EU Clinical Trials Register

Clinical trial results:
A Randomized, Open-Label, Multicenter Study to Evaluate the Efficacy and Safety of ABT-493/ABT-530 in Adults with Chronic Hepatitis C Virus Genotype 1 Infection (ENDURANCE-1)

Summary

EudraCT number	2015-002087-17
Trial protocol	HU PT BE AT SE DE LT ES PL GB IT
Global end of trial date	06 January 2017

Results information

Result version number	v1 (current)
This version publication date	07 December 2017
First version publication date	07 December 2017

Trial information

Trial identification

Sponsor protocol code	M13-590

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02604017
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	AbbVie Deutschland GmbH & Co. KG
Sponsor organisation address	AbbVie House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, United Kingdom, SL6-4UB
Public contact	Global Medical Services, Abbvie, 001 800-633-9110,
Scientific contact	Federico Mensa, Abbvie, federico.mensa@abbvie.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	06 January 2017
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	06 January 2017
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This study seeks to evaluate the efficacy and safety of ABT-493/ABT-530 in subjects with Genotype 1 hepatitis C virus infection without cirrhosis

Protection of trial subjects:

Subjects read and understood the information provided about the study and gave written permission.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	21 October 2015
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 39
Country: Number of subjects enrolled	Portugal: 21
Country: Number of subjects enrolled	Romania: 41
Country: Number of subjects enrolled	Spain: 34
Country: Number of subjects enrolled	Sweden: 6
Country: Number of subjects enrolled	United Kingdom: 28
Country: Number of subjects enrolled	Austria: 24
Country: Number of subjects enrolled	Belgium: 38
Country: Number of subjects enrolled	France: 25
Country: Number of subjects enrolled	Germany: 24
Country: Number of subjects enrolled	Hungary: 36
Country: Number of subjects enrolled	Lithuania: 6
Country: Number of subjects enrolled	Australia: 37
Country: Number of subjects enrolled	Canada: 46
Country: Number of subjects enrolled	Chile: 30
Country: Number of subjects enrolled	Israel: 34
Country: Number of subjects enrolled	Korea, Republic of: 35
Country: Number of subjects enrolled	Mexico: 5
Country: Number of subjects enrolled	New Zealand: 6
Country: Number of subjects enrolled	Puerto Rico: 24
Country: Number of subjects enrolled	Switzerland: 27
Country: Number of subjects enrolled	Taiwan: 35

Country: Number of subjects enrolled	United States: 72
Country: Number of subjects enrolled	Italy: 31
Worldwide total number of subjects	704
EEA total number of subjects	353

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	627
From 65 to 84 years	77
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -	

Pre-assignment

Screening details:

This study included a 35-day screening period.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Randomised - controlled
Blinding used	Not blinded

Arms

Are arms mutually exclusive?	Yes
Arm title	ABT-493/ABT-530 for 12 weeks

Arm description:

ABT-493/ABT-530 (300 mg/120 mg) coformulated once daily (QD) for 12 weeks.

Arm type	Experimental
Investigational medicinal product name	ABT-493/ABT-530
Investigational medicinal product code	
Other name	ABT-493 also known as glecaprevir, ABT-530 also known as pibrentasvir
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet; ABT-493 coformulated with ABT-530

Arm title	ABT-493/ABT-530 for 8 weeks

Arm description:

ABT-493/ABT-530 (300 mg/120 mg) coformulated once daily (QD) for 8 weeks.

Arm type	Experimental
Investigational medicinal product name	ABT-493/ABT-530
Investigational medicinal product code	
Other name	ABT-493 also known as glecaprevir, ABT-530 also known as pibrentasvir
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet; ABT-493 coformulated with ABT-530

Number of subjects in period 1[1]	ABT-493/ABT-530 for 12 weeks	ABT-493/ABT-530 for 8 weeks
Started	352	351
Completed	346	343
Not completed	6	8
Not specified	1	-

Lost to follow-up	5	6
Withdrew consent	-	2

Notes:

[1] - The number of subjects reported to be in the baseline period are not the same as the worldwide number enrolled in the trial. It is expected that these numbers will be the same.

