



Clinical trial results:

An Open-label, Randomized Crossover Study to Obtain a Preliminary Estimate of the Bioavailability of Atazanavir and Cobicistat When Administered in an Age-appropriate Fixeddose Combination Formulation Compared with Coadministration of the Age-appropriate Atazanavir and Cobicistat Individual Formulations and to Assess Preliminary Palatability/Acceptability in Healthy Adults

Summary

EudraCT number	2020-002885-15
Trial protocol	Outside EU/EEA
Global end of trial date	06 January 2021

Results information

Result version number	v1 (current)
This version publication date	03 December 2021
First version publication date	03 December 2021

Trial information

Trial identification

Sponsor protocol code	AI424-567
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Additional study identifiers

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

Notes:

Sponsors

Sponsor organisation name	Bristol-Myers Squibb
Sponsor organisation address	Chaussée de la Hulpe 185, Brussels, Belgium, 1170
Public contact	EU Study Start-Up Unit, Bristol-Myers Squibb International Corporation, Clinical.Trials@bms.com
Scientific contact	Bristol-Myers Squibb Study Director, Bristol-Myers Squibb, Clinical.Trials@bms.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMA-001465-PIP01-13
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	12 November 2020
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	06 January 2021
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To compare the bioavailability of ATV and COBI when administered as a mini-tablet formulation with coadministration as individual component formulations in healthy adults

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Conference on Harmonization Good Clinical Practice Guidelines. All the local regulatory requirements pertinent to safety of trial participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 February 2020
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	United States: 34
Worldwide total number of subjects	34
EEA total number of subjects	0

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)	34
From 65 to 84 years	0

85 years and over	0
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Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

34 participants were randomized and treated

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	Sequence Group 1 = A-B

Arm description:

Participants are randomly assigned to receive treatment A on day 1. There is a 7-day wash-out period. Participants receive treatment B on day 8.

Treatment A: Single oral dose of atazanavir (ATV) and cobicistat (COBI) mini-tablets (300 mg/150 mg), mixed with a small serving of food

Treatment B: Single oral dose of atazanavir (ATV) powder (300 mg, mixed with a small serving of food) + cobicistat (COBI) tablet (150 mg) followed by 240 mL of water.

Arm type	Experimental
Investigational medicinal product name	EVOTAZ
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Chewable/dispersible tablet
Routes of administration	Other use

Dosage and administration details:

once-daily (QD) fixed-dose combination (FDC) tablet comprising atazanavir (ATV) 300 mg and cobicistat (COBI) 150 mg, mixed with a small serving of food

Investigational medicinal product name	Cobicistat (COBI)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

150 mg

Investigational medicinal product name	Atazanavir (ATV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral powder
Routes of administration	Oral use

Dosage and administration details:

300 mg, mixed with a small serving of food

Arm title	Sequence Group 2 = B-A
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Arm description:

Participants are randomly assigned to receive treatment B on day 1. There is a 7-day wash-out period. Participants receive treatment A on day 8.

Treatment A: Single oral dose of atazanavir (ATV) and cobicistat (COBI) mini-tablets (300 mg/150 mg), mixed with a small serving of food

Treatment B: Single oral dose of atazanavir (ATV) powder (300 mg, mixed with a small serving of food) + cobicistat (COBI) tablet (150 mg) followed by 240 mL of water.

Arm type	Experimental
Investigational medicinal product name	Cobicistat (COBI)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Tablet
Routes of administration	Oral use

Dosage and administration details:

150 mg

Investigational medicinal product name	EVOTAZ
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Chewable/dispersible tablet
Routes of administration	Other use

Dosage and administration details:

once-daily (QD) fixed-dose combination (FDC) tablet comprising atazanavir (ATV) 300 mg and cobicistat (COBI) 150 mg, mixed with a small serving of food

Investigational medicinal product name	Atazanavir (ATV)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Oral powder
Routes of administration	Oral use

Dosage and administration details:

300 mg, mixed with a small serving of food

Number of subjects in period 1	Sequence Group 1 = A-B	Sequence Group 2 = B-A
Started	17	17
Completed	17	16
Not completed	0	1
Consent withdrawn by subject	-	1

Baseline characteristics

Reporting groups

Reporting group title	Sequence Group 1 = A-B
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Reporting group description:

Participants are randomly assigned to receive treatment A on day 1. There is a 7-day wash-out period.
Participants receive treatment B on day 8.

