Clinical trial results:
Long-Term Safety and Efficacy of ABT-126 in Subjects with Schizophrenia: A Double-Blind Extension Study for Subjects Completing Study M10-855

Due to the EudraCT – Results system being out of service between 31 July 2015 and 12 January 2016, these results have been published in compliance with revised timelines.

Summary

EudraCT number	2012-005661-13
Trial protocol	GB
Global end of trial date	03 December 2014

Results information

Result version number	v1 (current)
This version publication date	24 July 2016
First version publication date	24 July 2016

Trial information

Trial identification

Sponsor protocol code	M13-765

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01834638
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Abbvie Deutschland GmbH & Co.KG
Sponsor organisation address	Abbott House, Vanwall Business Park, Vanwall Road, Maidenhead, Berkshire, United Kingdom, SL6 4UB
Public contact	Global Medical Services, AbbVie, 001 800-633-9110,
Scientific contact	George Haig, AbbVie, george.haig@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	03 December 2014
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	03 December 2014
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

The objective of this study is to obtain long-term safety, efficacy and health outcomes data in patients with schizophrenia.

Protection of trial subjects:

Subject and/or legal guardian read and understood the information provided about the study and gave written permission.

Background therapy:

Subjects remained on their baseline antipsychotic treatment regimen during the entire study.

Evidence for comparator: -

Actual start date of recruitment	29 March 2013
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United Kingdom: 6
Country: Number of subjects enrolled	Russian Federation: 147
Country: Number of subjects enrolled	United States: 114
Worldwide total number of subjects	267
EEA total number of subjects	6

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)	265
From 65 to 84 years	2

85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Stable nonsmoking male and female subjects with a diagnosis of schizophrenia who were receiving one or more allowed antipsychotic medications and who completed Study M10-855 (EudraCT number 2012-005661-13) and met all inclusion criteria and none of the exclusion criteria were enrolled into the study.

Period 1

Period 1 title	Overall Study (overall period)
Is this the baseline period?	Yes
Allocation method	Non-randomised - controlled
Blinding used	Double blind
Roles blinded	Subject, Investigator

Blinding implementation details:

All subjects received ABT-126, but the investigator and the subject were blinded to the actual dose of ABT-126 in order to maintain the study blind from base Study M10-855.

Arms

Are arms mutually exclusive?	Yes
Arm title	ABT-126 25 mg QD

Arm description:

1 ABT-126 25 mg capsule and 2 placebo capsules taken orally once daily (QD) in the morning each day for 52 weeks

Arm type	Experimental
Investigational medicinal product name	ABT-126
Investigational medicinal product code	ABT-126
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects were instructed to take 3 capsules at approximately the same time each morning.

Arm title	ABT-126 50 mg QD

Arm description:

2 ABT-126 25 mg capsules and 1 placebo capsule taken orally QD in the morning each day for 52 weeks

Arm type	Experimental
Investigational medicinal product name	ABT-126
Investigational medicinal product code	ABT-126
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects were instructed to take 3 capsules at approximately the same time each morning.

Arm title	ABT-126 75 mg QD

Arm description:

3 ABT-126 25 mg capsules taken orally QD in the morning each day for 52 weeks

Arm type	Experimental

Investigational medicinal product name	ABT-126
Investigational medicinal product code	ABT-126
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Subjects were instructed to take 3 capsules at approximately the same time each morning.