Justification: A total of 704 subjects were randomized; 1 subject did not receive at least 1 dose of study drug and was excluded from the analyses.

Baseline characteristics

Reporting groups

Reporting group title	ABT-493/ABT-530 for 12 weeks
Reporting group description:	
ABT-493/ABT-530 (300 mg/120 mg) coformulated once daily (QD) for 12 weeks.	
Reporting group title	ABT-493/ABT-530 for 8 weeks
Reporting group description:	
ABT-493/ABT-530 (300 mg/120 mg) coformulated once daily (QD) for 8 weeks.	

Reporting group values	ABT-493/ABT-530 for 12 weeks	ABT-493/ABT-530 for 8 weeks	Total
Number of subjects	352	351	703
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	50.27	51.58	
standard deviation	± 11.62	± 11.9	-
Gender categorical			
Units: Subjects			
Female	176	184	360
Male	176	167	343

End points

End points reporting groups

Reporting group title	ABT-493/ABT-530 for 12 weeks
Reporting group description:	
ABT-493/ABT-530 (300 mg/120 mg) coformulated once daily (QD) for 12 weeks.	
Reporting group title	ABT-493/ABT-530 for 8 weeks
Reporting group description:	
ABT-493/ABT-530 (300 mg/120 mg) coformulated once daily (QD) for 8 weeks.	

Primary: Percentage of Subjects With Sustained Virologic Response 12 Weeks Post-treatment (SVR12) in Mono-infected Hepatitis C Virus Genotype 1 (HCV GT1), Direct-acting Antiviral Agent (DAA) Naïve Subjects in the 12-Week Treatment Arm

End point title	Percentage of Subjects With Sustained Virologic Response 12 Weeks Post-treatment (SVR12) in Mono-infected Hepatitis C Virus Genotype 1 (HCV GT1), Direct-acting Antiviral Agent (DAA) Naïve Subjects in the 12-Week Treatment Arm[1][2]

End point description:

SVR12 was defined as plasma hepatitis C virus ribonucleic acid (HCV RNA) level less than the lower limit of quantification [<LLOQ]) 12 weeks after the last dose of study drug. The primary efficacy endpoint was noninferiority of the percentage of subjects who achieved SVR12 in the 12-week treatment group compared with the historical control rate for HCV GT1 subjects who are treatment-naïve current standard of care (ombitasvir/paritaprevir/ritonavir + dasabuvir ± ribavirin [3D ± RBV] or previous standard of care (sofosbuvir/ledipasvir [SOF/LDV]). Subjects with missing data after backwards imputation were imputed as nonresponders. Based on a 2-sided significance level of 0.05 and an underlying rate of ≥97% in the 12-week arm, 270 subjects provides >90% power to demonstrate noninferiority with a noninferiority margin of 6% (based on the normal approximation of a single binomial proportion in a one-sample test for superiority).

End point type	Primary

End point timeframe:

12 weeks after the last actual dose of study drug

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: The lower confidence bound of the 2-sided 95% confidence interval (95% CI) for the percentage of subjects with SVR12 must exceed 91% to achieve noninferiority.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint compared the percentage of subjects with SVR12 in the 12-week arm with an historical control per protocol.

End point values	ABT-493/ABT-530 for 12 weeks			
Subject group type	Reporting group			
Number of subjects analysed	332[3]			
Units: percentage of subjects				
number (confidence interval 95%)	99.7 (99.1 to 100)			

Notes:

[3] - All subjects in the ITT population who were mono-infected HCV GT1, DAA-naïve

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Subjects With SVR12: Noninferiority of 8-Week Arm to 12-Week Arm in Mono-infected HCV GT1, DAA-Naïve Subjects, Excluding Those Who Discontinued/Experienced Virologic Failure by Week 8 or Had No HCV RNA Value at Week 12 or Later

End point title	Percentage of Subjects With SVR12: Noninferiority of 8-Week Arm to 12-Week Arm in Mono-infected HCV GT1, DAA-Naïve Subjects, Excluding Those Who Discontinued/Experienced Virologic Failure by Week 8 or Had No HCV RNA Value at Week 12 or Later

End point description:

SVR12 was defined as plasma HCV RNA level <LLOQ 12 weeks after the last dose of study drug. The primary efficacy endpoint was noninferiority of the percentage of mono-infected HCV GT1, DAA-naïve subjects (excluding those who discontinued/experienced virologic failure by Week 8 or had no HCV RNA value at Week 12 or later) who achieved SVR12 in the 8-week treatment arm compared with the 12-week treatment arm. Subjects with missing data after backwards imputation were imputed as nonresponders.