Treatment A: Single oral dose of atazanavir (ATV) and cobicistat (COBI) mini-tablets (300 mg/150 mg), mixed with a small serving of food

Treatment B: Single oral dose of atazanavir (ATV) powder (300 mg, mixed with a small serving of food) + cobicistat (COBI) tablet (150 mg) followed by 240 mL of water.

Reporting group title	Sequence Group 2 = B-A
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Reporting group description:

Participants are randomly assigned to receive treatment B on day 1. There is a 7-day wash-out period.
Participants receive treatment A on day 8.

Treatment A: Single oral dose of atazanavir (ATV) and cobicistat (COBI) mini-tablets (300 mg/150 mg), mixed with a small serving of food

Treatment B: Single oral dose of atazanavir (ATV) powder (300 mg, mixed with a small serving of food) + cobicistat (COBI) tablet (150 mg) followed by 240 mL of water.

Reporting group values	Sequence Group 1 = A-B	Sequence Group 2 = B-A	Total
Number of subjects	17	17	34
Age Categorical Units: Participants			
Adults (18-64 years)	17	17	34
Age Continuous Units: years			
arithmetic mean	36.4	35.8	
standard deviation	± 7.3	± 7.3	-
Gender Categorical Units: Participants			
Female	6	5	11
Male	11	12	23
Race Units: Subjects			
White	7	10	17
Black or African American	10	6	16
Other	0	1	1
Ethnicity Units: Subjects			
Hispanic or Latino	5	11	16
Not Hispanic or Latino	12	6	18

End points

End points reporting groups

Reporting group title	Sequence Group 1 = A-B
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Reporting group description:

Participants are randomly assigned to receive treatment A on day 1. There is a 7-day wash-out period. Participants receive treatment B on day 8.

Treatment A: Single oral dose of atazanavir (ATV) and cobicistat (COBI) mini-tablets (300 mg/150 mg), mixed with a small serving of food

Treatment B: Single oral dose of atazanavir (ATV) powder (300 mg, mixed with a small serving of food) + cobicistat (COBI) tablet (150 mg) followed by 240 mL of water.

Reporting group title	Sequence Group 2 = B-A
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Reporting group description:

Participants are randomly assigned to receive treatment B on day 1. There is a 7-day wash-out period. Participants receive treatment A on day 8.

Treatment A: Single oral dose of atazanavir (ATV) and cobicistat (COBI) mini-tablets (300 mg/150 mg), mixed with a small serving of food

Treatment B: Single oral dose of atazanavir (ATV) powder (300 mg, mixed with a small serving of food) + cobicistat (COBI) tablet (150 mg) followed by 240 mL of water.

Subject analysis set title	Treatment A: ATV/COBI mini-tablets
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Subject analysis set type	Full analysis
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Subject analysis set description:

1 X 300 mg ATV/150 mg COBI bottle of mini-tablets mixed with a small serving of chocolate pudding

Subject analysis set title	Treatment B: ATV powder and COBI tablet
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Subject analysis set type	Full analysis
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Subject analysis set description:

6 X REYATAZ (ATV) 50-mg powder packets (300 mg total) mixed with a small serving of applesauce and 1 X COBI 150-mg tablet followed by 240 mL of water.

Primary: C_{max}: Maximum observed plasma concentration

End point title	C _{max} : Maximum observed plasma concentration ^[1]
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End point description:

The maximum observed serum concentration was measured compare the bioavailability of Atazanavir (ATV) and Cobicistat (COBI) when administered as a mini-tablet formulation with co-administration as individual component formulations in healthy adults. Note: 99999 = NA

End point type	Primary
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End point timeframe:

Time points can include: Day 1 and 8 (Pre-dose, 1, 2, 2.30, 3, 4, 5, 6, 8, 12, and 16 hours post dose). Day 2 and 9 (24, 30, 36 hours post dose). Day 3 and 10 (48 hours post dose).

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 summary statistics were planned for these endpoints

End point values	Treatment A: ATV/COBI mini-tablets	Treatment B: ATV powder and COBI tablet		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33	33		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Atazanavir	2392.1 (± 99999)	3634.6 (± 99999)		

Cobicistat	1029.3 (\pm 99999)	1217.2 (\pm 99999)		
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Statistical analyses

No statistical analyses for this end point

Primary: AUC(INF): Area under the plasma concentration-time curve from time zero extrapolated to infinite time

End point title	AUC(INF): Area under the plasma concentration-time curve from time zero extrapolated to infinite time ^[2]
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End point description:

The area under the plasma concentration-time curve from time zero extrapolated to infinite time was measured compare the bioavailability of Atazanavir (ATV) and Cobicistat (COBI) when administered as a mini-tablet formulation with co-administration as individual component formulations in healthy adults. Note: 99999 = NA

End point type	Primary
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End point timeframe:

Time points can include: Day 1 and 8 (Pre-dose, 1, 2, 2.30, 3, 4, 5, 6, 8, 12, and 16 hours post dose). Day 2 and 9 (24, 30, 36 hours post dose). Day 3 and 10 (48 hours post dose).

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: Only summary statistics were planned for these endpoints

End point values	Treatment A: ATV/COBI mini-tablets	Treatment B: ATV powder and COBI tablet		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33	33		
Units: ng.h/mL				
geometric mean (geometric coefficient of variation)				
Atazanavir	22673.4 (\pm 99999)	34053.3 (\pm 99999)		
Cobicistat	7057.6 (\pm 99999)	8496.9 (\pm 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Tmax: Time of maximum observed plasma concentration

End point title	Tmax: Time of maximum observed plasma concentration
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End point description:

The time of maximum observed plasma concentration was measured to assess the pharmacokinetics of Atazanavir (ATV) and Cobicistat (COBI) when administered as a mini-tablet formulation and when co-administered as individual component formulations in healthy adults. Note: 99999 = NA

End point type	Secondary
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End point timeframe:

Time points can include: Day 1 and 8 (Pre-dose, 1, 2, 2.30, 3, 4, 5, 6, 8, 12, and 16 hours post dose). Day 2 and 9 (24, 30, 36 hours post dose). Day 3 and 10 (48 hours post dose).

End point values	Treatment A: ATV/COBI mini-tablets	Treatment B: ATV powder and COBI tablet		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33	33		
Units: Hours				
median (full range (min-max))				
Atazanavir	2.050 (1.00 to 5.00)	2.000 (1.00 to 4.00)		
Cobicistat	2.500 (1.00 to 5.00)	2.067 (1.00 to 5.00)		

Statistical analyses

No statistical analyses for this end point

Secondary: T-HALF: Terminal plasma half-life

End point title	T-HALF: Terminal plasma half-life
End point description: The terminal plasma half-life was measured to assess the pharmacokinetics of Atazanavir (ATV) and Cobicistat (COBI) when administered as a mini-tablet formulation and when co-administered as individual component formulations in healthy adults. Note: 99999 = NA	
End point type	Secondary
End point timeframe: Time points can include: Day 1 and 8 (Pre-dose, 1, 2, 2.30, 3, 4, 5, 6, 8, 12, and 16 hours post dose). Day 2 and 9 (24, 30, 36 hours post dose). Day 3 and 10 (48 hours post dose).	

End point values	Treatment A: ATV/COBI mini-tablets	Treatment B: ATV powder and COBI tablet		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33	33		
Units: Hour				
arithmetic mean (standard deviation)				
Atazanavir	7.064 (± 1.696)	7.624 (± 1.954)		
Cobicistat	3.974 (± 0.837)	4.215 (± 0.901)		

Statistical analyses

No statistical analyses for this end point

Secondary: AUC(0-T): Area under the plasma concentration-time curve from time zero to time of last quantifiable concentration

End point title	AUC(0-T): Area under the plasma concentration-time curve from time zero to time of last quantifiable concentration
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End point description:

The area under the plasma concentration-time curve from time zero to time of last quantifiable concentration was measured to assess the pharmacokinetics of Atazanavir (ATV) and Cobicistat (COBI) when administered as a mini-tablet formulation and when co-administered as individual component formulations in healthy adults. Note: 99999 = NA

End point type	Secondary
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End point timeframe:

Time points can include: Day 1 and 8 (Pre-dose, 1, 2, 2.30, 3, 4, 5, 6, 8, 12, and 16 hours post dose). Day 2 and 9 (24, 30, 36 hours post dose). Day 3 and 10 (48 hours post dose).

End point values	Treatment A: ATV/COBI mini-tablets	Treatment B: ATV powder and COBI tablet		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33	33		
Units: ng.h/mL				
geometric mean (geometric coefficient of variation)				
Atazanavir	22304.4 (± 99999)	33422.7 (± 99999)		
Cobicistat	6870.0 (± 99999)	8280.3 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: C24: Observed concentration at 24 hours

End point title	C24: Observed concentration at 24 hours
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End point description:

The observed concentration at 24 hours was measured to assess the pharmacokinetics of Atazanavir (ATV) and Cobicistat (COBI) when administered as a mini-tablet formulation and when co-administered as individual component formulations in healthy adults. Note: 99999 = NA

End point type	Secondary
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End point timeframe:

Time points can include: Day 1 and 8 (Pre-dose, 1, 2, 2.30, 3, 4, 5, 6, 8, 12, and 16 hours post dose). Day 2 and 9 (24, 30, 36 hours post dose). Day 3 and 10 (48 hours post dose).

End point values	Treatment A: ATV/COBI mini-tablets	Treatment B: ATV powder and COBI tablet		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	33	33		
Units: ng/mL				
geometric mean (geometric coefficient of variation)				
Atazanavir	278.97 (± 99999)	434.51 (± 99999)		
Cobicistat	21.187 (± 99999)	27.828 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Participants Experiencing Adverse Events (AEs)

End point title	The Number of Participants Experiencing Adverse Events (AEs)
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End point description:

The number of participants experiencing adverse events (AEs) to assess the safety and tolerability of Atazanavir (ATV) and Cobicistat (COBI) when administered as a mini-tablet formulation and when co-administered as individual component formulations in healthy adults.

An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study treatment and that does not necessarily have a causal relationship with this treatment.

End point type	Secondary
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End point timeframe:

From first dose up to approximately 1 year

End point values	Treatment A: ATV/COBI mini-tablets	Treatment B: ATV powder and COBI tablet		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34	34		
Units: Participants	2	2		

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Participants Experiencing Serious Adverse Events (SAEs)

End point title	The Number of Participants Experiencing Serious Adverse Events (SAEs)
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End point description:

The number of participants experiencing serious adverse events (SAEs) to assess the safety and tolerability of Atazanavir (ATV) and Cobicistat (COBI) when administered as a mini-tablet formulation and when co-administered as individual component formulations in healthy adults.

Serious Adverse Event (SAE) is defined as any untoward medical occurrence that, at any dose: results in death, is life-threatening, requires inpatient hospitalization or causes prolongation of existing hospitalization, results in persistent or significant disability/incapacity, is a congenital anomaly/birth defect, and is an important medical event

End point type	Secondary
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End point timeframe:

From first dose up to approximately 1 year

End point values	Treatment A: ATV/COBI mini-tablets	Treatment B: ATV powder and COBI tablet		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34	34		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Participants Experiencing Adverse Events (AEs) Leading to Discontinuation

End point title	The Number of Participants Experiencing Adverse Events (AEs) Leading to Discontinuation
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End point description:

The number of participants experiencing adverse events (AEs) leading to discontinuation to assess the safety and tolerability of Atazanavir (ATV) and Cobicistat (COBI) when administered as a mini-tablet formulation and when co-administered as individual component formulations in healthy adults.

An Adverse Event (AE) is defined as any new untoward medical occurrence or worsening of a preexisting medical condition in a clinical investigation participant administered study treatment and that does not necessarily have a causal relationship with this treatment.

End point type	Secondary
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End point timeframe:

From first dose up to approximately 1 year

End point values	Treatment A: ATV/COBI mini-tablets	Treatment B: ATV powder and COBI tablet		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34	34		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Participants Deaths

End point title	The Number of Participants Deaths
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End point description:

The number of participants deaths to assess the safety and tolerability of Atazanavir (ATV) and Cobicistat (COBI) when administered as a mini-tablet formulation and when co-administered as individual component formulations in healthy adults.

End point type	Secondary
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End point timeframe:

From first dose up to approximately 1 year

End point values	Treatment A: ATV/COBI mini-tablets	Treatment B: ATV powder and COBI tablet		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34	34		
Units: Participants	0	0		

Statistical analyses

No statistical analyses for this end point

Secondary: The Number of Participants Experiencing Clinical Laboratory Abnormalities

End point title	The Number of Participants Experiencing Clinical Laboratory Abnormalities
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End point description:

The number of participants experiencing clinical laboratory abnormalities to assess the safety and tolerability of Atazanavir (ATV) and Cobicistat (COBI) when administered as a mini-tablet formulation and when co-administered as individual component formulations in healthy adults.

End point type	Secondary
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End point timeframe:

Clinical laboratory tests performed on Days -1 and 7

End point values	Treatment A: ATV/COBI mini-tablets	Treatment B: ATV powder and COBI tablet		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34	34		
Units: Participants				
LOW NEUTROPHILS (ABSOLUTE) (X10 ⁹ C/L)	1	2		
HIGH ALANINE AMINOTRANSFERASE (ALT)(U/L)	1	1		
HIGH BILIRUBIN, TOTAL (UMOL/L)	1	3		
HIGH BILIRUBIN, DIRECT (UMOL/L)	1	0		
HIGH WHITE BLOOD CELL, URINE (HPF)	0	1		

Statistical analyses

No statistical analyses for this end point

Secondary: The number of Participants with Out-of-Range Vital Sign Findings

End point title	The number of Participants with Out-of-Range Vital Sign Findings
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End point description:

The number of participants who experienced out of range vital sign findings during the course of the study. The following parameters were analyzed for vital sign examination: body temperature, respiratory rate, and seated blood pressure and heart rate.

Blood pressure and heart rate should be measured after the participant has been resting quietly for at least 5 minutes.

End point type	Secondary
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End point timeframe:

Screening, Pre-dose on Days 1 and 8 for blood pressure and heart rate only. Full vital signs at study discharge (The approximate duration of this study will be 38 days, including a 28-day screening period and a 10-day treatment period.)

End point values	Treatment A: ATV/COBI mini-tablets	Treatment B: ATV powder and COBI tablet		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34	34		
Units: vital sign measurements	4	4		

Statistical analyses

No statistical analyses for this end point

Secondary: The number of Participants with Electrocardiogram (ECG) abnormalities Identified by the Investigator

End point title	The number of Participants with Electrocardiogram (ECG) abnormalities Identified by the Investigator
End point description: The number of participants who experienced a clinically relevant electrocardiogram (ECG) finding during the course of the study.	
Parameters Include: PR Interval (msec), QRS Duration (msec), QT Interval (msec), QTcF Interval (msec).	
End point type	Secondary
End point timeframe: From screening to 10 days after second treatment dose	

End point values	Sequence Group 1 = A-B	Sequence Group 2 = B-A		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	17	17		
Units: ECG recordings	9	14		

Statistical analyses

No statistical analyses for this end point

Secondary: Palatability Questionnaire Results

End point title	Palatability Questionnaire Results
End point description: The number of participants in each Palatability questionnaire category to assess the acceptability and palatability of the ATV/COBI mini-tablet formulation in healthy adults.	
A palatability assessment will be completed for the ATV/COBI mini-tablets only (Treatment A)	
End point type	Secondary
End point timeframe: Within 5 minutes post dose on Day 1 or 8.	

End point values	Treatment A: ATV/COBI mini-tablets			
Subject group type	Subject analysis set			
Number of subjects analysed	34			
Units: Participants				
Liked Treatment A	20			
Neither liked nor disliked Treatment A	11			
Disliked Treatment A	3			
Reported not chewing before swallowing	23			
Reported first impulse was to swallow	20			
Reported neither was their first impulse	3			
Rated a strong sweetness intensity	15			
Rated a moderate sweetness intensity	10			

Rated a weak sweetness intensity	9			
Rated a sweetness level just about right	20			
Rated a weak bitterness intensity	16			
Rated a strong bitterness intensity	13			
Rated a moderate bitterness intensity	5			
Rated a bitterness level just about right	11			
Rated a weak saltiness intensity	13			
Rated a moderate saltiness intensity	7			
Rated a saltiness level just about right	13			
Rated a weak sourness intensity	13			
Rated a sourness level just about right	11			
Rated a sourness level much too weak	10			
Rated a moderate astringency intensity	10			
Rated a weak astringency intensity	9			
Rated an astringency level just about right	14			
Rated a moderate sandiness/grittiness intensity	9			
Rated a weak sandiness/grittiness intensity	8			
Rated sandiness/grittiness level just about right	15			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information^[1]

Timeframe for reporting adverse events:

From 1st dose to 100 days after last dose (Up to approximately 110 days)

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	23.1
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Reporting groups

Reporting group title	Treatment B: ATV powder and COBI tablet
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Reporting group description:

6 X REYATAZ (ATV) 50-mg powder packets (300 mg total) mixed with a small serving of applesauce and 1 X COBI 150-mg tablet followed by 240 mL of water.

Reporting group title	Treatment A: ATV/COBI mini-tablets
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Reporting group description:

1 X 300 mg ATV/150 mg COBI bottle of mini-tablets mixed with a small serving of chocolate pudding

Serious adverse events	Treatment B: ATV powder and COBI tablet	Treatment A: ATV/COBI mini-tablets	
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	

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

Non-serious adverse events	Treatment B: ATV powder and COBI tablet	Treatment A: ATV/COBI mini-tablets	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 34 (0.00%)	0 / 34 (0.00%)	

Notes:

[1] - There are no non-serious adverse events recorded for these results. It is expected that there will be at least one non-serious adverse event reported.

Justification: There are no non-serious adverse events in this study

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

None reported