Number of subjects in period 1	ABT-126 25 mg QD	ABT-126 50 mg QD	ABT-126 75 mg QD
Started	47	172	48
Completed	10	11	8
Not completed	37	161	40
Consent withdrawn by subject	7	10	6
Not specified	27	147	31
Adverse event	1	1	-
Lost to follow-up	-	3	2
Noncompliance	2	-	1

Baseline characteristics

Reporting groups	
Reporting group title	ABT-126 25 mg QD
Reporting group description:	
1 ABT-126 25 mg capsule and 2 placebo capsules taken orally once daily (QD) in the morning each day for 52 weeks	
Reporting group title	ABT-126 50 mg QD
Reporting group description:	
2 ABT-126 25 mg capsules and 1 placebo capsule taken orally QD in the morning each day for 52 weeks	
Reporting group title	ABT-126 75 mg QD
Reporting group description:	
3 ABT-126 25 mg capsules taken orally QD in the morning each day for 52 weeks	

Reporting group values	ABT-126 25 mg QD	ABT-126 50 mg QD	ABT-126 75 mg QD
Number of subjects	47	172	48
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	 41.1 ± 10.26	 41.6 ± 11.91	 40.8 ± 10.9
Gender categorical Units: Subjects			
Female	26	84	25
Male	21	88	23

Reporting group values	Total		
Number of subjects	267		
Age categorical Units: Subjects			
Age continuous Units: years arithmetic mean standard deviation	 -		
Gender categorical Units: Subjects			
Female	135		
Male	132		

End points

End points reporting groups

Reporting group title	ABT-126 25 mg QD
Reporting group description:	
1 ABT-126 25 mg capsule and 2 placebo capsules taken orally once daily (QD) in the morning each day for 52 weeks	
Reporting group title	ABT-126 50 mg QD
Reporting group description:	
2 ABT-126 25 mg capsules and 1 placebo capsule taken orally QD in the morning each day for 52 weeks	
Reporting group title	ABT-126 75 mg QD
Reporting group description:	
3 ABT-126 25 mg capsules taken orally QD in the morning each day for 52 weeks	
Subject analysis set title	ABT-126 Total
Subject analysis set type	Full analysis
Subject analysis set description:	
1, 2, or 3 ABT-126 25 mg capsules (25 mg, 50 mg, or 75 mg ABT-126) taken orally QD in the morning each day for 52 weeks	

Primary: Number of Subjects with Treatment-emergent Adverse Events (AEs) or Serious AEs (SAEs)

End point title	Number of Subjects with Treatment-emergent Adverse Events (AEs) or Serious AEs (SAEs)[1]
End point description:	
AE: any untoward medical occurrence, which does not necessarily have a causal relationship with treatment. SAE: an AE that meets any of the following criteria: results in death; is life-threatening; results in hospitalization or prolongation of hospitalization; is a congenital anomaly; results in persistent or significant disability/incapacity; is an important medical event requiring medical or surgical intervention to prevent serious outcome. All AEs presented were treatment-emergent unless otherwise noted. Treatment-emergent AEs were defined as those that began or worsened in severity on or after the first dose of study drug in Study M13-765 and no more than 30 days after the last dose of study drug.	
End point type	Primary
End point timeframe:	
up to 52 weeks (+ 30 days)	

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: Descriptive statistics were planned and are presented for this safety endpoint.

End point values	ABT-126 25 mg QD	ABT-126 50 mg QD	ABT-126 75 mg QD	ABT-126 Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	47	172	48	267
Units: subjects				
Any AE	22	57	21	100
AE w/reasonable possibility of drug relatedness	5	14	6	25
Any severe AE	2	3	0	5
Any SAE	3	3	0	6
Any AE leading to discontinuation of study drug	3	2	0	5
Any fatal AE	0	0	0	0
Deaths (all deaths during the study)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with Potentially Clinically Significant Hematology Values

End point title	Number of Subjects with Potentially Clinically Significant Hematology Values[2]

End point description:

F=female; M=male

End point type	Primary

End point timeframe:

up to 52 weeks

Notes:

[2] - 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: Descriptive statistics were planned and are presented for this safety endpoint.