End point type	Primary

End point timeframe:

12 weeks after last actual dose of study drug

End point values	ABT-493/ABT-530 for 12 weeks	ABT-493/ABT-530 for 8 weeks		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	331[4]	332[5]		
Units: percentage of subjects				
number (confidence interval 95%)	100 (98.9 to 100)	100 (98.9 to 100)		

Notes:

[4] - ITT population;HCV GT1;DAA-naïve;exclude discontinued/virologic failure ≤Week 8/no HCV RNA ≥Week 12

[5] - ITT population;HCV GT1;DAA-naïve;exclude discontinued/virologic failure ≤Week 8/no HCV RNA ≥Week 12

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Based on a 2-sided significance level of 0.05 and an -5% noninferiority margin and an underlying rate of ≥97% in the 8-week arm (270 subjects) and ≥97% in the 12-week arm (270 subjects) provides >90% power to demonstrate noninferiority of the 8-week arm to the 12-week arm.

Comparison groups	ABT-493/ABT-530 for 12 weeks v ABT-493/ABT-530 for 8 weeks
Number of subjects included in analysis	663
Analysis specification	Pre-specified
Analysis type	non-inferiority[6]
Parameter estimate	Difference in percentage of subjects
Point estimate	0
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	1.1

Notes:

[6] - The noninferiority of the rate of SVR12 for the 8-week treatment group as compared with the 12-week treatment group was analyzed; the lower confidence bound of the 2-sided 95% confidence interval (95% CI) for the difference in percentage of subjects with SVR12 (8-week group minus 12-week group) must be above -5% to achieve noninferiority.

Primary: Percentage of Subjects With SVR12: Noninferiority of 8-Week Treatment Arm to 12-Week Treatment Arm in Mono-infected HCV GT1, DAA-Naïve Subjects

End point title	Percentage of Subjects With SVR12: Noninferiority of 8-Week Treatment Arm to 12-Week Treatment Arm in Mono-infected HCV GT1, DAA-Naïve Subjects

End point description:

SVR12 was defined as plasma HCV RNA level <LLOQ 12 weeks after the last dose of study drug. The primary efficacy endpoint was noninferiority of the percentage of mono-infected HCV GT1, DAA-naïve subjects who achieved SVR12 in the 8-week treatment arm compared with the 12-week treatment arm. Subjects with missing data after backwards imputation were imputed as nonresponders.

End point type	Primary

End point timeframe:

12 weeks after the last actual dose of study drug

End point values	ABT-493/ABT-530 for 12 weeks	ABT-493/ABT-530 for 8 weeks		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	332[7]	335[8]		
Units: percentage of subjects				
number (confidence interval 95%)	99.7 (99.1 to 100)	99.1 (98.1 to 100)		

Notes:

[7] - All subjects in the ITT population who were mono-infected HCV GT1, DAA-naïve

[8] - All subjects in the ITT population who were mono-infected HCV GT1, DAA-naïve

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Based on a 2-sided significance level of 0.05 and a -5% noninferiority margin, and an underlying rate of ≥97% in the 8-week arm (270 subjects) and ≥97% in the 12-week arm (270 subjects) provides >90% power to demonstrate noninferiority of the 8-week arm to the 12-week arm.

Comparison groups	ABT-493/ABT-530 for 12 weeks v ABT-493/ABT-530 for 8 weeks
Number of subjects included in analysis	667
Analysis specification	Pre-specified
Analysis type	non-inferiority[9]
Parameter estimate	Difference in percentage of subjects
Point estimate	-0.6
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.8
upper limit	0.6

Notes:

[9] - The noninferiority of the rate of SVR12 for the 8-week treatment group as compared with the 12-week treatment group was analyzed; the lower confidence bound of the 2-sided 95% confidence interval (95% CI) for the difference in percentage of subjects with SVR12 must be above -5% to achieve noninferiority.

