Efficacy and Safety of Telbivudine in Treatment naïve Patients With Hepatitis B e Antigen (HBeAg)-Positive Chronic Hepatitis B (CHB)

This study has been terminated.
(Enrollment stopped for safety issues)

Sponsor:
Novartis

Information provided by:
Novartis

ClinicalTrials.gov Identifier:
NCT00412750

First received: December 15, 2006
Last updated: June 14, 2011
Last verified: June 2011
History of Changes

Results First Received: December 2, 2010

Study Type:	Interventional
Study Design:	Allocation: Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Parallel Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Hepatitis B
Interventions:	Drug: Telbivudine (LdT) Drug: peginterferon alpha-2a

Participant Flow

Hide Participant Flow

Recruitment Details

Key information relevant to the recruitment process for the overall study, such as dates of the recruitment period and locations
This is a randomized, open-label, controlled, multi-center two-year study enrolling male and female subjects starting December 2006 and ending February 2009.

Pre-Assignment Details

Significant events and approaches for the overall study following participant enrollment, but prior to group assignment
No text entered.

Reporting Groups

	Description
LdT + PEG-INF	Telbivudine (LdT) 600 mg orally once a day for 104 weeks in combination with peg interferon (PEG-INF) alpha-2a 180 µg subcutaneous injection once a week for 52 weeks.
LdT Monotherapy	Telbivudine (LdT) monotherapy: 600 mg orally once daily for 104 weeks.
PEG-INF Monotherapy	Peg interferon (PEG- INF) alpha-2a monotherapy: 180 µg subcutaneous injection once a week for 52 weeks.

Participant Flow: Overall Study

	LdT + PEG-INF	LdT Monotherapy	PEG-INF Monotherapy

STARTED	**50**	**55**	**54**
COMPLETED	**19**	**34**	**31**
NOT COMPLETED	**31**	**21**	**23**
Abnormal laboratory value(s)	**1**	**0**	**0**
Administrative problems	**21**	**17**	**14**
Adverse Event	**8**	**3**	**3**
Lost to Follow-up	**1**	**0**	**1**
Withdrawal by Subject	**0**	**1**	**2**
Lack of Efficacy	**0**	**0**	**3**

Baseline Characteristics

Hide Baseline Characteristics

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
No text entered.

Reporting Groups

	Description
LdT + PEG-INF	Telbivudine (LdT) 600 mg orally once a day for 104 weeks in combination with peg interferon (PEG-INF) alpha-2a 180 µg subcutaneous injection once a week for 52 weeks.
LdT Monotherapy	Telbivudine (LdT) monotherapy: 600 mg orally once daily for 104 weeks.
PEG-INF Monotherapy	Peg interferon (PEG- INF) alpha-2a monotherapy: 180 µg subcutaneous injection once a week for 52 weeks.
Total	Total of all reporting groups

Baseline Measures

	LdT + PEG-INF	**LdT Monotherapy**	**PEG-INF Monotherapy**	**Total**
Number of Participants [units: participants]	**50**	**55**	**54**	**159**
Age [units: years] Mean (Standard Deviation)	**35.6 (10.00)**	**35.0 (11.48)**	**33.8 (9.47)**	**34.7 (10.33)**
Gender [units: participants]				
Female	**16**	**15**	**20**	**51**
Male	**34**	**40**	**34**	**108**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants Who Achieved HBV DNA Non-detectability With Peginterferon Alpha-2a Plus Telbivudine Combination Therapy Versus Peginterferon Alpha-2a Monotherapy [Time Frame: At week 52]

Measure Type	Primary

Measure Title	Percentage of Participants Who Achieved HBV DNA Non-detectability With Peginterferon Alpha-2a Plus Telbivudine Combination Therapy Versus Peginterferon Alpha-2a Monotherapy
Measure Description	The original primary efficacy variable was the percentage of patients achieving HBV DNA non-detectability utilizing polymerase chain reaction (PCR) (threshold for detection 300 copies/mL); however, this analysis was not performed due to premature study termination.
Time Frame	At week 52
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The analysis was planned on intention to treat (ITT) population. Due to premature study termination, the analysis was not performed.

Reporting Groups

	Description
LdT + PEG-INF	Telbivudine (LdT) 600 mg orally once a day for 104 weeks in combination with peg interferon (PEG-INF) alpha-2a 180 µg subcutaneous injection once a week for 52 weeks.
PEG-INF Monotherapy	Peg interferon (PEG- INF) alpha-2a monotherapy: 180 µg subcutaneous injection once a week for 52 weeks.

Measured Values

	LdT + PEG-INF	**PEG-INF Monotherapy**
Number of Participants Analyzed [units: participants]	**0**	**0**
Percentage of Participants Who Achieved HBV DNA Non-detectability With Peginterferon Alpha-2a Plus Telbivudine Combination Therapy Versus Peginterferon Alpha-2a Monotherapy [units: Percentage of participants]		

No statistical analysis provided for Percentage of Participants Who Achieved HBV DNA Non-detectability With Peginterferon Alpha-2a Plus Telbivudine Combination Therapy Versus Peginterferon Alpha-2a Monotherapy

2. Primary: Percentage of Participants With HBV DNA Non-detectability and Alanine Aminotransferase (ALT) Normalization at Week 12 and Week 24 in Participants With HBeAg-positive Chronic Hepatitis B (CHB) [Time Frame: Weeks 12 and 24]

Measure Type	Primary
Measure Title	Percentage of Participants With HBV DNA Non-detectability and Alanine Aminotransferase (ALT) Normalization at Week 12 and Week 24 in Participants With HBeAg-positive Chronic Hepatitis B (CHB)
Measure Description	The percentage of participants who achieved HBV DNA non-detectability using the COBAS Amplicor HBV Monitor assay utilizing polymerase chain reaction (PCR) (threshold for detection 300 copies/mL) and Alanine aminotransferase (ALT) normalization defined as ALT within normal limits on two successive visits for a patient with an elevated ALT (>1.0 x upper limit normal) at baseline summarized at Weeks 12 and 24.
Time Frame	Weeks 12 and 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to Treat (ITT) population. The study was terminated and some participants did not complete all visits. "n" in each of the categories represents the number of participants in each arm with non-missing efficacy endpoint observations for the respective week.

Reporting Groups

	Description
LdT + PEG-INF	Telbivudine (LdT) 600 mg orally once a day for 104 weeks in combination with peg interferon (PEG-INF) alpha-2a 180 µg subcutaneous injection once a week for 52 weeks.
LdT Monotherapy	Telbivudine (LdT) monotherapy: 600 mg orally once daily for 104 weeks.
PEG-INF Monotherapy	Peg interferon (PEG- INF) alpha-2a monotherapy: 180 µg subcutaneous injection once a week for 52 weeks.

Measured Values

	LdT + PEG-INF	LdT Monotherapy	PEG-INF Monotherapy
Number of Participants Analyzed [units: participants]	**49**	**53**	**53**
Percentage of Participants With HBV DNA Non-detectability and Alanine Aminotransferase (ALT) Normalization at Week 12 and Week 24 in Participants With HBeAg-positive Chronic Hepatitis B (CHB) [units: Percentage of participants]			
HBV DNA non-detectability Week 12 (n=37,52,50)	**13.5**	**9.6**	**0.0**
ALT normalization Week 12 (n=37,52,50)	**13.5**	**28.8**	**20.0**
HBV DNA non-detectability Week 24 (n=17,48,42)	**70.6**	**35.4**	**7.1**
ALT normalization Week 24 (n=17,48,41)	**11.8**	**54.2**	**31.7**

No statistical analysis provided for Percentage of Participants With HBV DNA Non-detectability and Alanine Aminotransferase (ALT) Normalization at Week 12 and Week 24 in Participants With HBeAg-positive Chronic Hepatitis B (CHB)

3. Secondary: Change From Baseline in HBV DNA Concentration [Time Frame: Weeks 12 and 24]

Measure Type	Secondary
Measure Title	Change From Baseline in HBV DNA Concentration
Measure Description	The change from baseline in HBV DNA concentration at Weeks 12 and 24 was analyzed using an analysis of covariance (ANCOVA) model with baseline HBV DNA concentration (log10 copies/ml) as a covariate, treatment and country as factors.
Time Frame	Weeks 12 and 24
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to Treat (ITT) population. n= the number of patients who have both baseline and post baseline observation for the respective week

Reporting Groups

	Description
LdT + PEG-INF	Telbivudine (LdT) 600 mg orally once a day for 104 weeks in combination with peg interferon (PEG-INF) alpha-2a 180 µg subcutaneous injection once a week for 52 weeks.
LdT Monotherapy	Telbivudine (LdT) monotherapy: 600 mg orally once daily for 104 weeks.
PEG-INF Monotherapy	Peg interferon (PEG- INF) alpha-2a monotherapy: 180 µg subcutaneous injection once a week for 52 weeks.

Measured Values

	LdT + PEG-INF	LdT Monotherapy	PEG-INF Monotherapy
Number of Participants Analyzed [units: participants]	**49**	**53**	**53**
Change From Baseline in HBV DNA Concentration [units: log 10 copies/ml] Least Squares Mean (Standard Error)			
Week 12 (n= 37, 52, 50)	**-6.0569 (0.3124)**	**-5.1658 (0.2717)**	**-1.8991 (0.2607)**
Week 24 (n= 17, 48, 42)	**-6.9187 (0.5462)**	**-5.9633 (0.3523)**	**-2.4513 (0.3485)**

No statistical analysis provided for Change From Baseline in HBV DNA Concentration

4. Secondary: Percentage of Participants Who Experienced Virologic Breakthrough at Weeks 48 and 52 [Time Frame: Weeks 48 and 52]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Experienced Virologic Breakthrough at Weeks 48 and 52
Measure Description	The percentage of participants with Virologic breakthrough at Week 48 and 52 by treatment. For the subgroup of patients on treatment who achieve HBV DNA >= 1 log10 copies/mL reduction from baseline on 2 consecutive visits, Virologic Breakthrough is defined as HBV DNA >= 1 log10 copies/mL from nadir on two consecutive visits.
Time Frame	Weeks 48 and 52
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to treat (ITT) population. As most patients did not reach Week 48 and Week 52, the LOCF was used.

Reporting Groups

	Description
LdT + PEG-INF	Telbivudine (LdT) 600 mg orally once a day for 104 weeks in combination with peg interferon (PEG-INF) alpha-2a 180 µg subcutaneous injection once a week for 52 weeks.
LdT Monotherapy	Telbivudine (LdT) monotherapy: 600 mg orally once daily for 104 weeks.
PEG-INF Monotherapy	Peg interferon (PEG- INF) alpha-2a monotherapy: 180 µg subcutaneous injection once a week for 52 weeks.

Measured Values

	LdT + PEG-INF	LdT Monotherapy	PEG-INF Monotherapy
Number of Participants Analyzed [units: participants]	**49**	**53**	**53**
Percentage of Participants Who Experienced Virologic Breakthrough at Weeks 48 and 52 [units: Percentage of participants]			
Virologic breakthrough Week 48	**0.0**	**5.7**	**7.5**
Virologic breakthrough Week 52	**0.0**	**7.5**	**9.4**

No statistical analysis provided for Percentage of Participants Who Experienced Virologic Breakthrough at Weeks 48 and 52

5. Secondary: Percentage of Participants With Hepatitis B 'e' Antigen (HBeAg) Loss and HBeAg Seroconversion [Time Frame: Weeks 18, 24,

48, 52 and Treatment completion (TC)]

Measure Type	Secondary
Measure Title	Percentage of Participants With Hepatitis B 'e' Antigen (HBeAg) Loss and HBeAg Seroconversion
Measure Description	HBeAg loss is defined as the loss of detectable serum HBeAg in a patient who was HBeAg positive at baseline. HBeAg seroconversion is defined as HBeAg loss with detectable Hepatitis B 'e' antibody (HBeAb). The efficacy was assessed for 18 weeks, 24 weeks, 48 weeks, 52 weeks and on treatment completion (TC).
Time Frame	Weeks 18, 24, 48, 52 and Treatment completion (TC)
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
Intent to Treat (ITT) population. The study was terminated and some participants did not complete all visits. "n" in each of the categories represents the number of participants in each arm with non-missing efficacy endpoint observations for the respective week and on treatment completion (TC).