End point values	ABT-126 25 mg QD	ABT-126 50 mg QD	ABT-126 75 mg QD	ABT-126 Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	47	170[3]	46[4]	263[5]
Units: subjects				
Hemoglobin: <90 G/L (F); <100 G/L (M)	1	1	0	2
Hemoglobin: >180 G/L (F); >180 G/L (M)	0	1	1	2
Hematocrit: <0.34 fraction (F); <0.35 fraction (M)	2	11	3	16
Hematocrit: >0.55 fraction (F); >0.55 fraction (M)	0	3	0	3
White Blood Cell Count: <2.8*10^9/L	0	3	0	3
Neutrophils: <1.2*10^9/L	1	4	0	5
Lymphocytes: <0.75*10^9/L	1	1	0	2

Notes:

[3] - subjects with an assessment

[4] - subjects with an assessment

[5] - subjects with an assessment

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with Potentially Clinically Significant Chemistry Values

End point title	Number of Subjects with Potentially Clinically Significant Chemistry Values[6]

End point description:

ULN=upper limit of normal

End point type	Primary

End point timeframe:

up to 52 weeks

Notes:

[6] - 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: Descriptive statistics were planned and are presented for this safety endpoint.

End point values	ABT-126 25 mg QD	ABT-126 50 mg QD	ABT-126 75 mg QD	ABT-126 Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	47	172	46[7]	265[8]
Units: subjects				
Alanine aminotransferase >3*ULN	0	3	0	3
Total bilirubin >29 mcmol/L	1	2	2	5
Creatine phosphokinase >1950 U/L	0	1	0	1
Potassium >6 mmol/L	1	0	0	1
Glucose <2.5 mmol/L	0	0	1	1
Clucose >16.7 mmol/L	0	1	0	1

Notes:

[7] - all subjects with an assessment

[8] - subjects with an assessment

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with AEs Related to Abnormal Urinalysis Parameters

End point title	Number of Subjects with AEs Related to Abnormal Urinalysis Parameters[9]

End point description:

End point type	Primary

End point timeframe:

up to 52 weeks

Notes:

[9] - 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: Descriptive statistics were planned and are presented for this safety endpoint.

End point values	ABT-126 25 mg QD	ABT-126 50 mg QD	ABT-126 75 mg QD	ABT-126 Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	47	172	48	267
Units: subjects	0	0	1	1

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with Potentially Clinically Significant

Electrocardiogram (ECG) Values

End point title	Number of Subjects with Potentially Clinically Significant Electrocardiogram (ECG) Values[10]

End point description:

End point type	Primary

End point timeframe:

up to 52 weeks

Notes:

[10] - 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: Descriptive statistics were planned and are presented for this safety endpoint.

End point values	ABT-126 25 mg QD	ABT-126 50 mg QD	ABT-126 75 mg QD	ABT-126 Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	47	172	46[11]	265[12]
Units: subjects				
Bazett QTC interval >480 msec	1	2	1	4
Bazett QTC interval >60 msec increase	0	1	0	1
Fridericia QTC interval >480 msec	0	0	0	0
Fridericia QTC interval >60 msec increase	0	0	0	0

Notes:

[11] - subjects with an assessment

[12] - subjects with an assessment

Statistical analyses

No statistical analyses for this end point

Primary: Number of Subjects with AEs Related to Physical Examinations

End point title	Number of Subjects with AEs Related to Physical

End point description:

End point type	Primary

End point timeframe:

up to 52 weeks

Notes:

[13] - 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: Descriptive statistics were planned and are presented for this safety endpoint.

End point values	ABT-126 25 mg QD	ABT-126 50 mg QD	ABT-126 75 mg QD	ABT-126 Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	47	172	48	267
Units: subjects	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Summary of Columbia-Suicide Severity Rating Scale (C-SSRS) Responses Through Study Follow-up

End point title	Summary of Columbia-Suicide Severity Rating Scale (C-SSRS) Responses Through Study Follow-up[14]

End point description:

The C-SSRS is a systematically administered instrument developed to track suicidal AEs across a treatment study. The instrument is designed to assess suicidal behavior and ideation and track and assess all suicidal events, as well as the lethality of attempts. The C-SSRS was conducted at all visits to assess suicidal ideation and behavior as well as other events related to suicidality. NS=non-specific; AT=active thoughts; SI=suicidal ideations; DS=during study; SB=suicidal behaviours.