Secondary: Percentage of Subjects With SVR12 in Mono-infected HCV GT1 Subjects

End point title	Percentage of Subjects With SVR12 in Mono-infected HCV GT1 Subjects
End point description:	
SVR12 was defined as plasma HCV RNA level <LLOQ 12 weeks after the last dose of study drug. Subjects with missing data after backwards imputation were imputed as nonresponders.	
End point type	Secondary
End point timeframe:	
12 weeks after last actual dose of study drug	

End point values	ABT-493/ABT-530 for 12 weeks	ABT-493/ABT-530 for 8 weeks		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	334[10]	336[11]		
Units: percentage of subjects				
number (confidence interval 95%)	99.7 (98.3 to 99.9)	99.1 (97.4 to 99.7)		

Notes:

[10] - All subjects in the ITT population who were mono-infected HCV GT1

[11] - All subjects in the ITT population who were mono-infected HCV GT1

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With SVR12

End point title	Percentage of Subjects With SVR12
End point description:	
SVR12 was defined as plasma HCV RNA level less than the <LLOQ 12 weeks after the last dose of study drug. Subjects with missing data after backwards imputation were imputed as nonresponders.	
End point type	Secondary
End point timeframe:	
12 weeks after last actual dose of study drug	

End point values	ABT-493/ABT-530 for 12 weeks	ABT-493/ABT-530 for 8 weeks		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	352[12]	351[13]		
Units: percentage of subjects				
number (confidence interval 95%)	99.7 (98.4 to 99.9)	99.1 (97.5 to 99.7)		

Notes:

[12] - All subjects in the ITT population

[13] - All subjects in the ITT population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With SVR12 in Co-infected HCV GT1/Human Immununovirus Type 1 (HIV-1) Subjects

End point title	Percentage of Subjects With SVR12 in Co-infected HCV GT1/Human Immununovirus Type 1 (HIV-1) Subjects
End point description:	
SVR12 was defined as plasma HCV RNA level <LLOQ 12 weeks after the last dose of study drug. Subjects with missing data after backwards imputation were imputed as nonresponders.	
End point type	Secondary
End point timeframe:	
12 weeks after last actual dose of study drug	

End point values	ABT-493/ABT-530 for 12 weeks	ABT-493/ABT-530 for 8 weeks		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18[14]	15[15]		
Units: percentage of subjects				
number (confidence interval 95%)	100 (82.4 to 100)	100 (79.6 to 100)		

Notes:

[14] - All subjects in the ITT population who were co-infected HCV GT1/HIV-1

[15] - All subjects in the ITT population who were co-infected HCV GT1/HIV-1

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With SVR12 in HCV GT1-infected, Prior Sofosbuvir (SOF) Treatment-Experienced Subjects

End point title	Percentage of Subjects With SVR12 in HCV GT1-infected, Prior Sofosbuvir (SOF) Treatment-Experienced Subjects
End point description:	
SVR12 was defined as plasma HCV RNA level <LLOQ 12 weeks after the last dose of study drug. Subjects with missing data after backwards imputation were imputed as nonresponders.	
End point type	Secondary
End point timeframe:	
12 weeks after last actual dose of study drug	

End point values	ABT-493/ABT-530 for 12 weeks	ABT-493/ABT-530 for 8 weeks		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	2[16]	1[17]		
Units: percentage of subjects				
number (confidence interval 95%)	100 (34.2 to 100)	100 (20.7 to 100)		

Notes:

[16] - All subjects in the ITT population who were HCV GT1-infected, prior SOF-treatment experienced

[17] - All subjects in the ITT population who were HCV GT1-infected, prior SOF-treatment experienced

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With On-treatment Virologic Failure

End point title	Percentage of Subjects With On-treatment Virologic Failure
End point description:	

On-treatment virologic failure was defined as confirmed increase of >1 $\log_{10}$ IU/mL above the lowest value post-baseline HCV RNA during treatment; confirmed HCV RNA ≥100 IU/mL after HCV RNA <LLOQ during treatment, or HCV RNA ≥LLOQ at end of treatment with at least 6 weeks of treatment.