Reporting Groups

	Description
LdT + PEG-INF	Telbivudine (LdT) 600 mg orally once a day for 104 weeks in combination with peg interferon (PEG-INF) alpha-2a 180 µg subcutaneous injection once a week for 52 weeks.
LdT Monotherapy	Telbivudine (LdT) monotherapy: 600 mg orally once daily for 104 weeks.
PEG-INF Monotherapy	Peg interferon (PEG- INF) alpha-2a monotherapy: 180 µg subcutaneous injection once a week for 52 weeks.

Measured Values

	LdT + PEG-INF	**LdT Monotherapy**	**PEG-INF Monotherapy**
Number of Participants Analyzed [units: participants]	**49**	**53**	**53**
Percentage of Participants With Hepatitis B 'e' Antigen (HBeAg) Loss and HBeAg Seroconversion [units: Percentage of participants]			
HBeAg loss Week 18 (n=28,51,45)	**17.9**	**7.8**	**8.9**
HBeAg seroconversion Week 18 (n=28,51,45)	**17.9**	**7.8**	**8.9**
HBeAg loss Week 24 (n=17,48,42)	**17.6**	**6.3**	**11.9**
HBeAg seroconversion Week 24 (n=17,48,42)	**7.6**	**4.2**	**11.9**
HBeAg loss Week 48 (n=0,19,12)	**NA** [1]	**36.8**	**25.0**
HBeAg seroconversion Week 48 (n=0,19,12)	**NA** [1]	**36.8**	**25.0**
HBeAg loss Week 52 (n=0,10,6)	**NA** [1]	**50.0**	**16.7**
HBeAg seroconversion Week 52 (n=0,10,6)	**NA** [1]	**50.0**	**16.7**
HBeAg loss TC (n=14,24,9)	**7.1**	**29.2**	**33.3**
HBeAg seroconversion TC (n=14,24,9)	**7.1**	**25.0**	**33.3**

[1] Participants in the LdT + PEG-INF arm were discontinued prior to week 48, hence no data is available

No statistical analysis provided for Percentage of Participants With Hepatitis B 'e' Antigen (HBeAg) Loss and HBeAg Seroconversion

6. Secondary: Percentage of Participants Who Achieved HBV DNA Non-detectability With Telbivudine Monotherapy Versus Peginterferon Alpha-2a Monotherapy [Time Frame: Week 52]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Achieved HBV DNA Non-detectability With Telbivudine Monotherapy Versus Peginterferon Alpha-2a Monotherapy
Measure Description	Antiviral efficacy was assessed by percentage of patients achieving HBV DNA non-detectability assay utilizing polymerase chain reaction (PCR) (threshold for detection 300 copies/mL); however, this analysis was not performed due to premature study termination.
Time Frame	Week 52
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.
The analysis was planned on intent to treat (ITT) population. Due to premature study termination, the analysis was not performed.

Reporting Groups

	Description
LdT Monotherapy	Telbivudine (LdT) monotherapy: 600 mg orally once daily for 104 weeks.
PEG-INF Monotherapy	Peg interferon (PEG- INF) alpha-2a monotherapy: 180 µg subcutaneous injection once a week for 52 weeks.