End point type	Primary

End point timeframe:

Collected at Weeks 2, 4, 8, 12, 18, 26, 32, 38, 44, 52

Notes:

[14] - 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: Descriptive statistics were planned and are presented for this safety endpoint.

End point values	ABT-126 25 mg QD	ABT-126 50 mg QD	ABT-126 75 mg QD	ABT-126 Total
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	47[15]	171[16]	46[17]	264[18]
Units: subjects				
Week (Wk) 2: Wish to be dead; n=47, 171, 46, 264	0	1	0	1
Wk 2:NS active suicidal thoughts;n=47, 171, 46,264	0	0	0	0
Wk 2: AT without intent to act; n=47, 171, 46, 264	0	0	0	0
Wk 2: AT with some intent no plan;n=47,171,46,264	0	0	0	0
Wk 2: AT with plan and intent; n=47, 171, 46, 264	0	0	0	0
Week 2: Actual attempt; n=47, 171, 46, 264	0	0	0	0
Week 2: Interrupted attempt; n=47, 171, 46, 264	0	0	0	0
Week 2: Aborted attempt; n=47, 171, 46, 264	0	0	0	0
Wk 2: Preparatory acts/behaviour; n=47,171,46,264	0	0	0	0
Week 2: Suicidal behaviour; n=47, 171, 46, 264	0	0	0	0
Week 2: Completed suicide; n=47, 171, 46, 264	0	0	0	0
Week 2: Subjects with SI; n=47, 171, 46, 264	0	1	0	1
Week 2: Subjects with SI only; n=47, 171, 46, 264	0	1	0	1
Week 4: Wish to be dead; n=47, 171, 46, 264	0	1	0	1
Wk 4: NS active suicidal thoughts;n=47,171,46, 264	0	0	0	0
Wk 4: AT without intent to act; n=47, 171, 46, 264	0	0	0	0
Wk 4: AT with some intent no plan;n=47,171,46,264	0	0	0	0

Wk 4: AT with plan and intent; n=47, 171, 46, 264	0	0	0	0
Week 4: Actual attempt; n=47, 171, 46, 264	1	0	1	2
Week 4: Interrupted attempt; n=47, 171, 46, 264	0	0	0	0
Week 4: Aborted attempt; n=47, 171, 46, 264	0	0	0	0
Wk 4: Preparatory acts/behaviour; n=47,171,46,264	0	0	0	0
Week 4: Suicidal behaviour; n=47, 171, 46, 264	0	0	0	0
Week 4: Completed suicide; n=47, 171, 46, 264	0	0	0	0
Week 4: Subjects with SI; n=47, 171, 46, 264	0	1	0	1
Week 4: Subjects with SI only; n=47, 171, 46, 264	0	1	0	1
Week 8: Wish to be dead; n=45, 168, 46, 259	0	2	0	2
Wk 8: NS active suicidal thoughts;n=45,168,46,259	0	0	0	0
Wk 8: AT without intent to act;n=45, 168, 46, 259	0	0	0	0
Wk 8: AT with some intent no plan; n=45,168,46,259	0	0	0	0
Wk 8: AT with plan and intent; n=45, 168, 46, 259	0	0	0	0
Week 8: Actual attempt; n=45, 168, 46, 259	0	2	0	2
Week 8: Interrupted attempt; n=45, 168, 46, 259	0	0	0	0
Week 8: Aborted attempt; n=45, 168, 46, 259	0	0	0	0
Wk 8: Preparatory acts/behaviour; n=45,168,46,259	0	0	0	0
Week 8: Suicidal behaviour; n=45, 168, 46, 259	0	0	0	0
Week 8: Completed suicide; n=45, 168, 46, 259	0	0	0	0
Week 8: Subjects with SI; n=45, 168, 46, 259	0	2	0	2
Week 8: Subjects with SI only; n=45, 168, 46, 259	0	2	0	2
Week 12: Wish to be dead; n=44, 163, 46, 253	0	0	1	1
Wk 12:NS active suicidal thoughts;n=44,163,46,253	0	0	0	0
Wk 12: AT without intent to act; n=44,163,46,253	0	0	0	0
Wk 12: AT with some intent no plan;n=44,163,46,253	0	0	0	0
Wk 12: AT with plan and intent; n=44, 163, 46, 253	0	0	0	0
Week 12: Actual attempt; n=44, 163, 46, 253	0	1	0	1
Week 12: Interrupted attempt; n=44, 163, 46, 253	0	0	0	0
Week 12: Aborted attempt; n=44, 163, 46, 253	0	0	0	0
Wk 12: Preparatory acts/behaviour; n=44,163,46,253	0	0	0	0

