	Participants received 90 micrograms (µg) peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 180 µg_24 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 90 µg_48 Weeks	Participants received 90 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.
Peginterferon Alfa-2a 180 µg_48 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.

Measured Values

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
Number of Participants Analyzed	142	140	132	130

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
Percentage of Participants With Hepatitis Be Antigen (HBeAg) Seroconversion 24 Weeks Following End of Treatment [units: Percentage of participants] Number (95% Confidence Interval)	14.08 (8.82 to 20.91)	22.86 (16.19 to 30.71)	25.76 (18.54 to 34.09)	36.15 (27.91 to 45.04)

2. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Hepatitis Be Antigen (HBeAg) Seroconversion at Week 72
Measure Description	Blood was collected for HBeAg. HBeAg seroconversion was defined as the absence of HBeAg (a negative result for HBeAg) and the presence of anti-HBe (a positive result for anti-HBs) determined at Week 72.
Time Frame	Week 72
Safety Issue?	No

Analysis Population Description

Per-protocol population defined as all participants who received study drug and who did not have any major protocol deviation. Patients were analyzed according to the treatment received, rather than the randomized treatment. 10 patients in the per-protocol population switched treatment groups for the analysis.

Reporting Groups

	Description
Peginterferon Alfa-2a 90 µg_24 Weeks	Participants received 90 micrograms (µg) peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 180 µg_24 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 90 µg_48 Weeks	Participants received 90 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.
Peginterferon Alfa-2a 180 µg_48 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.

Measured Values

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
Number of Participants Analyzed	142	140	132	130

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
Percentage of Participants With Hepatitis Be Antigen (HBeAg) Seroconversion at Week 72 [units: Percentage of participants] Number (95% Confidence Interval)	18.31 (12.32 to 25.67)	27.14 (19.98 to 35.30)	25.76 (18.54 to 34.09)	36.15 (27.91 to 45.04)

3. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Loss of Hepatitis Be Antigen (HBeAg) 24 Weeks Following End of Treatment
Measure Description	Blood was collected HBeAg 24 Weeks following the end of treatment. Loss of HBeAg is defined as the absence of HBeAg.
Time Frame	24 Weeks following end of treatment (Week 48 for 24 Week Treatment or Week 72 for 48 Week Treatment)
Safety Issue?	No

Analysis Population Description

Per-protocol population defined as all participants who received study drug and who did not have any major protocol deviation. Patients were analyzed according to the treatment received, rather than the randomized treatment. 10 patients in the Per protocol population switched treatment groups for the analysis.

Reporting Groups

	Description
Peginterferon Alfa-2a 90 µg_24 Weeks	Participants received 90 micrograms (µg) peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 180 µg_24 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 90 µg_48 Weeks	Participants received 90 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.
Peginterferon Alfa-2a 180 µg_48 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.

Measured Values

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
Number of Participants Analyzed	142	140	132	130

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
Percentage of Participants With Loss of Hepatitis Be Antigen (HBeAg) 24 Weeks Following End of Treatment [units: Percentage of participants] Number (95% Confidence Interval)	14.79 (9.39 to 21.71)	22.86 (16.19 to 30.71)	26.52 (19.21 to 34.90)	36.15 (27.91 to 45.04)

4. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Hepatitis B Surface Antigen (HBsAg) Seroconversion 24 Weeks Following the End of Treatment
Measure Description	HBsAg seroconversion was defined as the absence of HBsAg (a negative result for HBsAg) and the presence of anti-HBs (a positive result for anti-HBs) determined at 24 weeks after the end of treatment.
Time Frame	24 Weeks following end of treatment (Week 48 for 24 Week Treatment or Week 72 for 48 Week Treatment)
Safety Issue?	No

Analysis Population Description

Per-protocol population defined as all participants who received study drug and who did not have any major protocol deviation. Patients were analyzed according to the treatment received, rather than the randomized treatment. 10 patients in the per-protocol population switched treatment groups for the analysis.

Reporting Groups

	Description
Peginterferon Alfa-2a 90 µg_24 Weeks	Participants received 90 micrograms (µg) peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 180 µg_24 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 90 µg_48 Weeks	Participants received 90 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.
Peginterferon Alfa-2a 180 µg_48 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.

Measured Values

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
Number of Participants Analyzed	142	140	132	130
Percentage of Participants With Hepatitis B Surface Antigen (HBsAg) Seroconversion 24 Weeks Following the End of Treatment [units: Percentage of participants] Number (95% Confidence Interval)	0.0 (0.0 to 2.56)	0.0 (0.0 to 2.60)	1.52 (0.18 to 5.37)	2.31 (0.48 to 6.60)

5. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Loss of Hepatitis B Surface Antigen (HBsAg) 24 Weeks Following End of Treatment
Measure Description	Blood was collected for HBsAg 24 weeks following the end of treatment. Loss of HBsAg is defined as the absence of HBsAg.
Time Frame	24 Weeks following end of treatment (Week 48 for 24 Week Treatment or Week 72 for 48 Week Treatment)
Safety Issue?	No

Analysis Population Description

Per-protocol population defined as all participants who received study drug and who did not have any major protocol deviation. Patients were analyzed according to the treatment received, rather than the randomized treatment. 10 patients in the per-protocol population switched treatment groups for the analysis.

Reporting Groups

	Description
Peginterferon Alfa-2a 90 µg_24 Weeks	Participants received 90 micrograms (µg) peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 180 µg_24 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 90 µg_48 Weeks	Participants received 90 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.
Peginterferon Alfa-2a 180 µg_48 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.

Measured Values

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
Number of Participants Analyzed	142	140	132	130
Percentage of Participants With Loss of Hepatitis B Surface Antigen (HBsAg) 24 Weeks Following End of Treatment [units: Percentage of participants] Number (95% Confidence Interval)	0.70 (0.02 to 3.86)	0.0 (0.00 to 2.60)	2.27 (0.47 to 6.50)	2.31 (0.48 to 6.60)

6. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Normal Alanine Aminotransferase (ALT)
Measure Description	Blood was collected 24 weeks following the end of treatment for ALT and was analyzed at a local laboratory. A normal ALT is a value within the normal range of the assay.
Time Frame	24 Weeks following end of treatment (Week 48 for 24 Week Treatment or Week 72 for 48 Week Treatment)
Safety Issue?	No

Analysis Population Description

Per-protocol population defined as all participants who received study drug and who did not have any major protocol deviation. Patients were analyzed according to the treatment received, rather than the randomized treatment. 10 patients in the per-protocol population switched treatment groups for the analysis.

Reporting Groups

	Description
Peginterferon Alfa-2a 90 µg_24 Weeks	Participants received 90 micrograms (µg) peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 180 µg_24 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 90 µg_48 Weeks	Participants received 90 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.
Peginterferon Alfa-2a 180 µg_48 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.

Measured Values

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
Number of Participants Analyzed	142	140	132	130
Percentage of Participants With Normal Alanine Aminotransferase (ALT) [units: Percentage of participants] Number (95% Confidence Interval)	30.28 (22.86 to 38.55)	30.71 (23.20 to 39.06)	43.18 (34.59 to 52.08)	52.31 (43.37 to 61.14)

7. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Hepatitis B Virus Deoxyribonucleic Acid (HBV-DNA) Suppression < 20,000 IU/mL 24 Weeks Following End of Treatment
Measure Description	Blood was collected for HBV-DNA 24 weeks following the end of treatment and was analyzed at the central laboratory using the Roche approved polymerase chain reaction (PCR) methodology. Percentage of participants with a HBV-DNA suppression of < 20,000 IU/mL (Less than 100,000 copies/mL) is reported.
Time Frame	24 Weeks following end of treatment (Week 48 for 24 Week Treatment or Week 72 for 48 Week Treatment)
Safety Issue?	No

Analysis Population Description

Per-protocol population defined as all participants who received study drug and who did not have any major protocol deviation. Patients were analyzed according to the treatment received, rather than the randomized treatment. 10 patients in the per-protocol population switched treatment groups for the analysis.

Reporting Groups

	Description
Peginterferon Alfa-2a 90 µg_24 Weeks	Participants received 90 micrograms (µg) peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 180 µg_24 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 90 µg_48 Weeks	Participants received 90 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.
Peginterferon Alfa-2a 180 µg_48 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.

Measured Values

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
Number of Participants Analyzed	142	140	132	130
Percentage of Participants With Hepatitis B Virus Deoxyribonucleic Acid (HBV-DNA) Suppression < 20,000 IU/mL 24 Weeks Following End of Treatment [units: Percentage of participants] Number (95% Confidence Interval)	21.83 (15.34 to 29.53)	21.43 (14.95 to 29.16)	32.58 (24.68 to 41.27)	42.31 (33.70 to 51.28)

8. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Hepatitis Deoxyribonucleic Acid (HBV-DNA) Suppression < 2,000 IU/mL 24 Weeks Following End of Treatment
Measure Description	Blood was collected for HBV-DNA and was analyzed at the central laboratories using the Roche approved PCR methodology 24 weeks following the end of treatment. Percentage of participants with A HBV-DNA Suppression of < 2,000 IU/mL (Less than 10,000 copies/mL) is reported.
Time Frame	24 Weeks following end of treatment (Week 48 for 24 Week Treatment of Week 72 for 48 Week Treatment)
Safety Issue?	No

Analysis Population Description

Per-protocol population defined as all participants who received study drug and who did not have any major protocol deviation. Patients were analyzed according to the treatment received, rather than the randomized treatment. 10 patients in the per-protocol population switched treatment groups for the analysis.

Reporting Groups

	Description
Peginterferon Alfa-2a 90 µg_24 Weeks	Participants received 90 micrograms (µg) peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 180 µg_24 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 90 µg_48 Weeks	Participants received 90 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.
Peginterferon Alfa-2a 180 µg_48 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.

Measured Values

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
Number of Participants Analyzed	142	140	132	130
Percentage of Participants With Hepatitis Deoxyribonucleic Acid (HBV-DNA) Suppression < 2,000 IU/mL 24 Weeks Following End of Treatment [units: Percentage of participants] Number (95% Confidence Interval)	11.27 (6.58 to 17.65)	11.43 (6.68 to 17.90)	22.73 (15.89 to 30.83)	30.0 (22.28 to 38.66)

9. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Combined Endpoint Response 24 Weeks Following End of Treatment
Measure Description	Combined endpoint was defined as HBeAg seroconversion, a normal serum ALT and HBV-DNA suppression below 20,000 IU/mL.
Time Frame	24 Weeks following end of treatment (Week 48 for 24 Week Treatment or Week 72 for 48 Week Treatment)
Safety Issue?	No

Analysis Population Description

Per-protocol population defined as all participants who received study drug and who did not have any major protocol deviation. Patients were analyzed according to the treatment received, rather than the randomized treatment. 10 patients in the per-protocol population switched treatment groups for the analysis.

Reporting Groups

	Description
Peginterferon Alfa-2a 90 µg_24 Weeks	Participants received 90 micrograms (µg) peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 180 µg_24 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 90 µg_48 Weeks	Participants received 90 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.
Peginterferon Alfa-2a 180 µg_48 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.

Measured Values

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
Number of Participants Analyzed	142	140	132	130
Percentage of Participants With Combined Endpoint Response 24 Weeks Following End of Treatment [units: Percentage of participants] Number (95% Confidence Interval)	7.75 (3.93 to 13.44)	15.0 (9.53 to 22.01)	17.42 (11.38 to 24.99)	31.54 (23.67 to 40.27)

10. Secondary Outcome Measure:

Measure Title	Percentage of Participants With Dual Endpoint Response 24 Weeks Following End of Treatment
Measure Description	Dual endpoint was defined as the achievement of both HBeAg seroconversion and a HBV-DNA <2,000 IU/ml (Less than 10,000 copies/mL).
Time Frame	24 Weeks following end of treatment (Week 48 for 24 Week Treatment or Week 72 for 48 Week Treatment)
Safety Issue?	No

Analysis Population Description

Per-protocol population defined as all participants who received study drug and who did not have any major protocol deviation. Patients were analyzed according to the treatment received, rather than the randomized treatment. 10 patients in the per-protocol population switched treatment groups for the analysis.

Reporting Groups

	Description
Peginterferon Alfa-2a 90 µg_24 Weeks	Participants received 90 micrograms (µg) peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 180 µg_24 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 90 µg_48 Weeks	Participants received 90 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.
Peginterferon Alfa-2a 180 µg_48 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.

Measured Values

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
Number of Participants Analyzed	142	140	132	130
Percentage of Participants With Dual Endpoint Response 24 Weeks Following End of Treatment [units: Percentage of participants] Number (95% Confidence Interval)	7.75 (3.93 to 13.44)	9.29 (5.04 to 15.36)	13.64 (8.29 to 20.69)	24.62 (17.49 to 32.94)

11. Secondary Outcome Measure:

Measure Title	Quantitative Serum Alanine Aminotransferase (ALT) 24 Weeks Following End of Treatment
Measure Description	Blood was collected 24 weeks following the end of treatment for ALT and was analyzed at a local laboratory. A normal ALT is a value within the normal range of the assay: 0- 55 units/liter (U/L).
Time Frame	24 Weeks following end of treatment (Week 48 for 24 Week Treatment or Week 72 for 48 Week Treatment)
Safety Issue?	No

Analysis Population Description

Participants from the Per-protocol population defined as all participants who received study drug and who did not have any major protocol deviation who had data available for analysis. Patients were analyzed according to the treatment received. 10 patients in the per-protocol population switched treatment groups for the analysis.

Reporting Groups

	Description
Peginterferon Alfa-2a 90 µg_24 Weeks	Participants received 90 micrograms (µg) peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 180 µg_24 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 90 µg_48 Weeks	Participants received 90 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.
Peginterferon Alfa-2a 180 µg_48 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.

Measured Values

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
Number of Participants Analyzed	131	133	126	124
Quantitative Serum Alanine Aminotransferase (ALT) 24 Weeks Following End of Treatment [units: U/L] Mean (95% Confidence Interval)	1.90 (1.84 to 1.96)	1.97 (1.90 to 2.05)	1.90 (1.82 to 1.98)	1.73 (1.67 to 1.79)

12. Secondary Outcome Measure:

Measure Title	Quantitative HBV-DNA 24 Weeks Following End of Treatment
Measure Description	Blood was collected for HBV-DNA and was analyzed at the central laboratories using the Roche approved PCR methodology 24 weeks following the end of treatment.
Time Frame	24 Weeks following end of treatment (Week 48 for 24 Week Treatment or Week 72 for 48 Week Treatment)
Safety Issue?	No

Analysis Population Description

Participants from the Per-protocol population defined as all participants who received study drug and who did not have any major protocol deviation who had data available for analysis. Patients were analyzed according to the treatment received. 10 patients in the per-protocol population switched treatment groups for the analysis.

Reporting Groups

	Description
Peginterferon Alfa-2a 90 µg_24 Weeks	Participants received 90 micrograms (µg) peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 180 µg_24 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 90 µg_48 Weeks	Participants received 90 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.
Peginterferon Alfa-2a 180 µg_48 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.

Measured Values

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
Number of Participants Analyzed	128	129	125	124
Quantitative HBV-DNA 24 Weeks Following End of Treatment [units: IU/mL Log10] Mean (95% Confidence Interval)	6.33 (5.93 to 6.72)	6.38 (5.99 to 6.76)	5.98 (5.51 to 6.45)	5.29 (4.81 to 5.78)

Reported Adverse Events

Time Frame	[Not specified]
Additional Description	Safety set included randomized patients who received study drug and had at least 1 post-baseline assessment. 1 patient in the PEG-IFN 180 µg 24 week arm had no post-baseline assessments. 10 patients actually received drug for less time and switched arms for analysis (4 PEG-IFN 90 µg 48 weeks to 24 weeks and 6 PEG-IFN 180 µg 48 weeks to 24 weeks.

Reporting Groups

	Description
Peginterferon Alfa-2a 90 µg_24 Weeks	Participants received 90 micrograms (µg) peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 180 µg_24 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 24 weeks.
Peginterferon Alfa-2a 90 µg_48 Weeks	Participants received 90 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.
Peginterferon Alfa-2a 180 µg_48 Weeks	Participants received 180 µg peginterferon alfa-2a subcutaneous once a week for 48 weeks.

Serious Adverse Events

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	4/144 (2.78%)	4/141 (2.84%)	6/132 (4.55%)	5/130 (3.85%)

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Cardiac disorders				
Pericarditis [A] †	0/144 (0%)	0/141 (0%)	1/132 (0.76%)	0/130 (0%)
General disorders				
Malaise [A] †	0/144 (0%)	0/141 (0%)	1/132 (0.76%)	0/130 (0%)
Immune system disorders				
Drug hypersensitivity [A] †	1/144 (0.69%)	0/141 (0%)	0/132 (0%)	1/130 (0.77%)
Infections and infestations				
Appendicitis [A] †	1/144 (0.69%)	0/141 (0%)	0/132 (0%)	0/130 (0%)
Extradural abscess [A] †	0/144 (0%)	0/141 (0%)	0/132 (0%)	1/130 (0.77%)
Hepatitis B [A] †	1/144 (0.69%)	1/141 (0.71%)	1/132 (0.76%)	0/130 (0%)
Viral infection [A] †	0/144 (0%)	0/141 (0%)	1/132 (0.76%)	0/130 (0%)
Injury, poisoning and procedural complications				
Clavicle fracture [A] †	0/144 (0%)	0/141 (0%)	0/132 (0%)	1/130 (0.77%)
Foot fracture [A] †	1/144 (0.69%)	0/141 (0%)	0/132 (0%)	0/130 (0%)
Ligament injury [A] †	0/144 (0%)	0/141 (0%)	0/132 (0%)	1/130 (0.77%)
Rib fracture [A] †	0/144 (0%)	0/141 (0%)	0/132 (0%)	2/130 (1.54%)
Investigations				
Alanine aminotransferase increased [A] †	1/144 (0.69%)	0/141 (0%)	1/132 (0.76%)	0/130 (0%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)				
Adrenal adenoma [A] †	0/144 (0%)	0/141 (0%)	1/132 (0.76%)	0/130 (0%)
Nervous system disorders				
Cerebral haemorrhage [A] †	0/144 (0%)	1/141 (0.71%)	0/132 (0%)	0/130 (0%)
Spinal cord compression [A] †	0/144 (0%)	0/141 (0%)	0/132 (0%)	1/130 (0.77%)

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Renal and urinary disorders				
Calculus urinary [A] †	0/144 (0%)	1/141 (0.71%)	0/132 (0%)	0/130 (0%)
Respiratory, thoracic and mediastinal disorders				
Pleurisy [A] †	0/144 (0%)	1/141 (0.71%)	0/132 (0%)	0/130 (0%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (13.0)

Other Adverse Events

Frequency Threshold Above Which Other Adverse Events are Reported: 5%

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Total	94/144 (65.28%)	109/141 (77.3%)	92/132 (69.7%)	105/130 (80.77%)
Gastrointestinal disorders				
Diarrhoea [A] †	4/144 (2.78%)	4/141 (2.84%)	7/132 (5.3%)	14/130 (10.77%)
Dyspepsia [A] †	4/144 (2.78%)	1/141 (0.71%)	6/132 (4.55%)	10/130 (7.69%)
Nausea [A] †	3/144 (2.08%)	5/141 (3.55%)	3/132 (2.27%)	8/130 (6.15%)
General disorders				
Fatigue [A] †	27/144 (18.75%)	20/141 (14.18%)	29/132 (21.97%)	32/130 (24.62%)
Malaise [A] †	1/144 (0.69%)	9/141 (6.38%)	8/132 (6.06%)	6/130 (4.62%)
Pyrexia [A] †	40/144 (27.78%)	50/141 (35.46%)	43/132 (32.58%)	46/130 (35.38%)
Infections and infestations				
Nasopharyngitis [A] †	8/144 (5.56%)	7/141 (4.96%)	11/132 (8.33%)	8/130 (6.15%)
Upper respiratory tract infection [A] †	7/144 (4.86%)	6/141 (4.26%)	4/132 (3.03%)	9/130 (6.92%)
Metabolism and nutrition disorders				

	Peginterferon Alfa-2a 90 µg_24 Weeks	Peginterferon Alfa-2a 180 µg_24 Weeks	Peginterferon Alfa-2a 90 µg_48 Weeks	Peginterferon Alfa-2a 180 µg_48 Weeks
	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)	Affected/At Risk (%)
Decreased appetite [A] †	6/144 (4.17%)	10/141 (7.09%)	10/132 (7.58%)	13/130 (10%)
Musculoskeletal and connective tissue disorders				
Arthralgia [A] †	8/144 (5.56%)	6/141 (4.26%)	6/132 (4.55%)	8/130 (6.15%)
Myalgia [A] †	28/144 (19.44%)	35/141 (24.82%)	19/132 (14.39%)	37/130 (28.46%)
Nervous system disorders				
Dizziness [A] †	5/144 (3.47%)	8/141 (5.67%)	5/132 (3.79%)	10/130 (7.69%)
Headache [A] †	23/144 (15.97%)	35/141 (24.82%)	23/132 (17.42%)	25/130 (19.23%)
Psychiatric disorders				
Insomnia [A] †	8/144 (5.56%)	11/141 (7.8%)	11/132 (8.33%)	16/130 (12.31%)
Respiratory, thoracic and mediastinal disorders				
Cough [A] †	10/144 (6.94%)	9/141 (6.38%)	3/132 (2.27%)	3/130 (2.31%)
Oropharyngeal pain [A] †	3/144 (2.08%)	2/141 (1.42%)	4/132 (3.03%)	6/130 (4.62%)
Skin and subcutaneous tissue disorders				
Alopecia [A] †	17/144 (11.81%)	24/141 (17.02%)	26/132 (19.7%)	41/130 (31.54%)
Pruritus [A] †	5/144 (3.47%)	5/141 (3.55%)	4/132 (3.03%)	11/130 (8.46%)
Rash [A] †	7/144 (4.86%)	7/141 (4.96%)	5/132 (3.79%)	11/130 (8.46%)

† Indicates events were collected by systematic assessment.
A Term from vocabulary, MedDRA (13.0)

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.

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