Measured Values

	LdT Monotherapy	**PEG-INF Monotherapy**
Number of Participants Analyzed [units: participants]	**0**	**0**
Percentage of Participants Who Achieved HBV DNA Non-detectability With Telbivudine Monotherapy Versus Peginterferon Alpha-2a Monotherapy [units: Percentage of participants]		

No statistical analysis provided for Percentage of Participants Who Achieved HBV DNA Non-detectability With Telbivudine Monotherapy Versus Peginterferon Alpha-2a Monotherapy

7. Secondary: Percentage of Participants Who Achieved HBV DNA Non-detectability With Peginterferon Alpha-2a Plus Telbivudine Combination Therapy Versus Telbivudine Monotherapy [Time Frame: Week 52]

Measure Type	Secondary
Measure Title	Percentage of Participants Who Achieved HBV DNA Non-detectability With Peginterferon Alpha-2a Plus Telbivudine Combination Therapy Versus Telbivudine Monotherapy
Measure Description	Antiviral efficacy was assessed by percentage of patients achieving HBV DNA non-detectability assay utilizing polymerase chain reaction (PCR) (threshold for detection 300 copies/mL); however, this analysis was not performed due to premature study termination.
Time Frame	Week 52
Safety Issue	No

Population Description

Explanation of how the number of participants for analysis was determined. Includes whether analysis was per protocol, intention to treat, or another method. Also provides relevant details such as imputation technique, as appropriate.

The analysis was planned on intent to treat (ITT) population. Due to premature study termination, the analysis was not performed.

Reporting Groups

	Description
LdT + PEG-INF	Telbivudine (LdT) 600 mg orally once a day for 104 weeks in combination with peg interferon (PEG-INF) alpha-2a 180 µg subcutaneous injection once a week for 52 weeks.
LdT Monotherapy	Telbivudine (LdT) monotherapy: 600 mg orally once daily for 104 weeks.

Measured Values

	LdT + PEG-INF	LdT Monotherapy
Number of Participants Analyzed [units: participants]	**0**	**0**
Percentage of Participants Who Achieved HBV DNA Non-detectability With Peginterferon Alpha-2a Plus Telbivudine Combination Therapy Versus Telbivudine Monotherapy [units: percentage of participants]		

No statistical analysis provided for Percentage of Participants Who Achieved HBV DNA Non-detectability With Peginterferon Alpha-2a Plus Telbivudine Combination Therapy Versus Telbivudine Monotherapy

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	Safety Population defined as all patients who received one dose of study drug and had at least one post baseline assessment.

Reporting Groups

	Description
LdT + PEG-INF	Telbivudine (LdT) 600 mg orally once a day for 104 weeks in combination with peg interferon (PEG-INF) alpha-2a 180 µg subcutaneous injection once a week for 52 weeks.
LdT Monotherapy	Telbivudine (LdT) monotherapy: 600 mg orally once daily for 104 weeks.
PEG-INF Monotherapy	Peg interferon (PEG- INF) alpha-2a monotherapy: 180 µg subcutaneous injection once a week for 52 weeks.

Serious Adverse Events

	LdT + PEG-INF	LdT Monotherapy	PEG-INF Monotherapy
Total, serious adverse events			
# participants affected / at risk	**11/50 (22.00%)**	**2/54 (3.70%)**	**2/54 (3.70%)**
Congenital, familial and genetic disorders			
Mitochondrial myopathy † 1			
# participants affected / at risk	**1/50 (2.00%)**	**0/54 (0.00%)**	**0/54 (0.00%)**
General disorders			
Chest pain † 1			
# participants affected / at risk	**1/50 (2.00%)**	**0/54 (0.00%)**	**0/54 (0.00%)**
Pyrexia † 1			
# participants affected / at risk	**0/50 (0.00%)**	**0/54 (0.00%)**	**1/54 (1.85%)**

