Clinical trial results:
A Phase 2 Study of ABBV-3067 Alone and in Combination With ABBV-2222 in Cystic Fibrosis Subjects Who Are Homozygous for the F508del Mutation

Summary

EudraCT number	2019-000750-63
Trial protocol	GB HU NL BE FR PL RO
Global end of trial date	09 June 2022

Results information

Result version number	v1 (current)
This version publication date	24 June 2023
First version publication date	24 June 2023

Trial information

Trial identification

Sponsor protocol code	M19-530

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	-
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, Maidenhea, Maidenhead, United Kingdom, SL6 4UB
Public contact	Global Medical Services, AbbVie, AbbVie Deutschland GmbH & Co. KG, 0001 8006339110, abbvieclinicaltrials@abbvie.com
Scientific contact	Global Medical Services, AbbVie, AbbVie Deutschland GmbH & Co. KG, 001 8006339110, abbvieclinicaltrials@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	09 June 2022
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	09 June 2022
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

Main objective of the trial: Evaluate the safety, tolerability, and efficacy of ABBV-3067 given alone and in combination with varied dose levels of ABBV-2222 in adult subjects with CF who are homozygous for the F508del mutation.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 December 2019
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	Belgium: 11
Country: Number of subjects enrolled	Canada: 18
Country: Number of subjects enrolled	Czechia: 2
Country: Number of subjects enrolled	France: 17
Country: Number of subjects enrolled	Hungary: 6
Country: Number of subjects enrolled	New Zealand: 4
Country: Number of subjects enrolled	Poland: 2
Country: Number of subjects enrolled	Serbia: 6
Country: Number of subjects enrolled	Slovakia: 3
Country: Number of subjects enrolled	United Kingdom: 6
Country: Number of subjects enrolled	United States: 3
Worldwide total number of subjects	78
EEA total number of subjects	41

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)	77
From 65 to 84 years	1
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

In Part 1 participants received 2 different doses of ABBV-3067 as a single agent, and 5 different doses of ABBV-2222 as dual combination therapy with ABBV-3067 at a fixed dose. Part 2 of the study was not conducted as it was deemed not enrollable by the time Part 1 was completed, therefore only Part 1 is presented.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	ABBV-3067 50 mg + Placebo for ABBV-2222

Arm description:

Participants received ABBV-3067 50 mg tablet orally once daily (QD) plus placebo matching ABBV-2222 capsule, orally QD for 28 days.

Arm type	Experimental
Investigational medicinal product name	ABBV-3067
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet taken orally.

Investigational medicinal product name	Placebo ABBV-2222
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Capsule taken orally

Arm title	ABBV-3067 150 mg + Placebo for ABBV-2222

Arm description:

Participants received ABBV-3067 150 mg tablet orally QD plus placebo matching ABBV-2222 capsule, orally QD for 28 days.

Arm type	Experimental
Investigational medicinal product name	ABBV-3067
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet taken orally.

Investigational medicinal product name	Placebo ABBV-2222
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Capsule taken orally

Arm title	ABBV-3067 150 mg + ABBV-2222 10 mg

Arm description:

Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 10 mg capsule orally QD for 28 days.

Arm type	Experimental
Investigational medicinal product name	ABBV-3067
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet taken orally.

Investigational medicinal product name	Placebo ABBV-2222
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Capsule taken orally.

Arm title	ABBV-3067 150 mg + ABBV-2222 30 mg

Arm description:

Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 30 mg capsule orally QD for 28 days.

Arm type	Experimental
Investigational medicinal product name	ABBV-3067
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet taken orally.

Investigational medicinal product name	Placebo ABBV-2222
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Capsule taken orally.

Arm title	ABBV-3067 150 mg + ABBV-2222 100 mg

Arm description:

Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 100 mg capsule orally QD for 28 days.

Arm type	Experimental

Investigational medicinal product name	ABBV-3067
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet taken orally.

Investigational medicinal product name	Placebo ABBV-2222
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Capsule taken orally.

Arm title	ABBV-3067 150 mg + ABBV-2222 200 mg

Arm description:

Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 200 mg capsule, orally QD for 28 days.

Arm type	Experimental
Investigational medicinal product name	ABBV-3067
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet taken orally.

Investigational medicinal product name	Placebo ABBV-2222
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Capsule taken orally

Arm title	ABBV-3067 150 mg + ABBV-2222 300 mg

Arm description:

Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 300 mg capsule, orally QD for 28 days.

Arm type	Experimental
Investigational medicinal product name	ABBV-3067
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet taken orally.

Investigational medicinal product name	Placebo ABBV-2222
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Capsule taken orally.