End point type	Secondary
End point timeframe:	

Treatment Weeks 1, 2, 4, 8 (end of treatment for 8-week treatment arm), and 12 (end of treatment for 12-week treatment arm) or premature discontinuation from treatment

End point values	ABT-493/ABT-530 for 12 weeks	ABT-493/ABT-530 for 8 weeks		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	352[18]	351[19]		
Units: percentage of subjects				
number (confidence interval 95%)	0 (0 to 1.1)	0.3 (0.1 to 1.6)		

Notes:

[18] - All subjects in the ITT population

[19] - All subjects in the ITT population

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With On-treatment Virologic Failure in Mono-infected HCV GT1, DAA-Naïve Subjects

End point title	Percentage of Subjects With On-treatment Virologic Failure in Mono-infected HCV GT1, DAA-Naïve Subjects
End point description:	

On-treatment virologic failure was defined as confirmed increase of >1 $\log_{10}$ IU/mL above the lowest value post-baseline HCV RNA during treatment; confirmed HCV RNA ≥100 IU/mL after HCV RNA <LLOQ during treatment, or HCV RNA ≥LLOQ at end of treatment with at least 6 weeks of treatment.

End point type	Secondary

End point timeframe:

Treatment Weeks 1, 2, 4, 8 (end of treatment for 8-week treatment arm), and 12 (end of treatment for 12-week treatment arm) or premature discontinuation from treatment

End point values	ABT-493/ABT-530 for 12 weeks	ABT-493/ABT-530 for 8 weeks		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	332[20]	335[21]		
Units: percentage of subjects				
number (confidence interval 95%)	0 (0 to 1.1)	0.3 (0.1 to 1.7)		

Notes:

[20] - All subjects in the ITT population who were mono-infected HCV GT1, DAA-naïve

[21] - All subjects in the ITT population who were mono-infected HCV GT1, DAA-naïve

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Post-treatment Relapse

End point title	Percentage of Subjects With Post-treatment Relapse

End point description:

Post-treatment relapse was defined as confirmed HCV RNA ≥LLOQ between the end of treatment and 12 weeks after the last dose of study drug among subjects who completed treatment with HCV RNA levels <LLOQ at the end of treatment.

End point type	Secondary

End point timeframe:

From the end of treatment through 12 weeks after the last dose of study drug

End point values	ABT-493/ABT-530 for 12 weeks	ABT-493/ABT-530 for 8 weeks		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	352[22]	349[23]		
Units: percentage of subjects				
number (confidence interval 95%)	0 (0 to 1.1)	0 (0 to 1.1)		

Notes:

[22] - All subjects who received ≥1 dose study drug; completed treatment; HCV RNA <LLOQ at end of treatment

[23] - All subjects who received ≥1 dose study drug; completed treatment; HCV RNA <LLOQ at end of treatment

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Subjects With Post-treatment Relapse in Mono-infected HCV GT1, DAA-Naïve Subjects

End point title	Percentage of Subjects With Post-treatment Relapse in Mono-infected HCV GT1, DAA-Naïve Subjects

End point description:

Post-treatment relapse was defined as confirmed HCV RNA ≥LLOQ between the end of treatment and 12 weeks after the last dose of study drug among mono-infected HCV GT1, DAA-naïve subjects who completed treatment with HCV RNA levels <LLOQ at the end of treatment.

End point type	Secondary

End point timeframe:

From the end of treatment through 12 weeks after the last dose of study drug

End point values	ABT-493/ABT-530 for 12 weeks	ABT-493/ABT-530 for 8 weeks		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	332[24]	333[25]		
Units: percentage of subjects				
number (confidence interval 95%)	0 (0 to 1.1)	0 (0 to 1.1)		

Notes:

[24] - All subjects who received ≥1 dose study drug; completed treatment; HCV RNA <LLOQ at end of treatment

[25] - All subjects who received ≥1 dose study drug; completed treatment; HCV RNA <LLOQ at end of treatment

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Treatment-emergent adverse events (TEAEs) and serious adverse events (TESAEs) were collected from the time of study drug administration until 30 days after the last dose of study drug (up to 16 weeks).

Adverse event reporting additional description:

TEAEs and TESAEs are defined as any adverse event (AE) with an onset or worsening date that is after the first dose of study drug until 30 days after the last dose of study drug and were collected whether elicited or spontaneously reported by the subject.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	19.0

Reporting groups

Reporting group title	ABT-493/ABT-530 for 12 Weeks

Reporting group description:

ABT-493/ABT-530 (300 mg/120 mg) coformulated once daily (QD) for 12 weeks.

Reporting group title	ABT-493/ABT-530 for 8 Weeks

Reporting group description:

ABT-493/ABT-530 (300 mg/120 mg) coformulated once daily (QD) for 8 weeks.

Serious adverse events	ABT-493/ABT-530 for 12 Weeks	ABT-493/ABT-530 for 8 Weeks	
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 352 (1.14%)	5 / 351 (1.42%)	
number of deaths (all causes)	1	0	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Uterine leiomyoma			
subjects affected / exposed	0 / 352 (0.00%)	1 / 351 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Alcohol poisoning			
subjects affected / exposed	1 / 352 (0.28%)	0 / 351 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Arterial injury			

subjects affected / exposed	0 / 352 (0.00%)	1 / 351 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Radius fracture			
subjects affected / exposed	0 / 352 (0.00%)	1 / 351 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			
subjects affected / exposed	1 / 352 (0.28%)	0 / 351 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cardiac disorders			
Angina unstable			
subjects affected / exposed	0 / 352 (0.00%)	1 / 351 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	1 / 352 (0.28%)	0 / 351 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Transient ischaemic attack			
subjects affected / exposed	0 / 352 (0.00%)	1 / 351 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Irritable bowel syndrome			
subjects affected / exposed	1 / 352 (0.28%)	0 / 351 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Pneumonia aspiration			

	1 / 352 (0.28%)	0 / 351 (0.00%)	
subjects affected / exposed	1 / 352 (0.28%)	0 / 351 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Suicide attempt			
subjects affected / exposed	0 / 352 (0.00%)	1 / 351 (0.28%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchitis			
subjects affected / exposed	1 / 352 (0.28%)	0 / 351 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Frequency threshold for reporting non-serious adverse events: 5 %

Non-serious adverse events	ABT-493/ABT-530 for 12 Weeks	ABT-493/ABT-530 for 8 Weeks	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	130 / 352 (36.93%)	133 / 351 (37.89%)	
Nervous system disorders			
Headache			
subjects affected / exposed	62 / 352 (17.61%)	68 / 351 (19.37%)	
occurrences (all)	72	73	
General disorders and administration site conditions			
Fatigue			
subjects affected / exposed	43 / 352 (12.22%)	31 / 351 (8.83%)	
occurrences (all)	45	31	
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	29 / 352 (8.24%)	19 / 351 (5.41%)	
occurrences (all)	30	20	
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	17 / 352 (4.83%)	20 / 351 (5.70%)	
occurrences (all)	17	20	
Psychiatric disorders			

Insomnia			
subjects affected / exposed	15 / 352 (4.26%)	21 / 351 (5.98%)	
occurrences (all)	16	23	
Infections and infestations Nasopharyngitis			
subjects affected / exposed	31 / 352 (8.81%)	22 / 351 (6.27%)	
occurrences (all)	32	24	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
16 December 2015	The main purpose of this amendment was to evaluation of hepatitis C virus (HCV) genotype 1 (GT1)-infected non-cirrhotic subjects who are co-infected with human immununovirus type 1 (HIV-1) and/or sofosbuvir (SOF)-experienced plus ribivarin (RBV) with or without pegylated IFN (pegIFN) (SOF plus RBV ± pegIFN), and to clarify the time period for avoiding pregnancy and methods of contraception.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

 None reported