Hepatobiliary disorders			
Hepatitis † 1			
# participants affected / at risk	**1/50 (2.00%)**	**0/54 (0.00%)**	**0/54 (0.00%)**
Infections and infestations			
Appendicitis † 1			
# participants affected / at risk	**0/50 (0.00%)**	**0/54 (0.00%)**	**1/54 (1.85%)**
Urinary tract infection † 1			
# participants affected / at risk	**0/50 (0.00%)**	**0/54 (0.00%)**	**1/54 (1.85%)**
Investigations			
Blood creatine phosphokinase increased † 1			
# participants affected / at risk	**1/50 (2.00%)**	**0/54 (0.00%)**	**0/54 (0.00%)**
Musculoskeletal and connective tissue disorders			
Myopathy † 1			
# participants affected / at risk	**1/50 (2.00%)**	**0/54 (0.00%)**	**0/54 (0.00%)**
Nervous system disorders			
Dysaesthesia † 1			
# participants affected / at risk	**0/50 (0.00%)**	**1/54 (1.85%)**	**0/54 (0.00%)**
Hypoaesthesia † 1			
# participants affected / at risk	**1/50 (2.00%)**	**1/54 (1.85%)**	**0/54 (0.00%)**
Neuropathy peripheral † 1			
# participants affected / at risk	**3/50 (6.00%)**	**0/54 (0.00%)**	**0/54 (0.00%)**
Paraesthesia † 1			
# participants affected / at risk	**0/50 (0.00%)**	**1/54 (1.85%)**	**0/54 (0.00%)**
Peripheral sensory neuropathy † 1			
# participants affected / at risk	**2/50 (4.00%)**	**1/54 (1.85%)**	**0/54 (0.00%)**
Polyneuropathy † 1			
# participants affected / at risk	**1/50 (2.00%)**	**0/54 (0.00%)**	**0/54 (0.00%)**
Psychiatric disorders			
Depression suicidal † 1			
# participants affected / at risk	**1/50 (2.00%)**	**0/54 (0.00%)**	**0/54 (0.00%)**
Respiratory, thoracic and mediastinal disorders			
Dyspnoea † 1			
# participants affected / at risk	**1/50 (2.00%)**	**0/54 (0.00%)**	**0/54 (0.00%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Other Adverse Events

Hide Other Adverse Events

Time Frame	No text entered.
Additional Description	Safety Population defined as all patients who received one dose of study drug and had at least one post baseline assessment.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
LdT + PEG-INF	Telbivudine (LdT) 600 mg orally once a day for 104 weeks in combination with peg interferon (PEG-INF) alpha-2a 180 µg subcutaneous injection once a week for 52 weeks.
LdT Monotherapy	Telbivudine (LdT) monotherapy: 600 mg orally once daily for 104 weeks.
PEG-INF Monotherapy	Peg interferon (PEG- INF) alpha-2a monotherapy: 180 µg subcutaneous injection once a week for 52 weeks.

Other Adverse Events

	LdT + PEG-INF	LdT Monotherapy	PEG-INF Monotherapy
Total, other (not including serious) adverse events			
# participants affected / at risk	**38/50 (76.00%)**	**35/54 (64.81%)**	**47/54 (87.04%)**
Blood and lymphatic system disorders			
Leukopenia † [1]			
# participants affected / at risk	**1/50 (2.00%)**	**0/54 (0.00%)**	**5/54 (9.26%)**
Neutropenia † [1]			
# participants affected / at risk	**2/50 (4.00%)**	**0/54 (0.00%)**	**4/54 (7.41%)**
Thrombocytopenia † [1]			
# participants affected / at risk	**2/50 (4.00%)**	**0/54 (0.00%)**	**4/54 (7.41%)**
Ear and labyrinth disorders			
Tinnitus † [1]			
# participants affected / at risk	**1/50 (2.00%)**	**3/54 (5.56%)**	**0/54 (0.00%)**
Gastrointestinal disorders			
Abdominal distension † [1]			
# participants affected / at risk	**2/50 (4.00%)**	**3/54 (5.56%)**	**3/54 (5.56%)**
Abdominal pain † [1]			
# participants affected / at risk	**1/50 (2.00%)**	**3/54 (5.56%)**	**2/54 (3.70%)**
Abdominal pain upper † [1]			
# participants affected / at risk	**3/50 (6.00%)**	**2/54 (3.70%)**	**2/54 (3.70%)**
Diarrhoea † [1]			
# participants affected / at risk	**6/50 (12.00%)**	**3/54 (5.56%)**	**4/54 (7.41%)**
Dry mouth † [1]			
# participants affected / at risk	**1/50 (2.00%)**	**1/54 (1.85%)**	**3/54 (5.56%)**
Nausea † [1]			
# participants affected / at risk	**10/50 (20.00%)**	**4/54 (7.41%)**	**9/54 (16.67%)**
Vomiting † [1]			
# participants affected / at risk	**2/50 (4.00%)**	**1/54 (1.85%)**	**3/54 (5.56%)**
General disorders			
Asthenia † [1]			
# participants affected / at risk	**8/50 (16.00%)**	**6/54 (11.11%)**	**10/54 (18.52%)**
Fatigue † [1]			
# participants affected / at risk	**8/50 (16.00%)**	**3/54 (5.56%)**	**7/54 (12.96%)**

Influenza like illness [†1]			
# participants affected / at risk	8/50 (16.00%)	2/54 (3.70%)	12/54 (22.22%)
Irritability [†1]			
# participants affected / at risk	2/50 (4.00%)	2/54 (3.70%)	4/54 (7.41%)
Pain [†1]			
# participants affected / at risk	3/50 (6.00%)	2/54 (3.70%)	4/54 (7.41%)
Pyrexia [†1]			
# participants affected / at risk	11/50 (22.00%)	2/54 (3.70%)	13/54 (24.07%)
Infections and infestations			
Influenza [†1]			
# participants affected / at risk	1/50 (2.00%)	2/54 (3.70%)	5/54 (9.26%)
Nasopharyngitis [†1]			
# participants affected / at risk	0/50 (0.00%)	4/54 (7.41%)	2/54 (3.70%)
Sinusitis [†1]			
# participants affected / at risk	0/50 (0.00%)	3/54 (5.56%)	0/54 (0.00%)
Upper respiratory tract infection [†1]			
# participants affected / at risk	4/50 (8.00%)	11/54 (20.37%)	10/54 (18.52%)
Investigations			
Blood creatine phosphokinase increased [†1]			
# participants affected / at risk	4/50 (8.00%)	2/54 (3.70%)	0/54 (0.00%)
Neutrophil count decreased [†1]			
# participants affected / at risk	0/50 (0.00%)	0/54 (0.00%)	3/54 (5.56%)
Weight decreased [†1]			
# participants affected / at risk	3/50 (6.00%)	0/54 (0.00%)	1/54 (1.85%)
Metabolism and nutrition disorders			
Anorexia [†1]			
# participants affected / at risk	5/50 (10.00%)	3/54 (5.56%)	4/54 (7.41%)
Decreased appetite [†1]			
# participants affected / at risk	2/50 (4.00%)	2/54 (3.70%)	3/54 (5.56%)
Musculoskeletal and connective tissue disorders			
Arthralgia [†1]			
# participants affected / at risk	9/50 (18.00%)	1/54 (1.85%)	0/54 (0.00%)
Myalgia [†1]			
# participants affected / at risk	14/50 (28.00%)	5/54 (9.26%)	9/54 (16.67%)
Pain in extremity [†1]			
# participants affected / at risk	2/50 (4.00%)	0/54 (0.00%)	4/54 (7.41%)
Nervous system disorders			
Headache [†1]			
# participants affected / at risk	8/50 (16.00%)	9/54 (16.67%)	17/54 (31.48%)
Lethargy [†1]			
# participants affected / at risk	3/50 (6.00%)	0/54 (0.00%)	2/54 (3.70%)
Paraesthesia [†1]			
# participants affected / at risk	6/50 (12.00%)	0/54 (0.00%)	2/54 (3.70%)
Psychiatric disorders			

Anxiety † 1			
# participants affected / at risk	**3/50 (6.00%)**	**0/54 (0.00%)**	**2/54 (3.70%)**
Depression † 1			
# participants affected / at risk	**0/50 (0.00%)**	**0/54 (0.00%)**	**5/54 (9.26%)**
Insomnia † 1			
# participants affected / at risk	**3/50 (6.00%)**	**2/54 (3.70%)**	**9/54 (16.67%)**
Respiratory, thoracic and mediastinal disorders			
Cough † 1			
# participants affected / at risk	**10/50 (20.00%)**	**3/54 (5.56%)**	**3/54 (5.56%)**
Oropharyngeal pain † 1			
# participants affected / at risk	**1/50 (2.00%)**	**3/54 (5.56%)**	**2/54 (3.70%)**
Rhinorrhoea † 1			
# participants affected / at risk	**3/50 (6.00%)**	**3/54 (5.56%)**	**1/54 (1.85%)**
Skin and subcutaneous tissue disorders			
Alopecia † 1			
# participants affected / at risk	**6/50 (12.00%)**	**2/54 (3.70%)**	**15/54 (27.78%)**
Dry skin † 1			
# participants affected / at risk	**1/50 (2.00%)**	**0/54 (0.00%)**	**4/54 (7.41%)**
Pruritus † 1			
# participants affected / at risk	**5/50 (10.00%)**	**3/54 (5.56%)**	**9/54 (16.67%)**
Rash † 1			
# participants affected / at risk	**0/50 (0.00%)**	**2/54 (3.70%)**	**4/54 (7.41%)**

† Events were collected by systematic assessment
1 Term from vocabulary, MedDRA

Limitations and Caveats

Hide Limitations and Caveats

Limitations of the study, such as early termination leading to small numbers of participants analyzed and technical problems with measurement leading to unreliable or uninterpretable data
No text entered.

More Information

Hide More Information

Certain Agreements:

Principal Investigators are **NOT** employed by the organization sponsoring the study.
There **IS** an agreement between Principal Investigators and the Sponsor (or its agents) that restricts the PI's rights to discuss or publish trial results after the trial is completed.
The agreement is: ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **less than or equal to 60 days.** The sponsor cannot require changes to the communication and cannot extend the embargo. ☐ The only disclosure restriction on the PI is that the sponsor can review results communications prior to public release and can embargo communications regarding trial results for a period that is **more than 60 days but less than or equal to 180 days.** The sponsor cannot require changes to the communication and cannot extend the embargo.

☑ Other disclosure agreement that restricts the right of the PI to discuss or publish trial results after the trial is completed.

Restriction Description: The terms and conditions of Novartis' agreements with its investigators may vary. However, Novartis does not prohibit any investigator from publishing. Any publications from a single-site are postponed until the publication of the pooled data (i.e., data from all sites) in the clinical trial.

Results Point of Contact:

Name/Title: Study Director
Organization: Novartis Pharmaceuticals
phone: 862-778-8300

No publications provided by Novartis

Publications automatically indexed to this study:

Marcellin P, Wursthorn K, Wedemeyer H, Chuang WL, Lau G, Avila C, Peng CY, Gane E, Lim SG, Fainboim H, Foster GR, Safadi R, Rizzetto M, Manns M, Bao W, Trylesinski A, Naoumov N. Telbivudine plus pegylated interferon alfa-2a in a randomized study in chronic hepatitis B is associated with an unexpected high rate of peripheral neuropathy. J Hepatol. 2015 Jan;62(1):41-7. doi: 10.1016/j.jhep.2014.08.021. Epub 2014 Aug 23.

Responsible Party:	novartis, novatis
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Last Updated:	June 14, 2011
Health Authority:	United States: Food and Drug Administration Australia: Department of Health and Ageing Therapeutic Goods Administration Belgium: The Federal Public Service (FPS) Health, Food Chain Safety and Environment France: Afssaps - Agence française de sécurité sanitaire des produits de santé (Saint-Denis) Germany: Federal Institute for Drugs and Medical Devices Italy: Ministry of Health Netherlands: Medicines Evaluation Board (MEB) Spain: Ministry of Health and Consumption Switzerland: Federal Office of Public Health United Kingdom: Medicines and Healthcare Products Regulatory Agency Israel: Ministry of Health Argentina: Administracion Nacional de Medicamentos, Alimentos y Tecnologia Medica Taiwan: National Bureau of Controlled Drugs Singapore: Health Sciences Authority New Zealand: Health and Disability Ethics Committees Hong Kong: Department of Health