Arm title	Placebo for ABBV-3067 + Placebo for ABBV-2222

Arm description:

Participants received placebo matching ABBV-3067 tablet orally QD plus placebo matching ABBV-2222 capsule, orally QD for 28 days.

Arm type	Placebo
Investigational medicinal product name	Placebo ABBV-3067
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

Tablet taken orally.

Investigational medicinal product name	Placebo ABBV-2222
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Capsule taken orally.

Number of subjects in period 1	ABBV-3067 50 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + ABBV-2222 10 mg
Started	6	7	5
Completed	6	7	4
Not completed	0	0	1
Reason Not Specified	-	-	-
Never Received Study Drug	-	-	1

Number of subjects in period 1	ABBV-3067 150 mg + ABBV-2222 30 mg	ABBV-3067 150 mg + ABBV-2222 100 mg	ABBV-3067 150 mg + ABBV-2222 200 mg
Started	12	11	12
Completed	12	11	12
Not completed	0	0	0
Reason Not Specified	-	-	-
Never Received Study Drug	-	-	-

Number of subjects in period 1	ABBV-3067 150 mg + ABBV-2222 300 mg	Placebo for ABBV-3067 + Placebo for ABBV-2222
Started	14	11
Completed	13	10
Not completed	1	1
Reason Not Specified	-	1
Never Received Study Drug	1	-

Baseline characteristics

Reporting groups	
Reporting group title	ABBV-3067 50 mg + Placebo for ABBV-2222
Reporting group description:	
Participants received ABBV-3067 50 mg tablet orally once daily (QD) plus placebo matching ABBV-2222 capsule, orally QD for 28 days.	
Reporting group title	ABBV-3067 150 mg + Placebo for ABBV-2222
Reporting group description:	
Participants received ABBV-3067 150 mg tablet orally QD plus placebo matching ABBV-2222 capsule, orally QD for 28 days.	
Reporting group title	ABBV-3067 150 mg + ABBV-2222 10 mg
Reporting group description:	
Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 10 mg capsule orally QD for 28 days.	
Reporting group title	ABBV-3067 150 mg + ABBV-2222 30 mg
Reporting group description:	
Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 30 mg capsule orally QD for 28 days.	
Reporting group title	ABBV-3067 150 mg + ABBV-2222 100 mg
Reporting group description:	
Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 100 mg capsule orally QD for 28 days.	
Reporting group title	ABBV-3067 150 mg + ABBV-2222 200 mg
Reporting group description:	
Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 200 mg capsule, orally QD for 28 days.	
Reporting group title	ABBV-3067 150 mg + ABBV-2222 300 mg
Reporting group description:	
Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 300 mg capsule, orally QD for 28 days.	
Reporting group title	Placebo for ABBV-3067 + Placebo for ABBV-2222
Reporting group description:	
Participants received placebo matching ABBV-3067 tablet orally QD plus placebo matching ABBV-2222 capsule, orally QD for 28 days.	

Reporting group values	ABBV-3067 50 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + ABBV-2222 10 mg
Number of subjects	6	7	5
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			

Age continuous Units: years			
arithmetic mean	26.5	31.6	36.4
standard deviation	± 4.46	± 7.39	± 15.50
Gender categorical Units: Subjects			
Female	5	3	2
Male	1	4	3
Percent Predicted Forced Expiratory Volume in 1 Second (ppFEV1) at Baseline			
FEV1 is the volume of air that can forcibly be blown out in one second, after full inspiration.			
Units: percent predicted FEV1 (%)			
arithmetic mean	67.0	68.6	65.8
standard deviation	± 15.89	± 11.16	± 18.96

Reporting group values	ABBV-3067 150 mg + ABBV-2222 30 mg	ABBV-3067 150 mg + ABBV-2222 100 mg	ABBV-3067 150 mg + ABBV-2222 200 mg
Number of subjects	12	11	12
Age categorical Units: Subjects			
In utero Preterm newborn infants (gestational age < 37 wks) Newborns (0-27 days) Infants and toddlers (28 days-23 months) Children (2-11 years) Adolescents (12-17 years) Adults (18-64 years) From 65-84 years 85 years and over			
Age continuous Units: years			
arithmetic mean	33.8	32.5	32.5
standard deviation	± 12.67	± 12.53	± 13.13
Gender categorical Units: Subjects			
Female	6	5	2
Male	6	6	10
Percent Predicted Forced Expiratory Volume in 1 Second (ppFEV1) at Baseline			
FEV1 is the volume of air that can forcibly be blown out in one second, after full inspiration.			
Units: percent predicted FEV1 (%)			
arithmetic mean	64.6	68.1	62.0
standard deviation	± 16.84	± 14.48	± 15.18