Week 12: Suicidal behaviour; n=44, 163, 46, 253	0	0	0	0
Week 12: Completed suicide; n=44, 163, 46, 253	0	0	0	0
Week 12: Subjects with SI; n=44, 163, 46, 253	0	0	1	1
Week 12: Subjects with SI only; n=44, 163, 46, 253	0	0	1	1
Week 18: Wish to be dead; n=43, 130, 44, 217	0	1	0	1
Wk 18: NS active suicidal thoughts;n=43,130,44,217	0	0	0	0
Wk 18: AT without intent to act;n=43, 130, 44, 217	0	0	0	0
Wk 18: AT with some intent no plan;n=43,130,44,217	0	0	0	0
Wk 18: AT with plan and intent; n=43, 130, 44, 217	0	0	0	0
Week 18: Actual attempt; n=43, 130, 44, 217	0	0	0	0
Week 18: Interrupted attempt; n=43, 130, 44, 217	0	0	0	0
Week 18: Aborted attempt; n=43, 130, 44, 217	0	0	0	0
Wk 18: Preparatory acts/behaviour;n=43,130,44,217	0	0	0	0
Week 18: Suicidal behaviour; n=43, 130, 44, 217	0	0	0	0
Week 18: Completed suicide; n=43, 130, 44, 217	0	0	0	0
Week 18: Subjects with SI; n=43, 130, 44, 217	0	1	0	1
Week 18: Subjects with SI only; n=43, 130, 44, 217	0	1	0	1
Week 26: Wish to be dead; n=42, 101, 41, 184	1	1	1	3
Wk 26: NS active suicidal thoughts;n=42, 101, 184	1	0	0	1
Wk 26: AT without intent to act; n=42,101,41,184	1	0	0	1
Wk 26: AT with some intent no plan;n=42,101,41,184	1	0	0	1
Wk 26: AT with plan and intent; n=42, 101, 41, 184	1	0	0	1
Week 26: Actual attempt; n=42, 101, 41, 184	0	1	0	1
Week 26: Interrupted attempt; n=42, 101, 41, 184	0	0	0	0
Week 26: Aborted attempt; n=42, 101, 41, 184	0	0	0	0
Wk 26: Preparatory acts/behaviour;n=42,101,41,184	0	0	0	0
Week 26: Suicidal behaviour; n=42, 101, 41, 184	1	0	0	1
Week 26: Completed suicide; n=42, 101, 41, 184	0	0	0	0
Week 26: Subjects with SI; n=42, 101, 41, 184	1	1	1	3
Week 26: Subjects with SI only; n=42, 101, 41, 184	0	1	1	2
Week 32: Wish to be dead; n=40, 60, 38, 138	1	0	0	1

Wk 32: NS active suicidal thoughts; n=40,60,38,138	1	0	0	1
Wk 32: AT without intent to act; n=40, 60, 38, 138	1	0	0	1
Wk 32: AT with some intent no plan; n=40,60,38,138	1	0	0	1
Wk 32: AT with plan and intent; n=40, 60, 38, 138	1	0	0	1
Week 32: Actual attempt; n=40, 60, 38, 138	0	1	1	2
Week 32: Interrupted attempt; n=40, 60, 38, 138	0	0	0	0
Week 32: Aborted attempt; n=40, 60, 38, 138	0	0	0	0
Wk 32: Preparatory acts/behaviour; n=40,60,38,138	0	0	0	0
Week 32: Suicidal behaviour; n=40, 60, 38, 138	1	0	0	1
Week 32: Completed suicide; n=40, 60, 38, 138	0	0	0	0
Week 32: Subjects with SI; n=40, 60, 38, 138	1	0	0	1
Week 32: Subjects with SI only; n=40, 60, 38, 138	0	0	0	0
Week 38: Wish to be dead; n=33, 44, 32, 109	0	0	0	0
Wk 38: NS active suicidal thoughts; n=33,44,32,109	0	0	0	0
Wk 38: AT without intent to act; n=33, 44, 32, 109	0	0	0	0
Wk 38: AT with some intent no plan; n=33,44,32,109	0	0	0	0
Wk 38: AT with plan and intent; n=33, 44, 32, 109	0	0	0	0
Week 38: Actual attempt; n=33, 44, 32, 109	0	0	0	0
Week 38: Interrupted attempt; n=33, 44, 32, 109	0	0	0	0
Week 38: Aborted attempt; n=33, 44, 32, 109	0	0	0	0
Wk 38: Preparatory acts/behaviour; n=33,44,32,109	0	0	0	0
Week 38: Suicidal behaviour; n=33, 44, 32, 109	0	0	0	0
Week 38: Completed suicide; n=33, 44, 32, 109	0	0	0	0
Week 38: Subjects with SI; n=33, 44, 32, 109	0	0	0	0
Week 38: Subjects with SI only; n=33, 44, 32, 109	0	0	0	0
Week 44: Wish to be dead; n=25, 29, 24, 78	0	0	0	0
Wk 44: NS active suicidal thoughts; n=25,29,24,78	0	0	0	0
Wk 44: AT without intent to act; n=25, 29, 24, 78	0	0	0	0
Wk 44: AT with some intent no plan; n=25,29,24,78	0	0	0	0
Week 44: AT with plan and intent; n=25, 29, 24, 78	0	0	0	0
Week 44: Actual attempt; n=25, 29, 24, 78	1	0	0	1

Week 44: Interrupted attempt; n=25, 29, 24, 78	0	0	0	0
Week 44: Aborted attempt; n=25, 29, 24, 78	0	0	0	0
Wk 44: Preparatory acts/behaviour; n=25,29,24,78	0	0	0	0
Week 44: Suicidal behaviour; n=25, 29, 24, 78	0	0	0	0
Week 44: Completed suicide; n=25, 29, 24, 78	0	0	0	0
Week 44: Subjects with SI; n=25, 29, 24, 78	0	0	0	0
Week 44: Subjects with SI only; n=25, 29, 24, 78	0	0	0	0
Week 52: Wish to be dead; n=17, 17, 16, 50	0	0	1	1
Wk 52: NS active suicidal thoughts; n=17,17,16,50	0	0	0	0
Wk 52: AT without intent to act; n=17, 17, 16, 50	0	0	0	0
Wk 52: AT with some intent no plan; n=17,17,16,50	0	0	0	0
Week 52: AT with plan and intent; n=17, 17, 16, 50	0	0	0	0
Week 52: Actual attempt; n=17, 17, 16, 50	1	0	0	1
Week 52: Interrupted attempt; n=17, 17, 16, 50	0	0	0	0
Week 52: Aborted attempt; n=17, 17, 16, 50	0	0	0	0
Wk 52: Preparatory acts/behaviour; n=17,17,16,50	0	0	0	0
Week 52: Suicidal behaviour; n=17, 17, 16, 50	0	0	0	0
Week 52: Completed suicide; n=17, 17, 16, 50	0	0	0	0
Week 52: Subjects with SI; n=17, 17, 16, 50	0	0	1	1
Week 52: Subjects with SI only; n=17, 17, 16, 50	0	0	1	1
Follow-up: Wish to be dead; n=6, 4, 3, 13	1	0	0	1
Follow-up: NS active suicidal thoughts; n=6,4,3,13	0	0	0	0
Follow-up: AT without intent to act; n=6,4,3,13	0	0	0	0
Follow-up: AT with some intent no plan; n=6,4,3,13	0	0	0	0
Follow-up: AT with plan and intent; n=6, 4, 3, 13	0	0	0	0
Follow-up: Actual attempt; n=6, 4, 3, 13	1	0	0	1
Follow-up: Interrupted attempt; n=6, 4, 3, 13	0	0	0	0
Follow-up: Aborted attempt; n=6, 4, 3, 13	0	0	0	0
Follow-up: Preparatory acts/behaviour; n=6,4,3,13	0	0	0	0
Follow-up: Suicidal behaviour; n=6, 4, 3, 13	0	0	0	0
Follow-up: Completed suicide; n=6, 4, 3, 13	0	0	0	0

Follow-up: Subjects with SI; n=6, 4, 3, 13	1	0	0	1
Follow-up: Subjects with SI only; n=6, 4, 3, 13	0	0	0	0
DS: Wish to be dead; n=47, 172, 48, 267	3	2	1	6
DS: NS active suicidal thoughts;n=47, 172, 48, 267	2	0	0	2
DS: AT without intent to act;n=47, 172, 48, 267	2	0	0	2
DS: AT with some intent no plan;n=47, 172, 48, 267	2	0	0	2
DS: AT with plan and intent; n=47, 172, 48, 267	2	0	0	2
DS: Actual attempt; n=47, 172, 48, 267	4	4	2	10
DS: Interrupted attempt; n=47, 172, 48, 267	0	0	0	0
DS: Aborted attempt; n=47, 172, 48, 267	0	0	0	0
DS: Preparatory acts/behaviour; n=47, 172, 48, 267	0	0	0	0
DS: Suicidal behaviour; n=47, 172, 48, 267	2	0	0	2
DS: Completed suicide; n=47, 172, 48, 267	0	0	0	0
DS: Subjects with SI; n=47, 172, 48, 267	3	2	1	6
DS: Subjects with SI only; n=47, 172, 48, 267	0	2	1	3
DS: Subjects with SB; n=47, 172, 48, 267	6	4	2	12
DS: Subjects with SB or SI; n=47, 172, 48, 267	6	6	3	15

Notes:

[15] - subjects with an assessment; n=subjects with an assessment at given timepoint

[16] - subjects with an assessment; n=subjects with an assessment at given timepoint

[17] - subjects with an assessment; n=subjects with an assessment at given timepoint

[18] - subjects with an assessment; n=subjects with an assessment at given timepoint

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

AEs were reported from the time of study drug administration (Day 1) until 30 days following discontinuation of study drug administration have elapsed were collected. Total study duration was up to 52 weeks.

Adverse event reporting additional description:

All AEs presented in this section were treatment-emergent unless otherwise noted. Treatment-emergent AEs were defined as those that began or worsened in severity on or after the first dose of study drug in Study M13-765 and no more than 30 days after the last dose of study drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	17.1

Reporting groups

Reporting group title	ABT-126 25 mg QD

Reporting group description:

1 ABT-126 25 mg capsule and 2 placebo capsules taken orally QD in the morning each day for 52 weeks

Reporting group title	ABT-126 50 mg QD

Reporting group description:

2 ABT-126 25 mg capsules and 1 placebo capsule taken orally QD in the morning each day for 52 weeks

Reporting group title	ABT-126 75 mg QD

Reporting group description:

3 ABT-126 25 mg capsules taken orally QD in the morning each day for 52 weeks

Reporting group title	ABT-126 Total

Reporting group description:

1, 2, or 3 ABT-126 25 mg capsules taken orally QD in the morning each day for 52 weeks

Serious adverse events	ABT-126 25 mg QD	ABT-126 50 mg QD	ABT-126 75 mg QD
Total subjects affected by serious adverse events			
subjects affected / exposed	3 / 47 (6.38%)	3 / 172 (1.74%)	0 / 48 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Intraductal proliferative breast lesion			
subjects affected / exposed	0 / 47 (0.00%)	1 / 172 (0.58%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Intentional overdose			

subjects affected / exposed	1 / 47 (2.13%)	0 / 172 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Convulsion			
subjects affected / exposed	0 / 47 (0.00%)	1 / 172 (0.58%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 47 (0.00%)	1 / 172 (0.58%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Schizophrenia			
subjects affected / exposed	1 / 47 (2.13%)	0 / 172 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Self injurious behaviour			
subjects affected / exposed	1 / 47 (2.13%)	0 / 172 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Suicide attempt			
subjects affected / exposed	1 / 47 (2.13%)	0 / 172 (0.00%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 47 (0.00%)	1 / 172 (0.58%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hyponatraemia			

subjects affected / exposed	0 / 47 (0.00%)	1 / 172 (0.58%)	0 / 48 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	ABT-126 Total		
Total subjects affected by serious adverse events			
subjects affected / exposed	6 / 267 (2.25%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Intraductal proliferative breast lesion			
subjects affected / exposed	1 / 267 (0.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Intentional overdose			
subjects affected / exposed	1 / 267 (0.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Convulsion			
subjects affected / exposed	1 / 267 (0.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	1 / 267 (0.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Schizophrenia			
subjects affected / exposed	1 / 267 (0.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Self injurious behaviour			

subjects affected / exposed	1 / 267 (0.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Suicide attempt			
subjects affected / exposed	1 / 267 (0.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Abscess limb			
subjects affected / exposed	1 / 267 (0.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hyponatraemia			
subjects affected / exposed	1 / 267 (0.37%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	ABT-126 25 mg QD	ABT-126 50 mg QD	ABT-126 75 mg QD
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 47 (17.02%)	9 / 172 (5.23%)	11 / 48 (22.92%)
Nervous system disorders			
Headache			
subjects affected / exposed	2 / 47 (4.26%)	6 / 172 (3.49%)	5 / 48 (10.42%)
occurrences (all)	3	9	7
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	4 / 47 (8.51%)	2 / 172 (1.16%)	2 / 48 (4.17%)
occurrences (all)	4	2	4
Psychiatric disorders			
Schizophrenia			
subjects affected / exposed	0 / 47 (0.00%)	1 / 172 (0.58%)	3 / 48 (6.25%)
occurrences (all)	0	1	4
Infections and infestations			

Nasopharyngitis			
subjects affected / exposed	4 / 47 (8.51%)	3 / 172 (1.74%)	3 / 48 (6.25%)
occurrences (all)	4	4	3

Non-serious adverse events	ABT-126 Total		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	28 / 267 (10.49%)		
Nervous system disorders			
Headache			
subjects affected / exposed	13 / 267 (4.87%)		
occurrences (all)	19		
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	8 / 267 (3.00%)		
occurrences (all)	10		
Psychiatric disorders			
Schizophrenia			
subjects affected / exposed	4 / 267 (1.50%)		
occurrences (all)	5		
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	10 / 267 (3.75%)		
occurrences (all)	11		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? No

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

This study was terminated early due to insufficient efficacy of ABT-126 for treatment of cognitive impairment associated with schizophrenia in the double-blind Phase 2 Studies M10-855 and M13-608 to support further clinical development.

Notes: