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Trial record **1 of 1** for: CLDT600A2303
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Telbivudine in Adults Previously Treated in Idenix-Sponsored Telbivudine Studies

This study has been completed.

Sponsor:
Novartis Pharmaceuticals

Collaborator:
Merck Sharp & Dohme Corp.

Information provided by (Responsible Party):
Novartis (Novartis Pharmaceuticals)

ClinicalTrials.gov Identifier:
NCT00142298

First received: August 31, 2005
Last updated: March 24, 2015
Last verified: March 2015
History of Changes

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Results First Received: January 12, 2011

Study Type:	Interventional
Study Design:	Allocation: Non-Randomized; Endpoint Classification: Safety/Efficacy Study; Intervention Model: Single Group Assignment; Masking: Open Label; Primary Purpose: Treatment
Condition:	Chronic Hepatitis B
Intervention:	Drug: Telbivudine (LdT)

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
An open-label trial of telbivudine in adults with chronic hepatitis B previously treated in Idenix-sponsored telbivudine studies. Study start March 2005 and completed November 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
Group A : LdT Pool 2302/015	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B from phase III pivotal, registration studies 2302 (NCT00057265) and 015 (NCT00131742) treated with Telbivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks. The total telbivudine treatment time starting from feeder study baseline to the end of the on-treatment period in study 2303 was 208 weeks.
Group A : LAM Pool 2302/015	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B from phase III pivotal, registration studies 2302 (NCT00057265) and 015 (NCT00131742) treated with Lamivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group A: Feeder Study 2401	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B from phase IIIb, registration study CLDT600A2401 (NCT00115245) treated with Telbivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group A: Feeder Study 2402	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B from phase IIIb, registration study CLDT600A2402 (NCT00132652) and treated with Lamivudine or Telbivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group A: Feeder Study 010	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B were from phase IIb study NV-02B-010 (NCT00124241) of telbivudine, lamivudine or the combination of both agents. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group B: LdT 2301	Subjects with HBeAg (+) or HBeAg (-) decompensated chronic hepatitis B from phase III pivotal, registration study

	2301 (NCT00076336) treated with Telbivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks. The total telbivudine treatment time starting from feeder study baseline to the end of the on-treatment period in study 2303 was 208 weeks.
Group B: LAM 2301	Subjects with HBeAg (+) or HBeAg (-) decompensated chronic hepatitis B from phase III pivotal, registration studies 2301 (NCT00076336) treated with Lamivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group C: LdT Pool 2302/015	Subjects with either compensated or decompensated chronic hepatitis B from phase III pivotal, registration studies 2302 (NCT00057265) and 015 (NCT00131742) treated with Telbivudine. Patients were enrolled for off-treatment follow-up after the treatment discontinuation due to efficacy at their last visit of the feeder studies. Hence, patients did not receive any study drug except in case of patients who relapsed and reinitiated treatment.
Group C: LAM Pool 2302/015	Subjects with either compensated or decompensated chronic hepatitis B from phase III pivotal, registration studies 2302 (NCT00057265) and 015 (NCT00131742) treated with Lamivudine. Patients were enrolled for off-treatment follow-up after the treatment discontinuation due to efficacy at their last visit of the feeder studies. Hence, patients did not receive any study drug except in case of patients who relapsed and reinitiated treatment.
Group C: Other Feeder Studies	Patients with either compensated or decompensated chronic hepatitis B, from 2401 (NCT00115245), 2402 (NCT00132652) and 010 (NCT00124241). Patients were enrolled for off-treatment follow-up after the treatment discontinuation due to efficacy at their last visit of the feeder studies. Hence, patients did not receive any study drug except in case of patients who relapsed and reinitiated treatment.

Participant Flow: Overall Study

	Group A : LdT Pool 2302/015	Group A : LAM Pool 2302/015	Group A: Feeder Study 2401	Group A: Feeder Study 2402	Group A: Feeder Study 010	Group B: LdT 2301	Group B: LAM 2301	Group C: LdT Pool 2302/015	Group C: LAM Pool 2302/015	Group C: Other Feeder Studies
STARTED	667	632	123	206	56	26	23	66	57	13
Safety Population	655	626	122	206	50	26	23	66	57	13
Per Protocol Population	635	606	120	202	50	25	19	64	56	13
COMPLETED	507 [1]	456	90	121	46	10	15	58	52	13
NOT COMPLETED	160	176	33	85	10	16	8	8	5	0
Adverse Event	10	10	1	5	2	2	0	0	0	0
Clinical disease progression	1	0	0	0	0	0	0	0	0	0
Death	1	1	1	0	0	6	0	0	0	0
Lack of Efficacy	44	62	9	12	1	0	0	1	0	0
Non-compliance	15	13	0	6	1	0	0	3	3	0
Patient, Investigator,or Sponsor request	66	60	11	51	4	3	1	4	1	0
Pregnancy	4	4	2	3	0	0	0	0	1	0
Virologic breakthrough	19	23	9	7	2	3	3	0	0	0
Other- not specified	0	3	0	1	0	0	0	0	0	0
Lost to Follow-up	0	0	0	0	0	0	2	0	0	0
Treatment Failure	0	0	0	0	0	2	2	0	0	0

[1] Completed week 104/week 208.

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
Group A : LdT Pool 2302/015	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B from phase III pivotal, registration studies Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B from phase III pivotal, registration studies 2302 (NCT00057265) and 015 (NCT00131742) treated with Telbivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks. The total telbivudine treatment time starting from feeder study baseline to the end of the on-treatment period in study 2303 was 208 weeks.
Group A : LAM Pool 2302/015	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B from phase III pivotal, registration studies 2302 (NCT00057265) and 015 (NCT00131742) treated with Lamivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group A: Feeder Study 2401	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B from phase IIIb, registration study CLDT600A2401 (NCT00115245) treated with Telbivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group A: Feeder Study 2402	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B from phase IIIb, registration study CLDT600A2402 (NCT00132652) and treated with Lamivudine or Telbivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group A: Feeder Study 010	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B were from phase IIb study NV-02B-010 (NCT00124241) of telbivudine, lamivudine or the combination of both agents. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group B: LdT 2301	Subjects with HBeAg (+) or HBeAg (-) decompensated chronic hepatitis B from phase III pivotal, registration study 2301 (NCT00076336) treated with Telbivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks. The total telbivudine treatment time starting from feeder study baseline to the end of the on-treatment period in study 2303 was 208 weeks.
Group B: LAM 2301	Subjects with HBeAg (+) or HBeAg (-) decompensated chronic hepatitis B from phase III pivotal, registration studies 2301 (NCT00076336) treated with Lamivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group C: LdT Pool 2302/015	Subjects with either compensated or decompensated chronic hepatitis B from phase III pivotal, registration studies 2302 (NCT00057265) and 015 (NCT00131742) treated with Telbivudine. Patients were enrolled for off-treatment follow-up after the treatment discontinuation due to efficacy at their last visit of the feeder studies. Hence, patients did not receive any study drug except in case of patients who relapsed and reinitiated treatment.
Group C: LAM Pool 2302/015	Subjects with either compensated or decompensated chronic hepatitis B from phase III pivotal, registration studies 2302 (NCT00057265) and 015 (NCT00131742) treated with Lamivudine. Patients were enrolled for off-treatment follow-up after the treatment discontinuation due to efficacy at their last visit of the feeder studies. Hence, patients did not receive any study drug except in case of patients who relapsed and reinitiated treatment.
Group C: Other Feeder Studies	Patients with either compensated or decompensated chronic hepatitis B, from 2401 (NCT00115245), 2402 (NCT00132652) and 010 (NCT00124241). Patients were enrolled for off-treatment follow-up after the treatment discontinuation due to efficacy at their last visit of the feeder studies. Hence, patients did not receive any study drug except in case of patients who relapsed and reinitiated treatment.
Total	Total of all reporting groups

Baseline Measures

	Group A : LdT Pool 2302/015	**Group A : LAM Pool 2302/015**	**Group A: Feeder Study 2401**	**Group A: Feeder Study 2402**	**Group A: Feeder Study 010**	**Group B: LdT 2301**	**Group B: LAM 2301**	**Group C: LdT Pool 2302/015**	**Group C: LAM Pool 2302/015**	**Group C: Other Feeder Studies**	**Total**
Number of Participants [units: participants]	**667**	**632**	**123**	**206**	**56**	**26**	**23**	**66**	**57**	**13**	**1869**
Age, Customized [units: Participants]											
< 30 years	**276**	**207**	**51**	**54**	**9**	**1**	**0**	**30**	**27**	**8**	**663**
30-50 years	**320**	**325**	**66**	**122**	**40**	**10**	**5**	**31**	**24**	**5**	**948**
> 50 years	**71**	**100**	**6**	**30**	**7**	**15**	**18**	**5**	**6**	**0**	**258**

Gender [units: participants]											
Female	**147**	**142**	**30**	**53**	**9**	**9**	**6**	**20**	**14**	**3**	**433**
Male	**520**	**490**	**93**	**153**	**47**	**17**	**17**	**46**	**43**	**10**	**1436**

Outcome Measures

Hide All Outcome Measures

1. Primary: Percentage of Participants Who Maintained Therapeutic Response [Group A: LdT Pool 2302/015] [Time Frame: 156 weeks, 208 weeks (from feeder study baseline)]

Measure Type	Primary
Measure Title	Percentage of Participants Who Maintained Therapeutic Response [Group A: LdT Pool 2302/015]
Measure Description	The maintained therapeutic response is defined as hepatitis B virus (HBV) DNA < 5 log10 copies/mL and either hepatitis Be antigen (HBeAg) loss or alanine aminotransferase (ALT) normalized. HBeAg loss is loss of detectable serum HBeAg in a patient who was HBeAg-positive at feeder baseline. ALT normalized is defined as ALT within normal limits for a patient with an elevated ALT level (>1.0 × ULN) at either the feeder baseline or feeder screening visit. All efficacy data were analyzed separately for HBeAg-positive and HBeAg-negative patients.
Time Frame	156 weeks, 208 weeks (from feeder study baseline)
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.
Per protocol (PP) population. The PP analysis was done on separately for the HBeAg-positive and HBeAg-negative subpopulation (status at feeder baseline). n = the number of HBeAg-positive/HBeAg-negative patients who were eligible for maintained therapeutic response.

Reporting Groups

	Description
Group A : LdT Pool 2302/015	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B from phase III pivotal, registration studies 2302 (NCT00057265) and 015 (NCT00131742) treated with Telbivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks. The total telbivudine treatment time starting from feeder study baseline to the end of the on-treatment period in study 2303 was 208 weeks.

Measured Values

	Group A : LdT Pool 2302/015
Number of Participants Analyzed [units: participants]	**635**
Percentage of Participants Who Maintained Therapeutic Response [Group A: LdT Pool 2302/015] [units: Percentage of participants] Number (95% Confidence Interval)	
HBeAg Positive: week 156 (n=338)	**67.2 (61.9 to 72.1)**
HBeAg Positive: week 208 (n=252)	**73.8 (67.9 to 79.1)**
HBeAg Negative: week 156 (n=197)	**81.7 (75.6 to 86.9)**
HBeAg Negative: week 208 (n=168)	**86.3 (80.2 to 91.1)**

No statistical analysis provided for Percentage of Participants Who Maintained Therapeutic Response [Group A: LdT Pool 2302/015]

2. Primary: Percentage of Participants Who Maintained Therapeutic Response [Group A: LAM Pool 2302/015] [Time Frame: 52 weeks, 104 weeks]

Measure Type	Primary

Measure Title	Percentage of Participants Who Maintained Therapeutic Response [Group A: LAM Pool 2302/015]
Measure Description	The maintained therapeutic response is defined as hepatitis B virus (HBV) DNA < 5 log10 copies/mL and either hepatitis Be antigen (HBeAg) loss or alanine aminotransferase (ALT) normalized. HBeAg loss is loss of detectable serum HBeAg in a patient who was HBeAg-positive at feeder baseline. ALT normalized is defined as ALT within normal limits for a patient with an elevated ALT level (>1.0 × ULN) at either the feeder baseline or feeder screening visit. All efficacy data were analyzed separately for HBeAg-positive and HBeAg-negative patients.
Time Frame	52 weeks, 104 weeks
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.
Per protocol (PP) population. The PP analysis was done separately for the HBeAg-positive and HBeAg-negative subpopulation (status at feeder baseline). n = the number of HBeAg-positive/HBeAg-negative patients who were eligible for maintained therapeutic response.

Reporting Groups

	Description
Group A : LAM Pool 2302/015	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B from phase III pivotal, registration studies 2302 (NCT00057265) and 015 (NCT00131742) treated with Lamivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.

Measured Values

	Group A : LAM Pool 2302/015
Number of Participants Analyzed [units: participants]	**606**
Percentage of Participants Who Maintained Therapeutic Response [Group A: LAM Pool 2302/015] [units: Percentage of Participants] Number (95% Confidence Interval)	
HBeAg Positive: week 52 (n=338)	**60.1 (54.6 to 65.3)**
HBeAg Positive: week 104 (n=101)	**65.3 (55.2 to 74.5)**
HBeAg Negative: week 52 (n=182)	**80.8 (74.3 to 86.2)**
HBeAg Negative: week 104 (n=79)	**81.0 (70.6 to 89.0)**

No statistical analysis provided for Percentage of Participants Who Maintained Therapeutic Response [Group A: LAM Pool 2302/015]

3. Primary: Percentage of Participants Who Maintained Therapeutic Response [Group A: Feeder Studies 2401/2402/010] [Time Frame: 52 weeks, 104 weeks]

Measure Type	Primary
Measure Title	Percentage of Participants Who Maintained Therapeutic Response [Group A: Feeder Studies 2401/2402/010]
Measure Description	The maintained therapeutic response is defined as hepatitis B virus (HBV) DNA < 5 log10 copies/mL and either hepatitis Be antigen (HBeAg) loss or alanine aminotransferase (ALT) normalized. HBeAg loss is loss of detectable serum HBeAg in a patient who was HBeAg-positive at feeder baseline. ALT normalized is defined as ALT within normal limits for a patient with an elevated ALT level (>1.0 × ULN) at either the feeder baseline or feeder screening visit. All efficacy data were analyzed separately for HBeAg-positive and HBeAg-negative patients.
Time Frame	52 weeks, 104 weeks
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.
Per protocol (PP) population. The PP analysis was done on the PP population, separately for the HBeAg-positive and HBeAg-negative subpopulation (status as feeder baseline). n = the number of HBeAg-positive/HBeAg-negative patients who were eligible for maintained therapeutic response.

Reporting Groups

	Description
Group A: Feeder Study 2401	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B from phase IIIb, registration study CLDT600A2401 (NCT00115245) treated with Telbivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group A: Feeder Study 2402	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B from phase IIIb, registration study CLDT600A2402 (NCT00132652) and treated with Lamivudine or Telbivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group A: Feeder Study 010	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B were from phase IIb study NV-02B-010 (NCT00124241) of telbivudine, lamivudine or the combination of both agents. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.

Measured Values

	Group A: Feeder Study 2401	Group A: Feeder Study 2402	Group A: Feeder Study 010
Number of Participants Analyzed [units: participants]	**120**	**131**	**50**
Percentage of Participants Who Maintained Therapeutic Response [Group A: Feeder Studies 2401/2402/010] [units: Percentage of Participants] Number (95% Confidence Interval)			
HBeAg Positive: 52 week (n = 103, 79, 43)	**77.7 (68.4 to 85.3)**	**35.4 (25.0 to 47.0)**	**69.8 (53.9 to 82.8)**
HBeAg Positive: 104 week (n = 66, 15, 30)	**81.8 (70.4 to 90.2)**	**46.7 (21.3 to 73.4)**	**76.7 (57.7 to 90.1)**
HBeAg Negative: 52 week (n = 0, 37, 0)	**NA [1]**	**54.1 (36.9 to 70.5)**	**NA [2]**
HBeAg Negative: 104 week (n = 0, 10, 0)	**NA [3]**	**60.0 (26.2 to 87.8)**	**NA [4]**

[1] In per protocol population, all participants from feeder study 2401 are HBeAg-positive. So, no analysis was done at week 52.
[2] In per protocol population, all participants from feeder study 010 are HBeAg-positive. So, no analysis was done at week 52.
[3] In per protocol population, all participants from feeder study 2401 are HBeAg-positive. So, no analysis was done at week 104.
[4] In per protocol population, all participants from feeder study 010 are HBeAg-positive. So, no analysis was done at week 104.

No statistical analysis provided for Percentage of Participants Who Maintained Therapeutic Response [Group A: Feeder Studies 2401/2402/010]

4. Primary: Percentage of Participants With Maintained Clinical Response [Group B: LdT 2301] [Time Frame: 156 weeks, 208 weeks (from feeder study baseline)]

Measure Type	Primary
Measure Title	Percentage of Participants With Maintained Clinical Response [Group B: LdT 2301]
Measure Description	Maintained clinical response is defined as achievement of serum HBV DNA < 4 log10 copies/mL, normal serum ALT level and improvement or stabilization in Child-Turcotte-Pugh (CTP) score. Total CTP score ranges from 5 to 15; higher scores indicate liver impairment. Improvement is defined as a 2-point or greater reduction in CTP score, and stabilization is defined as a less than 2-point change in CTP score, compared to the patient's baseline value. Analysis was done on the overall per protocol (PP) population and separately for the HBeAg-positive and HBeAg-negative subpopulation.
Time Frame	156 weeks, 208 weeks (from feeder study baseline)
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.
Per protocol (PP) population. The PP analysis was done on the overall PP population and separately for the HBeAg-positive and HBeAg-negative subpopulation (status at feeder baseline). n = the number of patients who were eligible for maintained clinical response.

Reporting Groups

	Description
Group B : LdT 2301	Subjects with HBeAg (+) or HBeAg (-) decompensated chronic hepatitis B from phase III pivotal, registration study 2301 (NCT00076336) treated with Telbivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks. The total telbivudine treatment time starting from feeder study baseline to the end of the on-treatment period in study 2303 was 208 weeks.

Measured Values

	Group B : LdT 2301
Number of Participants Analyzed [units: participants]	**25**
Percentage of Participants With Maintained Clinical Response [Group B: LdT 2301] [units: Percentage of Participants] Number (95% Confidence Interval)	
HBeAg Positive: week 156 (n= 4)	**100 (39.8 to 100)**
HBeAg Positive: week 208 (n= 1)	**100 (2.5 to 100)**
HBeAg Negative: week 156 (n= 11)	**72.7 (39.0 to 94.0)**
HBeAg Negative: week 208 (n= 7)	**71.4 (29.0 to 96.3)**
Overall: Week 156 (n= 15)	**80.0 (51.9 to 95.7)**
Overall: Week 208 (n= 8)	**75.0 (34.9 to 96.8)**

No statistical analysis provided for Percentage of Participants With Maintained Clinical Response [Group B: LdT 2301]

5. Primary: Percentage of Participants With Maintained Clinical Response [Group B: LAM 2301] [Time Frame: 52 weeks,104 weeks]

Measure Type	Primary
Measure Title	Percentage of Participants With Maintained Clinical Response [Group B: LAM 2301]
Measure Description	Maintained clinical response is defined as achievement of serum HBV DNA < 4 log10 copies/mL, normal serum ALT level and improvement or stabilization in Child-Turcotte-Pugh (CTP) score. Total CTP score ranges from 5 to 15; higher scores indicate liver impairment. Improvement is defined as a 2-point or greater reduction in CTP score, and stabilization is defined as a less than 2-point change in CTP score, compared to the patient's baseline value. Analysis was done on the overall per protocol (PP) population and separately for the HBeAg-positive and HBeAg-negative subpopulation.
Time Frame	52 weeks,104 weeks
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.
Per protocol (PP) population. The PP analysis was done on the overall PP population and separately for the HBeAg-positive and HBeAg-negative subpopulation (status at feeder baseline). n = the number of patients who were eligible for maintained clinical response.

Reporting Groups

	Description
Group B : LAM 2301	Subjects with HBeAg (+) or HBeAg (-) decompensated chronic hepatitis B from phase III pivotal, registration studies 2301 (NCT00076336) treated with Lamivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.

Measured Values

	Group B : LAM 2301
Number of Participants Analyzed [units: participants]	**19**
Percentage of Participants With Maintained Clinical Response [Group B: LAM 2301] [units: Percentage of Participants] Number (95% Confidence Interval)	
HBeAg Positive: week 52 (n=4)	**100 (39.8 to 100)**
HBeAg Positive: week 104 (n=1)	**100 (2.5 to 100)**
HBeAg Negative: week 52 (n=11)	**72.7 (39.9 to 94)**
HBeAg Negative: week 104 (n=5)	**100**

	(47.8 to 100)
Overall: week 52 (n= 15)	**80.0 (51.9 to 95.7)**
Overall: week 104 (n= 6)	**100 (54.1 to 100)**

No statistical analysis provided for Percentage of Participants With Maintained Clinical Response [Group B: LAM 2301]

6. Primary: Percentage of Participants With Sustained Therapeutic Response [Group C: LdT Pool and LAM Pool (2302/015)] [Time Frame: 52 weeks,104 weeks]

Measure Type	Primary
Measure Title	Percentage of Participants With Sustained Therapeutic Response [Group C: LdT Pool and LAM Pool (2302/015)]
Measure Description	The primary efficacy endpoint for Group C patients was the percentage of patients with sustained therapeutic response (defined as HBV DNA < 5 log10 copies/mL and either HBeAg loss or ALT normalized) at Weeks 52 and 104 of off-treatment follow-up. HBeAg loss is loss of detectable serum HBeAg in a patient who was HBeAg-positive at feeder baseline. ALT normalized is ALT within normal limits for a patient with an elevated ALT level (>1.0 × ULN) at either the feeder baseline or feeder screening visit. All efficacy data were analyzed separately for HBeAg-positive and HBeAg-negative patients.
Time Frame	52 weeks,104 weeks
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 per protocol population. n= is the number of HBeAg-positive/HBeAg-negative patients from per protocol population who achieved maintained response at the end of treatment and had off-treatment assessment to determine the sustained response at that time point or lost sustained response before the off-treatment timepoint.

Reporting Groups

	Description
Group C : LdT Pool 2302/015	Subjects with either compensated or decompensated chronic hepatitis B from phase III pivotal, registration studies 2302 (NCT00057265) and 015 (NCT00131742) treated with Telbivudine. Patients were enrolled for off-treatment follow-up after the treatment discontinuation due to efficacy at their last visit of the feeder studies. Hence, patients did not receive any study drug except in case of patients who relapsed and reinitiated treatment.
Group C: LAM Pool 2302/015	Subjects with either compensated or decompensated chronic hepatitis B from phase III pivotal, registration studies 2302 (NCT00057265) and 015 (NCT00131742) treated with Lamivudine. Patients were enrolled for off-treatment follow-up after the treatment discontinuation due to efficacy at their last visit of the feeder studies. Hence, patients did not receive any study drug except in case of patients who relapsed and reinitiated treatment.

Measured Values

	Group C : LdT Pool 2302/015	**Group C: LAM Pool 2302/015**
Number of Participants Analyzed [units: participants]	**64**	**56**
Percentage of Participants With Sustained Therapeutic Response [Group C: LdT Pool and LAM Pool (2302/015)] [units: Percentage of Participants] Number (95% Confidence Interval)		
HBeAg Positive: week 52 (n= 53, 42)	**69.8 (55.7 to 81.7)**	**73.8 (58.0 to 86.1)**
HBeAg Positive: week 104 (n= 42, 32)	**57.1 (41.0 to 72.3)**	**62.5 (43.7 to 78.9)**
HBeAg Negative: week 52 (n= 3, 5)	**0.0 (0.0 to 70.8)**	**80.0 (28.4 to 99.5)**
HBeAg Negative: week 104 (n= 3, 6)	**0.0 (0.0 to 70.8)**	**83.3 (35.9 to 99.6)**

No statistical analysis provided for Percentage of Participants With Sustained Therapeutic Response [Group C: LdT Pool and LAM Pool (2302/015)]

7. Primary: Percentage of Participants With Sustained Therapeutic Response [Group C: Other Feeder Studies] [Time Frame: 52 weeks,104 weeks]

Measure Type	Primary
Measure Title	Percentage of Participants With Sustained Therapeutic Response [Group C: Other Feeder Studies]
Measure Description	The primary efficacy endpoint for Group C (other feeder studies) was the percentage of patients with sustained therapeutic response (defined as HBV DNA < 5 log10 copies/mL and either HBeAg loss or ALT normalized) at Weeks 52 and 104 of off-treatment follow-up. Patients were enrolled for off-treatment follow-up after the treatment discontinuation due to efficacy at their last visit of the feeder studies. Hence, patients did not receive study drug except in case of patients who relapsed and reinitiated treatment. No statistical summary was performed , only patient listing was generated.
Time Frame	52 weeks,104 weeks
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.
In "Group C: other feeder study" reporting group, there were only 13 patients; hence, no summary statistics were performed. Only listings were generated.

Reporting Groups

	Description
Group C : Other Feeder Studies	Patients with either compensated or decompensated chronic hepatitis B, from 2401 (NCT00115245), 2402 (NCT00132652) and 010 (NCT00124241). Patients were enrolled for off-treatment follow-up after the treatment discontinuation due to efficacy at their last visit of the feeder studies. Hence, patients did not receive any study drug except in case of patients who relapsed and reinitiated treatment.

Measured Values

	Group C : Other Feeder Studies
Number of Participants Analyzed [units: participants]	**0**
Percentage of Participants With Sustained Therapeutic Response [Group C: Other Feeder Studies]	

No statistical analysis provided for Percentage of Participants With Sustained Therapeutic Response [Group C: Other Feeder Studies]

8. Secondary: To Longitudinally Assess the Longer-term Antiviral Efficacy Achieved With Telbivudine Treatment [Time Frame: 52 weeks, 104 weeks, 156 weeks, 208 weeks]

Results not yet reported. Anticipated Reporting Date: No text entered. **Safety Issue:** No

9. Secondary: To Longitudinally Assess the Clinical Efficacy of Longer-term Treatment With Telbivudine [Time Frame: 52 weeks, 104 weeks, 156 weeks, 208 weeks]

Results not yet reported. Anticipated Reporting Date: No text entered. **Safety Issue:** No

10. Secondary: To Longitudinally Assess the Durability of HBeAg Responses Achieved With Telbivudine Treatment and Other Previous Treatments in Patients [Time Frame: 52 weeks, 104 weeks, 156 weeks, 208 weeks]

Results not yet reported. Anticipated Reporting Date: No text entered. **Safety Issue:** No

11. Secondary: To Determine the Longitudinal Frequency of Virologic Breakthrough and Characterize the Associated Mutations in the HBV Polymerase Gene in HBV DNA Amplified From Sera of Patients With Virologic Breakthrough [Time Frame: 52 weeks, 104 weeks, 156 weeks, 208 weeks]

Results not yet reported. Anticipated Reporting Date: No text entered. **Safety Issue:** No

Serious Adverse Events

Hide Serious Adverse Events

Time Frame	No text entered.
Additional Description	All safety analyses were performed on the safety populations defined for each reporting group.

Reporting Groups

	Description

Group A : LdT Pool 2302/015	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B from phase III pivotal, registration studies 2302 (NCT00057265) and 015 (NCT00131742) treated with Telbivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks. The total telbivudine treatment time starting from feeder study baseline to the end of the on-treatment period in study 2303 was 208 weeks.
Group A : LAM Pool 2302/015	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B from phase III pivotal, registration studies 2302 (NCT00057265) and 015 (NCT00131742) treated with Lamivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group A: Feeder Study 010	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B were from phase IIb study NV-02B-010 (NCT00124241) of telbivudine, lamivudine or the combination of both agents. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group A: Feeder 2401	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B from phase IIIb, registration study CLDT600A2401 (NCT00115245) treated with Telbivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group A: Feeder 2402	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B from phase IIIb, registration study CLDT600A2402 (NCT00132652) and treated with Lamivudine or Telbivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group B: LdT 2301	Subjects with HBeAg (+) or HBeAg (-) decompensated chronic hepatitis B from phase III pivotal, registration study 2301 (NCT00076336) treated with Telbivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks. The total telbivudine treatment time starting from feeder study baseline to the end of the on-treatment period in study 2303 was 208 weeks.
Group B: Lam 2301	Subjects with HBeAg (+) or HBeAg (-) decompensated chronic hepatitis B from phase III pivotal, registration studies 2301 (NCT00076336) treated with Lamivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group C : LdT Pool 2302/015	Subjects with either compensated or decompensated chronic hepatitis B from phase III pivotal, registration studies 2302 (NCT00057265) and 015 (NCT00131742) treated with Telbivudine. Patients were enrolled for off-treatment follow-up after the treatment discontinuation due to efficacy at their last visit of the feeder studies. Hence, patients did not receive any study drug except in case of patients who relapsed and reinitiated treatment.
Group C: Lam Pool 2302/015	Subjects with either compensated or decompensated chronic hepatitis B from phase III pivotal, registration studies 2302 (NCT00057265) and 015 (NCT00131742) treated with Lamivudine. Patients were enrolled for off-treatment follow-up after the treatment discontinuation due to efficacy at their last visit of the feeder studies. Hence, patients did not receive any study drug except in case of patients who relapsed and reinitiated treatment.
Group C : Other Feeder Studies	Patients with either compensated or decompensated chronic hepatitis B, from 2401 (NCT00115245), 2402 (NCT00132652) and 010 (NCT00124241). Patients were enrolled for off-treatment follow-up after the treatment discontinuation due to efficacy at their last visit of the feeder studies. Hence, patients did not receive any study drug except in case of patients who relapsed and reinitiated treatment.

Serious Adverse Events

	Group A : LdT Pool 2302/015	Group A : LAM Pool 2302/015	Group A: Feeder Study 010	Group A: Feeder 2401	Group A: Feeder 2402	Group B: LdT 2301	Group B: Lam 2301	Group C : LdT Pool 2302/015	G La 23
Total, serious adverse events									
# participants affected / at risk	**45/655 (6.87%)**	**21/626 (3.35%)**	**3/50 (6.00%)**	**10/122 (8.20%)**	**14/206 (6.80%)**	**16/26 (61.54%)**	**10/23 (43.48%)**	**1/66 (1.52%)**	**2/5**
Blood and lymphatic system disorders									
APLASIA PURE RED CELL † 1									
# participants affected / at risk	**0/655 (0.00%)**	**1/626 (0.16%)**	**0/50 (0.00%)**	**0/122 (0.00%)**	**0/206 (0.00%)**	**0/26 (0.00%)**	**0/23 (0.00%)**	**0/66 (0.00%)**	**0/**
LEUKOPENIA † 1									
# participants affected / at risk	**1/655 (0.15%)**	**0/626 (0.00%)**	**0/50 (0.00%)**	**0/122 (0.00%)**	**0/206 (0.00%)**	**0/26 (0.00%)**	**0/23 (0.00%)**	**0/66 (0.00%)**	**0/**
Cardiac disorders									
ANGINA PECTORIS † 1									
# participants affected / at risk	**0/655 (0.00%)**	**1/626 (0.16%)**	**0/50 (0.00%)**	**0/122 (0.00%)**	**0/206 (0.00%)**	**0/26 (0.00%)**	**0/23 (0.00%)**	**1/66 (1.52%)**	**0/**
ARRHYTHMIA † 1									
# participants affected / at risk	**0/655 (0.00%)**	**0/626 (0.00%)**	**0/50 (0.00%)**	**0/122 (0.00%)**	**0/206 (0.00%)**	**0/26 (0.00%)**	**0/23 (0.00%)**	**1/66 (1.52%)**	**0/**
CORONARY ARTERY DISEASE † 1									
# participants	**0/655 (0.00%)**	**0/626 (0.00%)**	**0/50 (0.00%)**	**0/122 (0.00%)**	**0/206 (0.00%)**	**0/26 (0.00%)**	**0/23 (0.00%)**	**1/66 (1.52%)**	**0/**

affected / at risk									
MYOCARDIAL INFARCTION † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	1/206 (0.49%)	0/26 (0.00%)	1/23 (4.35%)	0/66 (0.00%)	0/
MYOCARDIAL ISCHAEMIA † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
Ear and labyrinth disorders									
VESTIBULAR NEURONITIS † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
Gastrointestinal disorders									
ABDOMINAL PAIN † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	1/23 (4.35%)	0/66 (0.00%)	0/
ASCITES † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
ENTERITIS † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
GASTROINTESTINAL HAEMORRHAGE † 1									
# participants affected / at risk	0/655 (0.00%)	1/626 (0.16%)	0/50 (0.00%)	1/122 (0.82%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
HAEMORRHOIDAL HAEMORRHAGE † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
HAEMORRHOIDS † 1									
# participants affected / at risk	0/655 (0.00%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
INGUINAL HERNIA † 1									
# participants affected / at risk	0/655 (0.00%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	1/206 (0.49%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
LARGE INTESTINE PERFORATION † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	1/50 (2.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
MELAENA † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	1/206 (0.49%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
NAUSEA † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
OESOPHAGEAL HAEMORRHAGE † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	1/23 (4.35%)	0/66 (0.00%)	0/
OESOPHAGEAL VARICES HAEMORRHAGE † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	1/23 (4.35%)	0/66 (0.00%)	0/
PANCREATITIS ACUTE † 1									

# participants affected / at risk	0/655 (0.00%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
PERITONEAL ADHESIONS † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	1/206 (0.49%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
VARICES OESOPHAGEAL † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
VOMITING † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
General disorders									
APLASIA † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	1/
CONCOMITANT DISEASE PROGRESSION † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	1/122 (0.82%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
DEATH † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
NON-CARDIAC CHEST PAIN † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	1/66 (1.52%)	0/
Hepatobiliary disorders									
CHOLANGITIS ACUTE † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
CHRONIC HEPATITIS † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
HEPATITIS † 1									
# participants affected / at risk	2/655 (0.31%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
HEPATOMEGALY † 1									
# participants affected / at risk	0/655 (0.00%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
Infections and infestations									
APPENDICITIS † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	1/206 (0.49%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
BRONCHITIS † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
CELLULITIS † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
DENGUE FEVER † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	1/23 (4.35%)	0/66 (0.00%)	0/
DENTAL CARIES † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/

EPIGLOTTITIS † [1]									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	1/122 (0.82%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
HEPATITIS B † [1]									
# participants affected / at risk	3/655 (0.46%)	5/626 (0.80%)	1/50 (2.00%)	2/122 (1.64%)	1/206 (0.49%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
LEPTOSPIROSIS † [1]									
# participants affected / at risk	0/655 (0.00%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
PERITONITIS BACTERIAL † [1]									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
PHARYNGITIS † [1]									
# participants affected / at risk	0/655 (0.00%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
PNEUMONIA † [1]									
# participants affected / at risk	2/655 (0.31%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
POSTOPERATIVE INFECTION † [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
SEPTIC SHOCK † [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
SINUSITIS † [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
UPPER RESPIRATORY TRACT INFECTION † [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
URINARY TRACT INFECTION † [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
UROSEPSIS † [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
Injury, poisoning and procedural complications									
CONTUSION † [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	1/122 (0.82%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
EXCORIATION † [1]									
# participants affected / at risk	0/655 (0.00%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
FACIAL BONES FRACTURE † [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
FALL † [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
FIBULA FRACTURE † [1]									
# participants affected / at risk	0/655 (0.00%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
HEAD INJURY † [1]									

# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	1/206 (0.49%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
JOINT DISLOCATION † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
JOINT LIGAMENT RUPTURE † 1									
# participants affected / at risk	0/655 (0.00%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
JOINT SPRAIN † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	1/122 (0.82%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
LIMB INJURY † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	1/23 (4.35%)	0/66 (0.00%)	0/
LOWER LIMB FRACTURE † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
OVERDOSE † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
RIB FRACTURE † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
ROAD TRAFFIC ACCIDENT † 1									
# participants affected / at risk	2/655 (0.31%)	0/626 (0.00%)	0/50 (0.00%)	1/122 (0.82%)	2/206 (0.97%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
SKIN LACERATION † 1									
# participants affected / at risk	0/655 (0.00%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
TOOTH INJURY † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
WRIST FRACTURE † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
Investigations									
ALANINE AMINOTRANSFERASE INCREASED † 1									
# participants affected / at risk	4/655 (0.61%)	2/626 (0.32%)	0/50 (0.00%)	0/122 (0.00%)	1/206 (0.49%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
ASPARTATE AMINOTRANSFERASE INCREASED † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
BLOOD BILIRUBIN INCREASED † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
WEIGHT DECREASED † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
Metabolism and nutrition disorders									
DEHYDRATION † 1									

# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	1/122 (0.82%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
DIABETES MELLITUS INADEQUATE CONTROL † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	1/23 (4.35%)	0/66 (0.00%)	0/
DIABETIC HYPEROSMOLAR NON-KETOACIDOSIS † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
FLUID OVERLOAD † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
HYPERKALAEMIA † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
HYPONATRAEMIA † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
Musculoskeletal and connective tissue disorders									
MUSCLE ATROPHY † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
MUSCULAR WEAKNESS † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
MYOPATHY † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
MYOSITIS † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	1/50 (2.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
POLYMYOSITIS † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
ROTATOR CUFF SYNDROME † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	1/23 (4.35%)	0/66 (0.00%)	0/
Neoplasms benign, malignant and unspecified (incl cysts and polyps)									
ACOUSTIC NEUROMA † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
BILE DUCT CANCER † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
BREAST CANCER † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
COLON CANCER † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	1/50 (2.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	1/23 (4.35%)	0/66 (0.00%)	0/
DIFFUSE LARGE B-									

CELL LYMPHOMA † [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
GASTRIC CANCER † [1]									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	1/23 (4.35%)	0/66 (0.00%)	0/
HEPATIC NEOPLASM † [1]									
# participants affected / at risk	0/655 (0.00%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	1/23 (4.35%)	0/66 (0.00%)	0/
HEPATIC NEOPLASM MALIGNANT † [1]									
# participants affected / at risk	5/655 (0.76%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	1/206 (0.49%)	8/26 (30.77%)	3/23 (13.04%)	0/66 (0.00%)	0/
LYMPHOMA † [1]									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	1/206 (0.49%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
NASAL NEOPLASM BENIGN † [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
POLYP † [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
PROLACTINOMA † [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
RENAL CELL CARCINOMA STAGE UNSPECIFIED † [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	1/206 (0.49%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
THYROID GLAND CANCER † [1]									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	1/122 (0.82%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
Nervous system disorders									
CEREBRAL HAEMORRHAGE † [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
CEREBRAL ISCHAEMIA † [1]									
# participants affected / at risk	0/655 (0.00%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
CEREBROVASCULAR ACCIDENT † [1]									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
DIABETIC HYPEROSMOLAR COMA † [1]									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
DIZZINESS † [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
HEADACHE † [1]									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	1/206 (0.49%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
HEPATIC ENCEPHALOPATHY † [1]									

# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
SYNCOPE † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	1/206 (0.49%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
Pregnancy, puerperium and perinatal conditions									
ABORTION † 1									
# participants affected / at risk	0/655 (0.00%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
ABORTION MISSED † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
ABORTION SPONTANEOUS † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	1/
Psychiatric disorders									
ADJUSTMENT DISORDER † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
DEPRESSION † 1									
# participants affected / at risk	2/655 (0.31%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
HYPOMANIA † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
SUICIDE ATTEMPT † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
Renal and urinary disorders									
CALCULUS URETERIC † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	1/206 (0.49%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
CALCULUS URINARY † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
GLOMERULONEPHRITIS PROLIFERATIVE † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	1/122 (0.82%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
HAEMATURIA † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	1/122 (0.82%)	2/206 (0.97%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
OBSTRUCTIVE UROPATHY † 1									
# participants affected / at risk	0/655 (0.00%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
PROTEINURIA † 1									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
RENAL FAILURE ACUTE † 1									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
URINARY RETENTION †									

[1]									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
Reproductive system and breast disorders									
METRORRHAGIA [†] [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
PROSTATIC HYPERTROPHY [†] [1]									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	1/
VULVAL ANGIOKERATOMA [†] [1]									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/
Respiratory, thoracic and mediastinal disorders									
ACUTE RESPIRATORY DISTRESS SYNDROME [†] [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
CATARRH [†] [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
NASAL MUCOSAL DISORDER [†] [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
NASAL SEPTUM DEVIATION [†] [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
NASAL TURBINATE ABNORMALITY [†] [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
Skin and subcutaneous tissue disorders									
PRURITUS [†] [1]									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	1/206 (0.49%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
Surgical and medical procedures									
ABORTION INDUCED [†] [1]									
# participants affected / at risk	4/655 (0.61%)	2/626 (0.32%)	0/50 (0.00%)	1/122 (0.82%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
FRACTURE TREATMENT [†] [1]									
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/66 (0.00%)	0/
Vascular disorders									
BLEEDING VARICOSE VEIN [†] [1]									
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/66 (0.00%)	0/

† 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	All safety analyses were performed on the safety populations defined for each reporting group.

Frequency Threshold

Threshold above which other adverse events are reported	5%

Reporting Groups

	Description
Group A : LdT Pool 2302/015	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B from phase III pivotal, registration studies 2302 (NCT00057265) and 015 (NCT00131742) treated with Telbivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks. The total telbivudine treatment time starting from feeder study baseline to the end of the on-treatment period in study 2303 was 208 weeks.
Group A : LAM Pool 2302/015	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B from phase III pivotal, registration studies 2302 (NCT00057265) and 015 (NCT00131742) treated with Lamivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group A: Feeder Study 010	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B were from phase IIb study NV-02B-010 (NCT00124241) of telbivudine, lamivudine or the combination of both agents. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group A: Feeder 2401	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B from phase IIIb, registration study CLDT600A2401 (NCT00115245) treated with Telbivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group A: Feeder 2402	Subjects with HBeAg (+) or HBeAg (-) compensated chronic hepatitis B from phase IIIb, registration study CLDT600A2402 (NCT00132652) and treated with Lamivudine or Telbivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group B: LdT 2301	Subjects with HBeAg (+) or HBeAg (-) decompensated chronic hepatitis B from phase III pivotal, registration study 2301 (NCT00076336) treated with Telbivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks. The total telbivudine treatment time starting from feeder study baseline to the end of the on-treatment period in study 2303 was 208 weeks.
Group B: Lam 2301	Subjects with HBeAg (+) or HBeAg (-) decompensated chronic hepatitis B from phase III pivotal, registration studies 2301 (NCT00076336) treated with Lamivudine. Telbivudine 600 mg by mouth (p.o.) daily for 104 weeks.
Group C : LdT Pool 2302/015	Subjects with either compensated or decompensated chronic hepatitis B from phase III pivotal, registration studies 2302 (NCT00057265) and 015 (NCT00131742) treated with Telbivudine. Patients were enrolled for off-treatment follow-up after the treatment discontinuation due to efficacy at their last visit of the feeder studies. Hence, patients did not receive any study drug except in case of patients who relapsed and reinitiated treatment.
Group C: Lam Pool 2302/015	Subjects with either compensated or decompensated chronic hepatitis B from phase III pivotal, registration studies 2302 (NCT00057265) and 015 (NCT00131742) treated with Lamivudine. Patients were enrolled for off-treatment follow-up after the treatment discontinuation due to efficacy at their last visit of the feeder studies. Hence, patients did not receive any study drug except in case of patients who relapsed and reinitiated treatment.
Group C : Other Feeder Studies	Patients with either compensated or decompensated chronic hepatitis B, from 2401 (NCT00115245), 2402 (NCT00132652) and 010 (NCT00124241). Patients were enrolled for off-treatment follow-up after the treatment discontinuation due to efficacy at their last visit of the feeder studies. Hence, patients did not receive any study drug except in case of patients who relapsed and reinitiated treatment.

Other Adverse Events

	Group A : LdT Pool 2302/015	**Group A : LAM Pool 2302/015**	**Group A: Feeder Study 010**	**Group A: Feeder 2401**	**Group A: Feeder 2402**	**Group B: LdT 2301**	**Group B: Lam 2301**	**C L 2:**
Total, other (not including serious) adverse events								
# participants affected / at risk	**318/655 (48.55%)**	**309/626 (49.36%)**	**24/50 (48.00%)**	**74/122 (60.66%)**	**88/206 (42.72%)**	**21/26 (80.77%)**	**19/23 (82.61%)**	**40/6**
Blood and lymphatic system disorders								
THROMBOCYTHAEMIA † 1								
# participants affected / at risk	**0/655 (0.00%)**	**0/626 (0.00%)**	**0/50 (0.00%)**	**0/122 (0.00%)**	**0/206 (0.00%)**	**0/26 (0.00%)**	**0/23 (0.00%)**	**0/6**
Gastrointestinal disorders								

ABDOMINAL DISTENSION † 1								
# participants affected / at risk	**10/655 (1.53%)**	**13/626 (2.08%)**	**1/50 (2.00%)**	**2/122 (1.64%)**	**1/206 (0.49%)**	**1/26 (3.85%)**	**2/23 (8.70%)**	**0/6**
ABDOMINAL PAIN † 1								
# participants affected / at risk	**8/655 (1.22%)**	**10/626 (1.60%)**	**1/50 (2.00%)**	**2/122 (1.64%)**	**8/206 (3.88%)**	**1/26 (3.85%)**	**3/23 (13.04%)**	**1/6**
ABDOMINAL PAIN UPPER † 1								
# participants affected / at risk	**26/655 (3.97%)**	**15/626 (2.40%)**	**3/50 (6.00%)**	**5/122 (4.10%)**	**5/206 (2.43%)**	**3/26 (11.54%)**	**3/23 (13.04%)**	**3/6**
ABDOMINAL SYMPTOM † 1								
# participants affected / at risk	**0/655 (0.00%)**	**0/626 (0.00%)**	**0/50 (0.00%)**	**0/122 (0.00%)**	**0/206 (0.00%)**	**2/26 (7.69%)**	**0/23 (0.00%)**	**0/6**
ASCITES † 1								
# participants affected / at risk	**0/655 (0.00%)**	**1/626 (0.16%)**	**0/50 (0.00%)**	**0/122 (0.00%)**	**0/206 (0.00%)**	**1/26 (3.85%)**	**2/23 (8.70%)**	**0/6**
CONSTIPATION † 1								
# participants affected / at risk	**11/655 (1.68%)**	**8/626 (1.28%)**	**3/50 (6.00%)**	**1/122 (0.82%)**	**1/206 (0.49%)**	**0/26 (0.00%)**	**2/23 (8.70%)**	**1/6**
DIARRHOEA † 1								
# participants affected / at risk	**21/655 (3.21%)**	**21/626 (3.35%)**	**2/50 (4.00%)**	**1/122 (0.82%)**	**2/206 (0.97%)**	**1/26 (3.85%)**	**4/23 (17.39%)**	**3/6**
DYSPEPSIA † 1								
# participants affected / at risk	**12/655 (1.83%)**	**12/626 (1.92%)**	**1/50 (2.00%)**	**4/122 (3.28%)**	**2/206 (0.97%)**	**2/26 (7.69%)**	**0/23 (0.00%)**	**2/6**
GINGIVAL BLEEDING † 1								
# participants affected / at risk	**2/655 (0.31%)**	**0/626 (0.00%)**	**0/50 (0.00%)**	**0/122 (0.00%)**	**1/206 (0.49%)**	**2/26 (7.69%)**	**0/23 (0.00%)**	**0/6**
HAEMORRHOIDAL HAEMORRHAGE † 1								
# participants affected / at risk	**0/655 (0.00%)**	**0/626 (0.00%)**	**0/50 (0.00%)**	**1/122 (0.82%)**	**0/206 (0.00%)**	**0/26 (0.00%)**	**0/23 (0.00%)**	**0/6**
NAUSEA † 1								
# participants affected / at risk	**10/655 (1.53%)**	**18/626 (2.88%)**	**2/50 (4.00%)**	**3/122 (2.46%)**	**2/206 (0.97%)**	**3/26 (11.54%)**	**1/23 (4.35%)**	**1/6**
VOMITING † 1								
# participants affected / at risk	**6/655 (0.92%)**	**9/626 (1.44%)**	**2/50 (4.00%)**	**1/122 (0.82%)**	**1/206 (0.49%)**	**1/26 (3.85%)**	**2/23 (8.70%)**	**0/6**
General disorders								
ASTHENIA † 1								
# participants affected / at risk	**9/655 (1.37%)**	**6/626 (0.96%)**	**0/50 (0.00%)**	**6/122 (4.92%)**	**4/206 (1.94%)**	**0/26 (0.00%)**	**2/23 (8.70%)**	**1/6**
FATIGUE † 1								
# participants affected / at risk	**29/655 (4.43%)**	**33/626 (5.27%)**	**2/50 (4.00%)**	**7/122 (5.74%)**	**5/206 (2.43%)**	**0/26 (0.00%)**	**5/23 (21.74%)**	**12/**
MALAISE † 1								
# participants affected / at risk	**2/655 (0.31%)**	**2/626 (0.32%)**	**0/50 (0.00%)**	**2/122 (1.64%)**	**0/206 (0.00%)**	**2/26 (7.69%)**	**0/23 (0.00%)**	**0/6**
OEDEMA PERIPHERAL † 1								
# participants affected / at risk	**4/655 (0.61%)**	**4/626 (0.64%)**	**0/50 (0.00%)**	**0/122 (0.00%)**	**1/206 (0.49%)**	**4/26 (15.38%)**	**4/23 (17.39%)**	**0/6**
PITTING OEDEMA † 1								
# participants affected / at risk	**0/655 (0.00%)**	**0/626 (0.00%)**	**0/50 (0.00%)**	**0/122 (0.00%)**	**1/206 (0.49%)**	**2/26 (7.69%)**	**0/23 (0.00%)**	**0/6**
PYREXIA † 1								
# participants affected / at risk	**11/655 (1.68%)**	**11/626 (1.76%)**	**1/50 (2.00%)**	**2/122 (1.64%)**	**4/206 (1.94%)**	**4/26 (15.38%)**	**1/23 (4.35%)**	**2/6**
Hepatobiliary disorders								
HEPATIC LESION † 1								

# participants affected / at risk	2/655 (0.31%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/6
HEPATIC STEATOSIS † [1]								
# participants affected / at risk	1/655 (0.15%)	7/626 (1.12%)	0/50 (0.00%)	3/122 (2.46%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/6
Immune system disorders								
HYPERSENSITIVITY † [1]								
# participants affected / at risk	2/655 (0.31%)	0/626 (0.00%)	0/50 (0.00%)	1/122 (0.82%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	1/6
Infections and infestations								
BODY TINEA † [1]								
# participants affected / at risk	1/655 (0.15%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/6
GASTROENTERITIS † [1]								
# participants affected / at risk	5/655 (0.76%)	5/626 (0.80%)	1/50 (2.00%)	2/122 (1.64%)	2/206 (0.97%)	2/26 (7.69%)	0/23 (0.00%)	1/6
HEPATITIS B † [1]								
# participants affected / at risk	16/655 (2.44%)	7/626 (1.12%)	3/50 (6.00%)	2/122 (1.64%)	9/206 (4.37%)	1/26 (3.85%)	1/23 (4.35%)	2/6
INFLUENZA † [1]								
# participants affected / at risk	25/655 (3.82%)	22/626 (3.51%)	11/50 (22.00%)	6/122 (4.92%)	1/206 (0.49%)	1/26 (3.85%)	0/23 (0.00%)	4/6
NASOPHARYNGITIS † [1]								
# participants affected / at risk	69/655 (10.53%)	73/626 (11.66%)	1/50 (2.00%)	18/122 (14.75%)	6/206 (2.91%)	1/26 (3.85%)	3/23 (13.04%)	2/6
TINEA VERSICOLOUR † [1]								
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/6
TONSILLITIS † [1]								
# participants affected / at risk	4/655 (0.61%)	2/626 (0.32%)	0/50 (0.00%)	0/122 (0.00%)	2/206 (0.97%)	0/26 (0.00%)	0/23 (0.00%)	1/6
UPPER RESPIRATORY TRACT INFECTION † [1]								
# participants affected / at risk	50/655 (7.63%)	60/626 (9.58%)	2/50 (4.00%)	24/122 (19.67%)	9/206 (4.37%)	4/26 (15.38%)	4/23 (17.39%)	15/
VIRAL INFECTION † [1]								
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/6
Injury, poisoning and procedural complications								
CONTUSION † [1]								
# participants affected / at risk	2/655 (0.31%)	3/626 (0.48%)	0/50 (0.00%)	1/122 (0.82%)	0/206 (0.00%)	3/26 (11.54%)	1/23 (4.35%)	1/6
JOINT SPRAIN † [1]								
# participants affected / at risk	4/655 (0.61%)	4/626 (0.64%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/6
POST PROCEDURAL PAIN † [1]								
# participants affected / at risk	4/655 (0.61%)	1/626 (0.16%)	0/50 (0.00%)	2/122 (1.64%)	0/206 (0.00%)	0/26 (0.00%)	2/23 (8.70%)	1/6
THERMAL BURN † [1]								
# participants affected / at risk	0/655 (0.00%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/6
Investigations								
ALANINE AMINOTRANSFERASE INCREASED † [1]								
# participants affected / at risk	18/655 (2.75%)	12/626 (1.92%)	1/50 (2.00%)	0/122 (0.00%)	9/206 (4.37%)	0/26 (0.00%)	0/23 (0.00%)	0/6

BLOOD CREATINE PHOSPHOKINASE INCREASED † 1								
# participants affected / at risk	56/655 (8.55%)	47/626 (7.51%)	2/50 (4.00%)	5/122 (4.10%)	24/206 (11.65%)	3/26 (11.54%)	4/23 (17.39%)	2/6
HBV DNA INCREASED † 1								
# participants affected / at risk	1/655 (0.15%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	12/206 (5.83%)	0/26 (0.00%)	0/23 (0.00%)	0/6
WEIGHT DECREASED † 1								
# participants affected / at risk	3/655 (0.46%)	4/626 (0.64%)	0/50 (0.00%)	1/122 (0.82%)	3/206 (1.46%)	1/26 (3.85%)	2/23 (8.70%)	0/6
WEIGHT INCREASED † 1								
# participants affected / at risk	1/655 (0.15%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	2/23 (8.70%)	0/6
Metabolism and nutrition disorders								
DIABETES MELLITUS NON-INSULIN-DEPENDENT † 1								
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	1/50 (2.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/6
HYPERCHOLESTEROLAEMIA † 1								
# participants affected / at risk	0/655 (0.00%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	1/206 (0.49%)	0/26 (0.00%)	0/23 (0.00%)	0/6
Musculoskeletal and connective tissue disorders								
ARTHRALGIA † 1								
# participants affected / at risk	18/655 (2.75%)	15/626 (2.40%)	1/50 (2.00%)	4/122 (3.28%)	6/206 (2.91%)	1/26 (3.85%)	3/23 (13.04%)	1/6
BACK PAIN † 1								
# participants affected / at risk	16/655 (2.44%)	16/626 (2.56%)	1/50 (2.00%)	2/122 (1.64%)	8/206 (3.88%)	1/26 (3.85%)	2/23 (8.70%)	3/6
MUSCLE CRAMP † 1								
# participants affected / at risk	1/655 (0.15%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	1/26 (3.85%)	2/23 (8.70%)	0/6
MUSCLE SPASMS † 1								
# participants affected / at risk	1/655 (0.15%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/6
MUSCULAR WEAKNESS † 1								
# participants affected / at risk	3/655 (0.46%)	0/626 (0.00%)	3/50 (6.00%)	1/122 (0.82%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/6
MUSCULOSKELETAL CHEST PAIN † 1								
# participants affected / at risk	2/655 (0.31%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/6
NECK PAIN † 1								
# participants affected / at risk	5/655 (0.76%)	1/626 (0.16%)	0/50 (0.00%)	0/122 (0.00%)	1/206 (0.49%)	0/26 (0.00%)	0/23 (0.00%)	1/6
PAIN IN EXTREMITY † 1								
# participants affected / at risk	8/655 (1.22%)	10/626 (1.60%)	0/50 (0.00%)	2/122 (1.64%)	2/206 (0.97%)	2/26 (7.69%)	1/23 (4.35%)	1/6
Neoplasms benign, malignant and unspecified (incl cysts and polyps)								
HEPATIC NEOPLASM † 1								
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	1/6
Nervous system disorders								
DIZZINESS † 1								
# participants affected / at								

risk	7/655 (1.07%)	7/626 (1.12%)	1/50 (2.00%)	4/122 (3.28%)	4/206 (1.94%)	2/26 (7.69%)	1/23 (4.35%)	2/6
HEADACHE † 1								
# participants affected / at risk	28/655 (4.27%)	28/626 (4.47%)	2/50 (4.00%)	5/122 (4.10%)	9/206 (4.37%)	2/26 (7.69%)	2/23 (8.70%)	2/6
Psychiatric disorders								
DEPRESSION † 1								
# participants affected / at risk	5/655 (0.76%)	4/626 (0.64%)	0/50 (0.00%)	0/122 (0.00%)	1/206 (0.49%)	0/26 (0.00%)	0/23 (0.00%)	1/6
Renal and urinary disorders								
GLOMERULONEPHRITIS PROLIFERATIVE † 1								
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/6
HAEMATURIA † 1								
# participants affected / at risk	0/655 (0.00%)	1/626 (0.16%)	0/50 (0.00%)	1/122 (0.82%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/6
Respiratory, thoracic and mediastinal disorders								
COUGH † 1								
# participants affected / at risk	27/655 (4.12%)	22/626 (3.51%)	1/50 (2.00%)	4/122 (3.28%)	12/206 (5.83%)	3/26 (11.54%)	2/23 (8.70%)	3/6
NASAL CONGESTION † 1								
# participants affected / at risk	3/655 (0.46%)	2/626 (0.32%)	0/50 (0.00%)	0/122 (0.00%)	1/206 (0.49%)	0/26 (0.00%)	0/23 (0.00%)	0/6
PHARYNGOLARYNGEAL PAIN † 1								
# participants affected / at risk	17/655 (2.60%)	11/626 (1.76%)	1/50 (2.00%)	7/122 (5.74%)	5/206 (2.43%)	1/26 (3.85%)	0/23 (0.00%)	3/6
RHINITIS ALLERGIC † 1								
# participants affected / at risk	5/655 (0.76%)	1/626 (0.16%)	0/50 (0.00%)	3/122 (2.46%)	2/206 (0.97%)	0/26 (0.00%)	2/23 (8.70%)	0/6
Skin and subcutaneous tissue disorders								
ACNE † 1								
# participants affected / at risk	1/655 (0.15%)	3/626 (0.48%)	1/50 (2.00%)	0/122 (0.00%)	1/206 (0.49%)	0/26 (0.00%)	0/23 (0.00%)	0/6
ECZEMA † 1								
# participants affected / at risk	3/655 (0.46%)	3/626 (0.48%)	1/50 (2.00%)	1/122 (0.82%)	0/206 (0.00%)	1/26 (3.85%)	0/23 (0.00%)	0/6
PALMAR ERYTHEMA † 1								
# participants affected / at risk	0/655 (0.00%)	1/626 (0.16%)	0/50 (0.00%)	1/122 (0.82%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/6
PSORIASIS † 1								
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	3/50 (6.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/6
RASH † 1								
# participants affected / at risk	12/655 (1.83%)	6/626 (0.96%)	0/50 (0.00%)	7/122 (5.74%)	2/206 (0.97%)	2/26 (7.69%)	0/23 (0.00%)	2/6
SPIDER NAEVUS † 1								
# participants affected / at risk	2/655 (0.31%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	2/26 (7.69%)	0/23 (0.00%)	0/6
Surgical and medical procedures								
EYE OPERATION † 1								
# participants affected / at risk	0/655 (0.00%)	0/626 (0.00%)	0/50 (0.00%)	0/122 (0.00%)	0/206 (0.00%)	0/26 (0.00%)	0/23 (0.00%)	0/6
Vascular disorders								

HYPERTENSION † 1								
# participants affected / at risk	**11/655 (1.68%)**	**15/626 (2.40%)**	**0/50 (0.00%)**	**5/122 (4.10%)**	**1/206 (0.49%)**	**1/26 (3.85%)**	**2/23 (8.70%)**	**0/6**
VARICOSE VEIN † 1								
# participants affected / at risk	**2/655 (0.31%)**	**0/626 (0.00%)**	**0/50 (0.00%)**	**0/122 (0.00%)**	**0/206 (0.00%)**	**2/26 (7.69%)**	**0/23 (0.00%)**	**0/6**

† 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; or the publication of the trial results in their entirety.

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:

Hsu CW, Chao YC, Lee CM, Chang TT, Chen YC. Efficacy of telbivudine in Taiwanese chronic hepatitis B patients compared with GLOBE extension study and predicting treatment outcome by HBV DNA kinetics at week 24. BMC Gastroenterol. 2012 Dec 13;12:178. doi: 10.1186/1471-230X-12-178.

Responsible Party:	Novartis (Novartis Pharmaceuticals)
ClinicalTrials.gov Identifier:	NCT00142298 History of Changes
Other Study ID Numbers:	**CLDT600A2303** NV-02B-022 (Other Identifier: Idenix)
Study First Received:	August 31, 2005
Results First Received:	January 12, 2011
Last Updated:	March 24, 2015
Health Authority:	United States: Food and Drug Administration