Reporting group values	ABBV-3067 150 mg + ABBV-2222 300 mg	Placebo for ABBV-3067 + Placebo for ABBV-2222	Total
Number of subjects	14	11	78

Age categorical Units: Subjects			
In utero			0
Preterm newborn infants (gestational age < 37 wks)			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)			0
From 65-84 years			0
85 years and over			0
Age continuous Units: years			
arithmetic mean	31.8	26.8	
standard deviation	± 9.0	± 6.68	-
Gender categorical Units: Subjects			
Female	3	4	30
Male	11	7	48
Percent Predicted Forced Expiratory Volume in 1 Second (ppFEV1) at Baseline			
FEV1 is the volume of air that can forcibly be blown out in one second, after full inspiration.			
Units: percent predicted FEV1 (%)			
arithmetic mean		67.8	
standard deviation	±	± 13.19	-

Subject analysis sets

Subject analysis set title	ABBV-3067 150 mg + ABBV-2222 300 mg
Subject analysis set type	Sub-group analysis

Subject analysis set description:

Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 300 mg capsule, orally QD for 28 days.

Reporting group values	ABBV-3067 150 mg + ABBV-2222 300 mg		
Number of subjects	13		
Age categorical Units: Subjects			
In utero			
Preterm newborn infants (gestational age < 37 wks)			
Newborns (0-27 days)			
Infants and toddlers (28 days-23 months)			
Children (2-11 years)			
Adolescents (12-17 years)			
Adults (18-64 years)			
From 65-84 years			
85 years and over			

Age continuous Units: years arithmetic mean standard deviation	 ±		
Gender categorical Units: Subjects			
Female Male			
Percent Predicted Forced Expiratory Volume in 1 Second (ppFEV1) at Baseline			
FEV1 is the volume of air that can forcibly be blown out in one second, after full inspiration.			
Units: percent predicted FEV1 (%) arithmetic mean standard deviation	 67.6 ± 17.83		

End points

End points reporting groups

Reporting group title	ABBV-3067 50 mg + Placebo for ABBV-2222
Reporting group description:	
Participants received ABBV-3067 50 mg tablet orally once daily (QD) plus placebo matching ABBV-2222 capsule, orally QD for 28 days.	
Reporting group title	ABBV-3067 150 mg + Placebo for ABBV-2222
Reporting group description:	
Participants received ABBV-3067 150 mg tablet orally QD plus placebo matching ABBV-2222 capsule, orally QD for 28 days.	
Reporting group title	ABBV-3067 150 mg + ABBV-2222 10 mg
Reporting group description:	
Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 10 mg capsule orally QD for 28 days.	
Reporting group title	ABBV-3067 150 mg + ABBV-2222 30 mg
Reporting group description:	
Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 30 mg capsule orally QD for 28 days.	
Reporting group title	ABBV-3067 150 mg + ABBV-2222 100 mg
Reporting group description:	
Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 100 mg capsule orally QD for 28 days.	
Reporting group title	ABBV-3067 150 mg + ABBV-2222 200 mg
Reporting group description:	
Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 200 mg capsule, orally QD for 28 days.	
Reporting group title	ABBV-3067 150 mg + ABBV-2222 300 mg
Reporting group description:	
Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 300 mg capsule, orally QD for 28 days.	
Reporting group title	Placebo for ABBV-3067 + Placebo for ABBV-2222
Reporting group description:	
Participants received placebo matching ABBV-3067 tablet orally QD plus placebo matching ABBV-2222 capsule, orally QD for 28 days.	
Subject analysis set title	ABBV-3067 150 mg + ABBV-2222 300 mg
Subject analysis set type	Sub-group analysis
Subject analysis set description:	
Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 300 mg capsule, orally QD for 28 days.	

Primary: Absolute Change From Baseline Through Day 29 in Percent Predicted Forced Expiratory Volume in 1 Second (ppFEV1)

End point title	Absolute Change From Baseline Through Day 29 in Percent Predicted Forced Expiratory Volume in 1 Second (ppFEV1)[1]
End point description:	
End point type	Primary
End point timeframe:	
Day 1 (Baseline) through Day 29	

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: Only descriptive analysis was planned to be performed for this end point.

End point values	ABBV-3067 50 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + ABBV-2222 10 mg	ABBV-3067 150 mg + ABBV-2222 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	2	5
Units: percent predicted FEV1 (%)				
least squares mean (confidence interval 95%)	0.3 (-4.38 to 4.98)	-2.2 (-7.03 to 2.66)	2.0 (-5.07 to 9.07)	4.5 (-0.16 to 9.08)

End point values	ABBV-3067 150 mg + ABBV-2222 100 mg	ABBV-3067 150 mg + ABBV-2222 200 mg	ABBV-3067 150 mg + ABBV-2222 300 mg	Placebo for ABBV-3067 + Placebo for ABBV-2222
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	11	9
Units: percent predicted FEV1 (%)				
least squares mean (confidence interval 95%)	0.3 (-3.13 to 3.68)	4.0 (0.79 to 7.28)	2.4 (-0.85 to 5.74)	-2.2 (-5.83 to 1.43)

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change From Baseline Through Day 29 in Sweat Chloride (SwCl)

End point title	Absolute Change From Baseline Through Day 29 in Sweat Chloride (SwCl)

End point description:

Sweat collection was performed to evaluate sweat chloride concentration. SwCl is a biomarker of cystic fibrosis transmembrane conductance regulator (CFTR) activity. Persons with CF have higher levels of chloride in their sweat. MMRM was used for the analysis.

End point type	Secondary

End point timeframe:

Day 1 (Baseline) through Day 29

End point values	ABBV-3067 50 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + ABBV-2222 10 mg	ABBV-3067 150 mg + ABBV-2222 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	2	5
Units: millimole per liter (mmol/L)				
least squares mean (confidence interval 95%)	-4.5 (-15.78 to 6.81)	-8.9 (-18.64 to 0.78)	-2.3 (-16.76 to 12.25)	-15.7 (-23.37 to -7.98)

End point values	ABBV-3067 150 mg + ABBV-2222 100 mg	ABBV-3067 150 mg + ABBV-2222 200 mg	ABBV-3067 150 mg + ABBV-2222 300 mg	Placebo for ABBV-3067 + Placebo for ABBV-2222
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	11	9
Units: millimole per liter (mmol/L)				
least squares mean (confidence interval 95%)	-12.3 (-20.34 to -4.26)	-18.6 (-25.98 to -11.16)	-19.9 (-27.17 to -12.64)	-2.1 (-10.63 to 6.36)

Statistical analyses

No statistical analyses for this end point

Secondary: Absolute Change From Baseline Through Day 29 in Forced Vital Capacity (FVC)

End point title	Absolute Change From Baseline Through Day 29 in Forced Vital Capacity (FVC)

End point description:

FVC is the total amount of air exhaled during forced expiratory volume (FEV) test and is a lung function test that is measured during spirometry. MMRM was used for the analyses.

End point type	Secondary

End point timeframe:

Day 1 (Baseline) through Day 29

End point values	ABBV-3067 50 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + ABBV-2222 10 mg	ABBV-3067 150 mg + ABBV-2222 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	2	5
Units: liter (L)				
least squares mean (confidence interval 95%)	0.0 (-0.22 to 0.23)	-0.0 (-0.24 to 0.20)	0.0 (-0.28 to 0.35)	0.1 (-0.16 to 0.28)

End point values	ABBV-3067 150 mg + ABBV-2222 100 mg	ABBV-3067 150 mg + ABBV-2222 200 mg	ABBV-3067 150 mg + ABBV-2222 300 mg	Placebo for ABBV-3067 + Placebo for ABBV-2222
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	11	9
Units: liter (L)				
least squares mean (confidence interval 95%)	0.1 (-0.08 to 0.24)	0.0 (-0.11 to 0.19)	0.0 (-0.12 to 0.19)	-0.2 (-0.38 to -0.03)

Statistical analyses

No statistical analyses for this end point

Secondary: Measure: Measure Title Absolute Change From Baseline Through Day 29 in Forced Expiratory Flow at Mid-lung Capacity (FEF25-75)

End point title	Measure: Measure Title Absolute Change From Baseline Through Day 29 in Forced Expiratory Flow at Mid-lung Capacity (FEF25-75)

End point description:

FEF25-75 is a lung function test that is measured during spirometry, and is defined as the forced expiratory flow between 25% and 75% of vital capacity (mid-lung capacity). MMRM was used for analyses

End point type	Secondary

End point timeframe:

Day 1 (Baseline) through Day 29

End point values	ABBV-3067 50 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + ABBV-2222 10 mg	ABBV-3067 150 mg + ABBV-2222 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	2	5
Units: liter per seconds (L/sec)				
least squares mean (confidence interval 95%)	0.0 (-0.27 to 0.29)	-0.0 (-0.29 to 0.27)	0.2 (-0.26 to 0.57)	0.2 (-0.08 to 0.47)

End point values	ABBV-3067 150 mg + ABBV-2222 100 mg	ABBV-3067 150 mg + ABBV-2222 200 mg	ABBV-3067 150 mg + ABBV-2222 300 mg	Placebo for ABBV-3067 + Placebo for ABBV-2222
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	11	9
Units: liter per seconds (L/sec)				
least squares mean (confidence interval 95%)	-0.0 (-0.23 to 0.18)	0.3 (0.08 to 0.47)	0.1 (-0.08 to 0.31)	0.0 (-0.20 to 0.24)

Statistical analyses

No statistical analyses for this end point

Secondary: Relative Change From Baseline Through Day 29 in Percent Predicted Forced Expiratory Volume in 1 Second (ppFEV1)

End point title	Relative Change From Baseline Through Day 29 in Percent Predicted Forced Expiratory Volume in 1 Second (ppFEV1)

End point description:

FEV1 is the volume of air that can forcibly be blown out in one second, after full inspiration and is used as a measure of lung function. MMRM was used for analyses.

End point type	Secondary

End point timeframe:

Day 1 (Baseline) through Day 29

End point values	ABBV-3067 50 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + ABBV-2222 10 mg	ABBV-3067 150 mg + ABBV-2222 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	2	5
Units: percent predicted FEV1				
least squares mean (confidence interval 95%)	1.0 (-6.22 to 8.22)	-2.9 (-10.38 to 4.60)	3.4 (-7.46 to 14.34)	8.0 (0.87 to 15.14)

End point values	ABBV-3067 150 mg + ABBV-2222 100 mg	ABBV-3067 150 mg + ABBV-2222 200 mg	ABBV-3067 150 mg + ABBV-2222 300 mg	Placebo for ABBV-3067 + Placebo for ABBV-2222
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	11	9
Units: percent predicted FEV1				
least squares mean (confidence interval 95%)	1.4 (-3.82 to 6.69)	5.7 (0.70 to 10.73)	4.7 (-0.35 to 9.84)	-3.3 (-8.86 to 2.34)

Statistical analyses

No statistical analyses for this end point

Secondary: Relative Change From Baseline Through Day 29 in Forced Expiratory Flow at Mid-lung Capacity (FEF25-75)

End point title	Relative Change From Baseline Through Day 29 in Forced Expiratory Flow at Mid-lung Capacity (FEF25-75)

End point description:

FEF25-75 is a lung function test that is measured during spirometry, and is defined as the forced expiratory flow between 25% and 75% of vital capacity (mid-lung capacity). MMRM was used for analyses.

End point type	Secondary

End point timeframe:

Day 1 (Baseline) through Day 29

End point values	ABBV-3067 50 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + ABBV-2222 10 mg	ABBV-3067 150 mg + ABBV-2222 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	2	5
Units: L/sec				
least squares mean (confidence interval 95%)	0.8 (-18.01 to 19.55)	-0.1 (-18.94 to 18.76)	8.8 (-18.69 to 36.38)	19.9 (1.61 to 38.28)

End point values	ABBV-3067 150 mg + ABBV-2222 100 mg	ABBV-3067 150 mg + ABBV-2222 200 mg	ABBV-3067 150 mg + ABBV-2222 300 mg	Placebo for ABBV-3067 + Placebo for ABBV-2222
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	11	9
Units: L/sec				
least squares mean (confidence interval 95%)	0.1 (-13.46 to 13.65)	18.5 (5.60 to 31.50)	10.9 (-2.21 to 24.01)	1.0 (-13.69 to 15.62)

Statistical analyses

No statistical analyses for this end point

Secondary: Relative Change From Baseline Through Day 29 in Forced Vital Capacity (FVC)

End point title	Relative Change From Baseline Through Day 29 in Forced Vital Capacity (FVC)

End point description:

FVC is the total amount of air exhaled during FEV test and is a lung function test that is measured during spirometry. MMRM was used for the analyses.

End point type	Secondary

End point timeframe:

Day 1 (Baseline) through Day 29

End point values	ABBV-3067 50 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + ABBV-2222 10 mg	ABBV-3067 150 mg + ABBV-2222 30 mg
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	5	2	5
Units: liter				
least squares mean (confidence interval 95%)	0.1 (-5.20 to 5.35)	-1.0 (-6.38 to 4.30)	0.2 (-7.37 to 7.82)	2.2 (-3.03 to 7.43)

End point values	ABBV-3067 150 mg + ABBV-2222 100 mg	ABBV-3067 150 mg + ABBV-2222 200 mg	ABBV-3067 150 mg + ABBV-2222 300 mg	Placebo for ABBV-3067 + Placebo for ABBV-2222
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	10	11	11	9
Units: liter				
least squares mean (confidence interval 95%)	2.2 (-1.51 to 6.01)	0.9 (-2.77 to 4.54)	1.1 (-2.58 to 4.73)	-4.3 (-8.37 to -0.20)

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality is reported from enrollment to end of study; maximum median time was 28.0 days. Treatment-emergent adverse events (TEAEs) and serious adverse events (SAEs) were collected from first dose of study drug until 30 days after last dose of

Adverse event reporting additional description:

All-cause mortality: all enrolled participants. SAEs and other adverse events: FAS includes all randomized participants who received at least 1 dose of study drug.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25

Reporting groups

Reporting group title	ABBV-3067 50 mg + Placebo for ABBV-2222

Reporting group description:

Participants received ABBV-3067 50 mg tablet orally once daily (QD) plus placebo matching ABBV-2222 capsule, orally QD for 28 days.

Reporting group title	ABBV-3067 150 mg + Placebo for ABBV-2222

Reporting group description:

Participants received ABBV-3067 150 mg tablet orally QD plus placebo matching ABBV-2222 capsule, orally QD for 28 days.

Reporting group title	ABBV-3067 150 mg + ABBV-2222 10 mg

Reporting group description:

Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 10 mg capsule orally QD for 28 days.

Reporting group title	ABBV-3067 150 mg + ABBV-2222 30 mg

Reporting group description:

Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 30 mg capsule orally QD for 28 days.

Reporting group title	ABBV-3067 150 mg + ABBV-2222 100 mg

Reporting group description:

Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 100 mg capsule orally QD for 28 days.

Reporting group title	ABBV-3067 150 mg + ABBV-2222 200 mg

Reporting group description:

Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 200 mg capsule, orally QD for 28 days.

Reporting group title	ABBV-3067 150 mg + ABBV-2222 300 mg

Reporting group description:

Participants received ABBV-3067 150 mg tablet orally QD plus ABBV-2222 300 mg capsule, orally QD for 28 days.

Reporting group title	Placebo for ABBV-3067 + Placebo for ABBV-2222

Reporting group description:

Participants received placebo matching ABBV-3067 tablet orally QD plus placebo matching ABBV-2222 capsule, orally QD for 28 days.

Serious adverse events	ABBV-3067 50 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + ABBV-2222 10 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Gastrointestinal disorders			
ILEUS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
CHOLECYSTITIS ACUTE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	ABBV-3067 150 mg + ABBV-2222 30 mg	ABBV-3067 150 mg + ABBV-2222 100 mg	ABBV-3067 150 mg + ABBV-2222 200 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Gastrointestinal disorders			
ILEUS			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
CHOLECYSTITIS ACUTE			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	ABBV-3067 150 mg + ABBV-2222 300 mg	Placebo for ABBV-3067 + Placebo for ABBV-2222	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 13 (0.00%)	2 / 12 (16.67%)	

number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Gastrointestinal disorders			
ILEUS			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
CHOLECYSTITIS ACUTE			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	ABBV-3067 50 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + Placebo for ABBV-2222	ABBV-3067 150 mg + ABBV-2222 10 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 6 (33.33%)	5 / 7 (71.43%)	4 / 4 (100.00%)
Vascular disorders			
FLUSHING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
FATIGUE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
CHEST PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
CHEST DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PYREXIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal			

disorders			
COUGH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
BRONCHOSPASM			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ASTHMA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
DRY THROAT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INCREASED VISCOSITY OF UPPER RESPIRATORY SECRETION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
HAEMOPTYSIS			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	1 / 4 (25.00%)
occurrences (all)	0	1	1
EPISTAXIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PHARYNGEAL ERYTHEMA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PLEURITIC PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
RALES			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
SPUTUM INCREASED			

subjects affected / exposed	1 / 6 (16.67%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
WHEEZING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
PANIC ATTACK			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Investigations			
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
BLOOD GLUCOSE DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
FORCED EXPIRATORY VOLUME DECREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
NEUTROPHIL COUNT INCREASED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
ARTHROPOD BITE			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
LIMB INJURY			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
MUSCLE STRAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
CYSTIC FIBROSIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
HEADACHE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DIZZINESS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
PRESYNCOPE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
MYOPIA			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DYSPEPSIA			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
DIARRHOEA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DRY MOUTH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	2 / 4 (50.00%)
occurrences (all)	0	1	2
NAUSEA			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
FREQUENT BOWEL MOVEMENTS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
FAECES DISCOLOURED			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
RETCHING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
PAPULE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
ALOPECIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

ACNE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RASH			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
URTICARIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
MYALGIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
MYOSITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
BACTERIURIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
INFECTIVE PULMONARY EXACERBATION OF CYSTIC FIBROSIS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
NASOPHARYNGITIS			
subjects affected / exposed	1 / 6 (16.67%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	1	1	0
SINUSITIS			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	1 / 4 (25.00%)
occurrences (all)	1	0	1
RESPIRATORY TRACT INFECTION VIRAL			

subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
RASH PUSTULAR			
subjects affected / exposed	1 / 6 (16.67%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	1	0	0
ORAL HERPES			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
SIALOADENITIS			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
INCREASED APPETITE			
subjects affected / exposed	0 / 6 (0.00%)	1 / 7 (14.29%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
DECREASED APPETITE			
subjects affected / exposed	0 / 6 (0.00%)	0 / 7 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	ABBV-3067 150 mg + ABBV-2222 30 mg	ABBV-3067 150 mg + ABBV-2222 100 mg	ABBV-3067 150 mg + ABBV-2222 200 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 11 (54.55%)	10 / 11 (90.91%)	6 / 12 (50.00%)
Vascular disorders			
FLUSHING			
subjects affected / exposed	1 / 11 (9.09%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
FATIGUE			

subjects affected / exposed	0 / 11 (0.00%)	1 / 11 (9.09%)	2 / 12 (16.67%)
occurrences (all)	0	1	2
CHEST PAIN			
subjects affected / exposed	0 / 11 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
CHEST DISCOMFORT			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
PYREXIA			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	2 / 11 (18.18%)	2 / 11 (18.18%)	1 / 12 (8.33%)
occurrences (all)	2	2	1
BRONCHOSPASM			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
ASTHMA			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
DRY THROAT			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
INCREASED VISCOSITY OF UPPER RESPIRATORY SECRETION			
subjects affected / exposed	0 / 11 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
HAEMOPTYSIS			
subjects affected / exposed	0 / 11 (0.00%)	2 / 11 (18.18%)	0 / 12 (0.00%)
occurrences (all)	0	3	0
EPISTAXIS			
subjects affected / exposed	0 / 11 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
PHARYNGEAL ERYTHEMA			

subjects affected / exposed	0 / 11 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
PLEURITIC PAIN			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
RALES			
subjects affected / exposed	0 / 11 (0.00%)	2 / 11 (18.18%)	0 / 12 (0.00%)
occurrences (all)	0	2	0
SPUTUM INCREASED			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
WHEEZING			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Psychiatric disorders			
PANIC ATTACK			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Investigations			
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
BLOOD GLUCOSE DECREASED			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 11 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
FORCED EXPIRATORY VOLUME DECREASED			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
INTERNATIONAL NORMALISED RATIO INCREASED			

subjects affected / exposed	0 / 11 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	0 / 11 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
NEUTROPHIL COUNT INCREASED			
subjects affected / exposed	0 / 11 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
ARTHROPOD BITE			
subjects affected / exposed	0 / 11 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
LIMB INJURY			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
MUSCLE STRAIN			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Congenital, familial and genetic disorders			
CYSTIC FIBROSIS			
subjects affected / exposed	1 / 11 (9.09%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
HEADACHE			
subjects affected / exposed	2 / 11 (18.18%)	2 / 11 (18.18%)	0 / 12 (0.00%)
occurrences (all)	2	2	0
DIZZINESS			
subjects affected / exposed	1 / 11 (9.09%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
PRESYNCOPE			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
VERTIGO			

subjects affected / exposed	1 / 11 (9.09%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
MYOPIA			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
DYSPEPSIA			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
ABDOMINAL PAIN UPPER			
subjects affected / exposed	2 / 11 (18.18%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	2	0	0
DIARRHOEA			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
DRY MOUTH			
subjects affected / exposed	0 / 11 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
ABDOMINAL PAIN			
subjects affected / exposed	0 / 11 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
NAUSEA			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
FREQUENT BOWEL MOVEMENTS			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
FAECES DISCOLOURED			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
RETCHING			

subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
VOMITING			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
PAPULE			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
ALOPECIA			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
ACNE			
subjects affected / exposed	0 / 11 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
RASH			
subjects affected / exposed	1 / 11 (9.09%)	0 / 11 (0.00%)	2 / 12 (16.67%)
occurrences (all)	1	0	2
URTICARIA			
subjects affected / exposed	0 / 11 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
MYALGIA			
subjects affected / exposed	0 / 11 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
MYOSITIS			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
Infections and infestations			
BACTERIURIA			
subjects affected / exposed	0 / 11 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
INFECTIVE PULMONARY EXACERBATION OF CYSTIC			

FIBROSIS			
subjects affected / exposed	2 / 11 (18.18%)	3 / 11 (27.27%)	0 / 12 (0.00%)
occurrences (all)	2	3	0
NASOPHARYNGITIS			
subjects affected / exposed	1 / 11 (9.09%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0
SINUSITIS			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
RESPIRATORY TRACT INFECTION VIRAL			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
RASH PUSTULAR			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
ORAL HERPES			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	1 / 12 (8.33%)
occurrences (all)	0	0	1
SIALOADENITIS			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 11 (0.00%)	1 / 11 (9.09%)	0 / 12 (0.00%)
occurrences (all)	0	1	0
Metabolism and nutrition disorders			
INCREASED APPETITE			
subjects affected / exposed	0 / 11 (0.00%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	0	0	0
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 11 (0.00%)	1 / 11 (9.09%)	1 / 12 (8.33%)
occurrences (all)	0	1	1
DECREASED APPETITE			
subjects affected / exposed	1 / 11 (9.09%)	0 / 11 (0.00%)	0 / 12 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	ABBV-3067 150 mg + ABBV-2222 300 mg	Placebo for ABBV-3067 + Placebo for ABBV-2222	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	6 / 13 (46.15%)	8 / 12 (66.67%)	
Vascular disorders			
FLUSHING			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
FATIGUE			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
CHEST PAIN			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
CHEST DISCOMFORT			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
PYREXIA			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
COUGH			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
BRONCHOSPASM			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
ASTHMA			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
DRY THROAT			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
INCREASED VISCOSITY OF UPPER RESPIRATORY SECRETION			

subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
HAEMOPTYSIS			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
EPISTAXIS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
PHARYNGEAL ERYTHEMA			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
PLEURITIC PAIN			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
PRODUCTIVE COUGH			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
RALES			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
SPUTUM INCREASED			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
WHEEZING			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Psychiatric disorders			
PANIC ATTACK			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Investigations			
BLOOD CREATINE PHOSPHOKINASE INCREASED			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
BLOOD GLUCOSE DECREASED			

subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
C-REACTIVE PROTEIN INCREASED			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
FORCED EXPIRATORY VOLUME DECREASED			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
INTERNATIONAL NORMALISED RATIO INCREASED			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
WHITE BLOOD CELL COUNT INCREASED			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
NEUTROPHIL COUNT INCREASED			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
ARTHROPOD BITE			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
LIMB INJURY			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
MUSCLE STRAIN			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Congenital, familial and genetic disorders			
CYSTIC FIBROSIS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
HEADACHE			

subjects affected / exposed	1 / 13 (7.69%)	1 / 12 (8.33%)	
occurrences (all)	1	1	
DIZZINESS			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
PRESYNCOPE			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
VERTIGO			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
MYOPIA			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
ABDOMINAL DISCOMFORT			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
DYSPEPSIA			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
ABDOMINAL PAIN UPPER			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
DIARRHOEA			
subjects affected / exposed	1 / 13 (7.69%)	1 / 12 (8.33%)	
occurrences (all)	1	1	
DRY MOUTH			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
ABDOMINAL PAIN			
subjects affected / exposed	1 / 13 (7.69%)	2 / 12 (16.67%)	
occurrences (all)	1	3	
NAUSEA			

subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
FREQUENT BOWEL MOVEMENTS			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
FAECES DISCOLOURED			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
RETCHING			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
VOMITING			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
PAPULE			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
ALOPECIA			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
ACNE			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
RASH			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
URTICARIA			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
BACK PAIN			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
MYALGIA			

subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
MYOSITIS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
Infections and infestations			
BACTERIURIA			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
INFECTIVE PULMONARY EXACERBATION OF CYSTIC FIBROSIS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
NASOPHARYNGITIS			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
SINUSITIS			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
RESPIRATORY TRACT INFECTION VIRAL			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
RASH PUSTULAR			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
ORAL HERPES			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
SIALOADENITIS			
subjects affected / exposed	1 / 13 (7.69%)	0 / 12 (0.00%)	
occurrences (all)	1	0	
UPPER RESPIRATORY TRACT INFECTION			
subjects affected / exposed	0 / 13 (0.00%)	1 / 12 (8.33%)	
occurrences (all)	0	1	
Metabolism and nutrition disorders			

INCREASED APPETITE			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
HYPOGLYCAEMIA			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	
DECREASED APPETITE			
subjects affected / exposed	0 / 13 (0.00%)	0 / 12 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 August 2019	The following changes were implemented with Protocol amendment 1; Correcting minor clerical errors for consistency throughout the protocol in addition to the following, adding that the of oral cannabis is not allowed under Eligibility Criteria, a requirement was added for all females of childbearing potential to supplement with a barrier method when hormonal contraception methods are the preferred methods of birth control.
04 February 2022	The following changes were implemented with Protocol amendment 2: Modified rescreening language regarding SwCl test, added eligibility criteria to specify the requirements for subjects from Study M19-771, added Montelukast to prohibited medication list

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported