Clinical trial results:
A Phase 2, Randomized, Double-blind, Placebo-controlled, 2-part Study to Evaluate EDP-938 Regimens In Subjects Aged 28 Days to 36 Months Infected with Respiratory Syncytial Virus (RSV)

Summary

EudraCT number	2020-001966-13
Trial protocol	DE PL ES RO
Global end of trial date	19 August 2024

Results information

Result version number	v2 (current)
This version publication date	02 August 2025
First version publication date	06 March 2025
Version creation reason	• New data added to full data set Secondary analysis data added.

Trial information

Trial identification

Sponsor protocol code	EDP 938-201

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04816721
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Enanta Pharmaceuticals, Inc.
Sponsor organisation address	4 Kingsbury Ave, Watertown, MA, United States, 02472
Public contact	Medical Monitor, Enanta Pharmaceuticals, Inc., +1 6176070800, enquiries@enanta.com
Scientific contact	Medical Monitor, Enanta Pharmaceuticals, Inc., +1 6176070800, enquiries@enanta.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-003609-PIP01-24
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?	Yes

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	19 August 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	19 August 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objectives of Part 1 of the study were to evaluate the pharmacokinetics (PK) of EDP-938 and to assess the safety and tolerability of EDP-938. The main objective of Part 2 of the study was to evaluate the antiviral activity of EDP-938.

Protection of trial subjects:

The study was conducted in compliance with the protocol, principles of E6 Good Clinical Practice: Consolidated Guidance (ICH-GCP), Declaration of Helsinki, and all applicable local laws and regulations governing clinical studies.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	26 April 2022
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 States: 29
Country: Number of subjects enrolled	Spain: 23
Country: Number of subjects enrolled	Poland: 3
Country: Number of subjects enrolled	Argentina: 8
Country: Number of subjects enrolled	South Africa: 8
Country: Number of subjects enrolled	Taiwan: 8
Country: Number of subjects enrolled	Mexico: 5
Country: Number of subjects enrolled	Israel: 7
Country: Number of subjects enrolled	Brazil: 4
Country: Number of subjects enrolled	Romania: 2
Country: Number of subjects enrolled	Australia: 2
Worldwide total number of subjects	99
EEA total number of subjects	28

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)	87
Children (2-11 years)	12
Adolescents (12-17 years)	0
Adults (18-64 years)	0
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 99 participants were enrolled at 78 sites across 15 countries between April 2022 and August 2024.

Pre-assignment

Screening details:

Participants were randomized 2:1 (Part 1) or 4:1 (Part 2) to EDP-938:placebo. One participant was randomized to placebo, but received 7.5 mg/kg EDP-938 in error.

Pre-assignment period milestones

Number of subjects started	99
Number of subjects completed	96

Pre-assignment subject non-completion reasons

Reason: Number of subjects	Miscellaneous: 1
Reason: Number of subjects	Withdrawal by Subject: 2

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Part 1, Group 1: EDP-938

Arm description:

Participants aged ≥ 6 months to < 12 months received oral 5 mg/kg doses of EDP-938 once daily (QD) from Day 1 to Day 5 of the study. Participants aged ≥ 12 months to ≤ 36 months received oral 5 mg/kg or 7.5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.

Arm type	Experimental
Investigational medicinal product name	EDP-938
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for oral suspension
Routes of administration	Oral use

Dosage and administration details:

EDP-938 was received orally by mouth, nasogastric tube, or orogastric tube.

Arm title	Part 1, Group 2: EDP-938

Arm description:

Participants aged ≥ 28 days to < 6 months received oral 5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.

Arm type	Experimental

Investigational medicinal product name	EDP-938
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for oral suspension
Routes of administration	Oral use

Dosage and administration details:

EDP-938 was received orally by mouth, nasogastric tube, or orogastric tube.

Arm title	Part 1, Group 1: Placebo

Arm description:

Participants aged ≥ 6 months to ≤ 36 months received oral doses of placebo matching EDP-938 QD from Day 1 to Day 5 of the study.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Placebo matching EDP-938 was received orally by mouth, nasogastric tube, or orogastric tube.

Arm title	Part 1, Group 2: Placebo

Arm description:

Participants aged between ≥ 28 days and < 6 months received oral doses of placebo matching EDP-938 QD from Day 1 to Day 5 of the study.

Arm type	Experimental
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Placebo matching EDP-938 was received orally by mouth, nasogastric tube, or orogastric tube.

Arm title	Part 2, Group 1: EDP-938

Arm description:

Participants aged ≥ 6 months to < 12 months received oral 5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study. Participants aged ≥ 12 months to ≤ 36 months received oral 7.5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.

Arm type	Experimental
Investigational medicinal product name	EDP-938
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for oral suspension
Routes of administration	Oral use

Dosage and administration details:

EDP-938 was received orally by mouth, nasogastric tube, or orogastric tube.

Arm title	Part 2, Group 2: EDP-938

Arm description:

Participants aged ≥ 28 days to < 6 months received oral 5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.

Arm type	Experimental

Investigational medicinal product name	EDP-938
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for oral suspension
Routes of administration	Oral use

Dosage and administration details:

EDP-938 was received orally by mouth, nasogastric tube, or orogastric tube.

Arm title	Part 2, Group 1: Placebo

Arm description:

Participants aged between ≥ 6 months and ≤ 36 months received oral doses of placebo matching EDP-938 QD from Day 1 to Day 5 of the study.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Placebo matching EDP-938 was received orally by mouth, nasogastric tube, or orogastric tube.

Arm title	Part 2, Group 2: Placebo

Arm description:

Participants aged between ≥ 28 days and < 6 months received oral doses of placebo matching EDP-938 QD from Day 1 to Day 5 of the study.

Arm type	Placebo
Investigational medicinal product name	Placebo
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Powder for oral suspension
Routes of administration	Oral use

Dosage and administration details:

Placebo matching EDP-938 was received orally by mouth, nasogastric tube, or orogastric tube.

Number of subjects in period 1[1]	Part 1, Group 1: EDP-938	Part 1, Group 2: EDP-938	Part 1, Group 1: Placebo
Started	22	13	11
Treated With 5 mg/kg EDP-938	14 [2]	13	0 [3]
Treated With 7.5 mg/kg EDP-938	9 [4]	0 [5]	0 [6]
Treated With Placebo	0 [7]	0 [8]	11
Completed	22	12	11
Not completed	0	1	0
Lost to Follow-up	-	-	-
Withdrawal by Subject	-	1	-

Number of subjects in period 1[1]	Part 1, Group 2: Placebo	Part 2, Group 1: EDP-938	Part 2, Group 2: EDP-938
Started	6	19	15

Treated With 5 mg/kg EDP-938	0 [9]	8 [10]	15
Treated With 7.5 mg/kg EDP-938	0 [11]	11 [12]	0 [13]
Treated With Placebo	6	0 [14]	0 [15]
Completed	4	19	15
Not completed	2	0	0
Lost to Follow-up	1	-	-
Withdrawal by Subject	1	-	-

Number of subjects in period 1[1]	Part 2, Group 1: Placebo	Part 2, Group 2: Placebo
Started	6	4
Treated With 5 mg/kg EDP-938	0 [16]	0 [17]
Treated With 7.5 mg/kg EDP-938	0 [18]	0 [19]
Treated With Placebo	6	4
Completed	6	4
Not completed	0	0
Lost to Follow-up	-	-
Withdrawal by Subject	-	-

Notes:

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

[2] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Milestone N/A for this arm as participants received one of two EDP-938 doses and are represented in different milestones.

[3] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Milestone N/A for this arm as participants received one of two EDP-938 doses and are represented in different milestones.

[4] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Milestone N/A for this arm as participants received one of two EDP-938 doses and are represented in different milestones.

[5] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Milestone N/A for this arm as participants received one of two EDP-938 doses and are represented in different milestones.

[6] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Milestone N/A for this arm as participants received one of two EDP-938 doses and are represented in different milestones.

[7] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Milestone N/A for this arm as participants received one of two EDP-938 doses and are represented in different milestones.

[8] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.
Justification: Milestone N/A for this arm as participants received one of two EDP-938 doses and are

represented in different milestones.

[9] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestone N/A for this arm as participants received one of two EDP-938 doses and are represented in different milestones.

[10] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestone N/A for this arm as participants received one of two EDP-938 doses and are represented in different milestones.

[11] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestone N/A for this arm as participants received one of two EDP-938 doses and are represented in different milestones.

[12] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestone N/A for this arm as participants received one of two EDP-938 doses and are represented in different milestones.

[13] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestone N/A for this arm as participants received one of two EDP-938 doses and are represented in different milestones.

[14] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestone N/A for this arm as participants received one of two EDP-938 doses and are represented in different milestones.

[15] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestone N/A for this arm as participants received one of two EDP-938 doses and are represented in different milestones.

[16] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestone N/A for this arm as participants received one of two EDP-938 doses and are represented in different milestones.

[17] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestone N/A for this arm as participants received one of two EDP-938 doses and are represented in different milestones.

[18] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestone N/A for this arm as participants received one of two EDP-938 doses and are represented in different milestones.

[19] - The number of subjects at this milestone seems inconsistent with the number of subjects in the arm. It is expected that the number of subjects will be greater than, or equal to the number that completed, minus those who left.

Justification: Milestone N/A for this arm as participants received one of two EDP-938 doses and are represented in different milestones.

Baseline characteristics

Reporting groups	
Reporting group title	Overall Study

Reporting group description: -

Reporting group values	Overall Study	Total	
Number of subjects	96	96	
Age categorical Units: Subjects			
≥ 28 days to < 3 months	22	22	
≥ 3 months to < 6 months	16	16	
≥ 6 months to < 12 months	22	22	
≥ 12 months to ≤ 36 months	36	36	
Gender categorical Units: Subjects			
Female	49	49	
Male	47	47	
Race Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	9	9	
Black or African American	15	15	
Native Hawaiian or Other Pacific Islander	0	0	
White	62	62	
Other	6	6	
Not Reported	3	3	
Unknown	1	1	
Ethnicity Units: Subjects			
Hispanic or Latino	38	38	
Not Hispanic or Latino	57	57	
Not Reported	1	1	
Hospitalization Status on Day 1 Units: Subjects			
Yes	77	77	
No	19	19	

End points

End points reporting groups

Reporting group title	Part 1, Group 1: EDP-938
Reporting group description:	
Participants aged ≥ 6 months to < 12 months received oral 5 mg/kg doses of EDP-938 once daily (QD) from Day 1 to Day 5 of the study. Participants aged ≥ 12 months to ≤ 36 months received oral 5 mg/kg or 7.5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.	
Reporting group title	Part 1, Group 2: EDP-938
Reporting group description:	
Participants aged ≥ 28 days to < 6 months received oral 5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.	
Reporting group title	Part 1, Group 1: Placebo
Reporting group description:	
Participants aged ≥ 6 months to ≤ 36 months received oral doses of placebo matching EDP-938 QD from Day 1 to Day 5 of the study.	
Reporting group title	Part 1, Group 2: Placebo
Reporting group description:	
Participants aged between ≥ 28 days and < 6 months received oral doses of placebo matching EDP-938 QD from Day 1 to Day 5 of the study.	
Reporting group title	Part 2, Group 1: EDP-938
Reporting group description:	
Participants aged ≥ 6 months to < 12 months received oral 5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study. Participants aged ≥ 12 months to ≤ 36 months received oral 7.5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.	
Reporting group title	Part 2, Group 2: EDP-938
Reporting group description:	
Participants aged ≥ 28 days to < 6 months received oral 5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.	
Reporting group title	Part 2, Group 1: Placebo
Reporting group description:	
Participants aged between ≥ 6 months and ≤ 36 months received oral doses of placebo matching EDP-938 QD from Day 1 to Day 5 of the study.	
Reporting group title	Part 2, Group 2: Placebo
Reporting group description:	
Participants aged between ≥ 28 days and < 6 months received oral doses of placebo matching EDP-938 QD from Day 1 to Day 5 of the study.	
Subject analysis set title	Part 1: EDP-938 5mg/kg (≥ 28 Days to < 3 Months)
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants aged between ≥ 28 days and < 3 months received oral 5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.	
Subject analysis set title	Part 1: EDP-938 5mg/kg (≥ 3 Months to < 6 Months)
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants aged between ≥ 3 months and < 6 months received oral 5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.	
Subject analysis set title	Part 1: EDP-938 5mg/kg (≥ 6 Months to < 12 Months)
Subject analysis set type	Full analysis
Subject analysis set description:	
Participants aged between ≥ 6 months and < 12 months received oral 5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.	
Subject analysis set title	Part 1: EDP-938 5mg/kg (≥ 12 Months to ≤ 36 Months)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants aged between ≥ 12 months to ≤ 36 months received oral 5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.

Subject analysis set title	Part 1: EDP-938 7.5 mg/kg (≥ 12 Months to ≤ 36 Months)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants aged between ≥ 12 months to ≤ 36 months received oral 7.5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.

Subject analysis set title	Part 1: EDP-938
Subject analysis set type	Full analysis

Subject analysis set description:

Participants who received oral doses of EDP-938 QD from Day 1 to Day 5 of the study.

Subject analysis set title	Part 1: Placebo
Subject analysis set type	Full analysis

Subject analysis set description:

Participants who received oral doses of placebo matching EDP-938 QD from Day 1 to Day 5 of the study.

Subject analysis set title	Part 2: EDP-938
Subject analysis set type	Full analysis

Subject analysis set description:

Participants who received oral doses of EDP-938 QD from Day 1 to Day 5 of the study.

Subject analysis set title	Part 2: Placebo
Subject analysis set type	Full analysis

Subject analysis set description:

Participants who received oral doses of placebo matching EDP-938 QD from Day 1 to Day 5 of the study.

Subject analysis set title	Combined EDP-938
Subject analysis set type	Full analysis

Subject analysis set description:

Participants in Part 1 and Part 2 who received oral doses of EDP-938 QD from Day 1 to Day 5 of the study.

Subject analysis set title	Combined Placebo
Subject analysis set type	Full analysis

Subject analysis set description:

Participants in Part 1 and Part 2 who received oral doses of placebo matching EDP-938 QD from Day 1 to Day 5 of the study.

Subject analysis set title	Part 2: EDP-938 5mg/kg (≥ 28 Days to < 3 Months)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants aged between ≥ 28 days and < 3 months received oral 5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.

Subject analysis set title	Part 2: EDP-938 5mg/kg (≥ 3 Months to < 6 Months)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants aged between ≥ 3 months and < 6 months received oral 5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.

Subject analysis set title	Part 2: EDP-938 5mg/kg (≥ 6 Months to < 12 Months)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants aged between ≥ 6 months and < 12 months received oral 5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.

Subject analysis set title	Part 2: EDP-938 7.5 mg/kg (≥ 12 Months to ≤ 36 Months)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants aged between ≥ 12 months to ≤ 36 months received oral 7.5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.

Subject analysis set title	Combined EDP-938 5mg/kg (≥ 28 Days to < 3 Months)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants aged between ≥ 28 days and < 3 months received oral 5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.

Subject analysis set title	Combined EDP-938 5mg/kg (≥ 3 Months to < 6 Months)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants aged between ≥ 3 months and < 6 months received oral 5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.

Subject analysis set title	Combined EDP-938 5mg/kg (≥ 6 Months to < 12 Months)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants aged between ≥ 6 months and < 12 months received oral 5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.

Subject analysis set title	Combined EDP-938 5mg/kg (≥ 12 Months to ≤ 36 Months)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants aged between ≥ 12 months to ≤ 36 months received oral 5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.

Subject analysis set title	Combined EDP-938 7.5 mg/kg (≥ 12 Months to ≤ 36 Months)
Subject analysis set type	Full analysis

Subject analysis set description:

Participants aged between ≥ 12 months to ≤ 36 months received oral 7.5 mg/kg doses of EDP-938 QD from Day 1 to Day 5 of the study.

Primary: Part 1: Concentrations of EDP-938 in Plasma

End point title	Part 1: Concentrations of EDP-938 in Plasma[1]

End point description:

Plasma concentrations of EDP-938 were assessed at the designated time points. 99999 = Data not available.

PK Population: Included all participants in Part 1 who received one full dose of study drug and had samples with quantifiable plasma levels to allow for estimation of PK parameters. Per protocol, data were analyzed per age group and dose received.

End point type	Primary

End point timeframe:

3 hours post-dose on Day 1 and pre-dose on Day 2 (hospitalized participants only), Day 3, and Day 5

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: No additional statistical analysis was pre-specified for this endpoint.

End point values	Part 1: EDP-938 5mg/kg (≥ 28 Days to < 3 Months)	Part 1: EDP-938 5mg/kg (≥ 3 Months to < 6 Months)	Part 1: EDP-938 5mg/kg (≥ 6 Months to < 12 Months)	Part 1: EDP-938 5mg/kg (≥ 12 Months to ≤ 36 Months)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	9[2]	4[3]	7[4]	7[5]
Units: ng/mL				
arithmetic mean (standard deviation)				
Day 1	1132.222 (± 397.4289)	1989.500 (± 1331.5646)	1819.286 (± 809.9508)	1420.000 (± 604.8140)
Day 2	368.400 (± 149.8741)	399.250 (± 423.9515)	502.350 (± 379.6487)	249.675 (± 294.5416)
Day 3	448.000 (± 229.1026)	99999 (± 99999)	346.000 (± 54.7449)	97.533 (± 64.9043)

Day 5	528.563 (± 284.6010)	201.750 (± 98.6623)	431.429 (± 637.5664)	252.043 (± 329.2155)

Notes:

[2] - Day 1 N = 9
Day 2 N = 7
Day 3 N = 2
Day 5 N = 7

[3] - Day 1 N = 4
Day 2 N = 4
Day 3 N = 0
Day 5 N = 4

[4] - Day 1 N = 7
Day 2 N = 4
Day 3 N = 3
Day 5 N = 7

[5] - Day 1 N = 6
Day 2 N = 4
Day 3 N = 3
Day 5 N = 7

End point values	Part 1: EDP-938 7.5 mg/kg (≥ 12 Months to ≤ 36 Months)			
Subject group type	Subject analysis set			
Number of subjects analysed	9[6]			
Units: ng/mL				
arithmetic mean (standard deviation)				
Day 1	1428.250 (± 817.4801)			
Day 2	238.900 (± 239.0287)			
Day 3	116.250 (± 43.4871)			
Day 5	180.622 (± 158.3268)			

Notes:

[6] - Day 1 N = 8
Day 2 N = 7
Day 3 N = 2
Day 5 N = 9

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of Participants Who Experienced a Treatment-emergent Adverse Event (TEAE)

End point title	Part 1: Number of Participants Who Experienced a Treatment-emergent Adverse Event (TEAE)[7]

End point description:

TEAEs were defined as any event, side effect, or untoward medical occurrence in a participant enrolled in a clinical study whether or not it was considered to have a causal relationship to the study drug and first occurred or worsened during the post-baseline phase compared to baseline. Clinically significant changes from baseline in vital signs and clinical laboratory results were reported as TEAEs.

Safety Population: Included all participants in Part 1 who received any dose (including partial doses) of any study drug. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose.

End point type	Primary

End point timeframe:

Day 1 to Day 28

Notes:

[7] - 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: No additional statistical analysis was pre-specified for this endpoint.

End point values	Part 1: EDP-938	Part 1: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	36	16		
Units: participants	14	9		

Statistical analyses

No statistical analyses for this end point

Primary: Part 2: Model-adjusted Daily Change From Baseline in Respiratory Syncytial Virus (RSV) Shedding in Nasal Swab Samples

End point title	Part 2: Model-adjusted Daily Change From Baseline in Respiratory Syncytial Virus (RSV) Shedding in Nasal Swab Samples

End point description:

Daily change from baseline in RSV shedding was defined as the daily change from baseline in RSV ribonucleic acid (RNA) viral load and was measured using reverse transcription-quantitative polymerase chain reaction (RT-qPCR) from nasal swabs. The model included treatment group (EDP-938, placebo) and Day (3, 5, 9, and 14) as fixed effect, associated baseline, and treatment group by Day interaction term as factors. An unstructured covariance matrix was imposed. The Satterthwaite approximation is used to estimate the denominator degrees of freedom.

Efficacy Population: Included all participants in Part 2 who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose.

End point type	Primary

End point timeframe:

Baseline and pre-dose on Days 3, 5, 9, and 14

End point values	Part 2: EDP-938	Part 2: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34	10		
Units: log10 copies/mL				
least squares mean (standard error)				
Day 3	-1.33 (± 0.297)	-0.37 (± 0.533)		
Day 5	-3.04 (± 0.354)	-1.62 (± 0.627)		
Day 9	-3.65 (± 0.381)	-3.22 (± 0.680)		
Day 14	-4.87 (± 0.388)	-5.71 (± 0.677)		

Statistical analyses

Statistical analysis title	Day 3: EDP-938 Versus Placebo

Statistical analysis description:

The model included treatment group (EDP-938, placebo) and Day (3, 5, 9, and 14) as fixed effect, associated baseline, and treatment group by day interaction term as factors. An unstructured covariance matrix was imposed. The Satterthwaite approximation was used to estimate the denominator degrees of freedom.

Comparison groups	Part 2: EDP-938 v Part 2: Placebo
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1249
Method	Mixed-effect Model of Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.21
upper limit	0.28

Statistical analysis title	Day 5: EDP-938 Versus Placebo

Statistical analysis description:

The model included treatment group (EDP-938, placebo) and Day (3, 5, 9, and 14) as fixed effect, associated baseline, and treatment group by day interaction term as factors. An unstructured covariance matrix was imposed. The Satterthwaite approximation was used to estimate the denominator degrees of freedom.

Comparison groups	Part 2: EDP-938 v Part 2: Placebo
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.058
Method	Mixed-effect Model of Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-1.41
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.88
upper limit	0.05

Statistical analysis title	Day 9: EDP-938 Versus Placebo

Statistical analysis description:

The model included treatment group (EDP-938, placebo) and Day (3, 5, 9, and 14) as fixed effect, associated baseline, and treatment group by day interaction term as factors. An unstructured covariance matrix was imposed. The Satterthwaite approximation was used to estimate the denominator degrees of freedom.

Comparison groups	Part 2: EDP-938 v Part 2: Placebo
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5877
Method	Mixed-effect Model of Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.43
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.02
upper limit	1.16

Statistical analysis title	Day 14: EDP-938 Versus Placebo

Statistical analysis description:

The model included treatment group (EDP-938, placebo) and Day (3, 5, 9, and 14) as fixed effect, associated baseline, and treatment group by day interaction term as factors. An unstructured covariance matrix was imposed. The Satterthwaite approximation was used to estimate the denominator degrees of freedom.

Comparison groups	Part 2: EDP-938 v Part 2: Placebo
Number of subjects included in analysis	44
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2932
Method	Mixed-effect Model of Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	0.84
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.76
upper limit	2.43

Primary: Pooled Population: Model-adjusted Daily Change From Baseline in RSV Shedding in Nasal Swab Samples

End point title	Pooled Population: Model-adjusted Daily Change From Baseline in RSV Shedding in Nasal Swab Samples

End point description:

Daily change from baseline in RSV shedding was defined as the daily change from baseline in RSV RNA viral load and was measured using RT-qPCR from nasal swabs. The model included treatment group (EDP-938, placebo) and Day (3, 5, 9, and 14) as fixed effect, associated baseline, and treatment group by Day interaction term as factors. An unstructured covariance matrix was imposed. The Satterthwaite

approximation is used to estimate the denominator degrees of freedom.

Efficacy Population: Included all participants who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose.

End point type	Primary

End point timeframe:

Baseline and pre-dose on Days 3, 5, 9, and 14

End point values	Combined EDP-938	Combined Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	69	27		
Units: log10 copies/mL				
least squares mean (standard error)				
Day 3	-1.53 (± 0.192)	-1.36 (± 0.331)		
Day 5	-2.95 (± 0.230)	-2.62 (± 0.392)		
Day 9	-4.57 (± 0.275)	-3.87 (± 0.475)		
Day 14	-5.01 (± 0.278)	-5.35 (± 0.462)		

Statistical analyses

Statistical analysis title	Day 3: EDP-938 Versus Placebo

Statistical analysis description:

The model included treatment group (EDP-938, placebo) and Day (3, 5, 9, and 14) as fixed effect, associated baseline, and treatment group by day interaction term as factors. An unstructured covariance matrix was imposed. The Satterthwaite approximation was used to estimate the denominator degrees of freedom.

Comparison groups	Combined EDP-938 v Combined Placebo
Number of subjects included in analysis	96
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6574
Method	Mixed-effect Model of Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.17
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.93
upper limit	0.59

Statistical analysis title	Day 5: EDP-938 Versus Placebo

Statistical analysis description:

The model includes treatment group (EDP-938, placebo) and Day (3, 5, 9, and 14) as fixed effect, associated baseline, and treatment group by Day interaction term as factors. An unstructured covariance matrix is imposed. The Satterthwaite approximation is used to estimate the denominator degrees of freedom.

Comparison groups	Combined EDP-938 v Combined Placebo
Number of subjects included in analysis	96
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4728
Method	Mixed-effect Model of Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.23
upper limit	0.58

Statistical analysis title	Day 9: EDP-938 Versus Placebo

Statistical analysis description:

The model includes treatment group (EDP-938, placebo) and Day (3, 5, 9, and 14) as fixed effect, associated baseline, and treatment group by Day interaction term as factors. An unstructured covariance matrix is imposed. The Satterthwaite approximation is used to estimate the denominator degrees of freedom.

Comparison groups	Combined EDP-938 v Combined Placebo
Number of subjects included in analysis	96
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.2058
Method	Mixed-effect Model of Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.7
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.79
upper limit	0.39

Statistical analysis title	Day 14: EDP-938 Versus Placebo

Statistical analysis description:

The model includes treatment group (EDP-938, placebo) and Day (3, 5, 9, and 14) as fixed effect, associated baseline, and treatment group by Day interaction term as factors. An unstructured covariance matrix is imposed. The Satterthwaite approximation is used to estimate the denominator degrees of freedom.

Comparison groups	Combined EDP-938 v Combined Placebo

Number of subjects included in analysis	96
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5391
Method	Mixed-effect Model of Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	0.33
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.74
upper limit	1.41

Secondary: Part 1 and Part 2: Area Under the Curve (AUC) for RSV RNA Viral Load

End point title	Part 1 and Part 2: Area Under the Curve (AUC) for RSV RNA Viral Load

End point description:

The RSV RNA viral load was measured using RT-qPCR from nasal swabs. The AUC was calculated using the trapezoid rule. The AUC was calculated based on all available assessments collected on Days 1, 3, 5, 9 and 14 and the actual date/time of each assessment was used for the calculation.

Efficacy Population: Included all participants who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose.

End point type	Secondary

End point timeframe:

Pre-dose on Day 1 through pre-dose on Days 3, 5, 9 and 14

End point values	Part 1: EDP-938	Part 1: Placebo	Part 2: EDP-938	Part 2: Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	34	12	29[8]	9
Units: log10 copies/mL*Days				
arithmetic mean (standard deviation)				
Day 1 through Day 3	17.80 (± 4.522)	17.26 (± 4.691)	17.15 (± 4.663)	16.91 (± 3.266)
Day 1 through Day 5	25.54 (± 8.301)	24.55 (± 8.457)	24.76 (± 7.914)	26.22 (± 7.069)
Day 1 through Day 9	36.03 (± 16.229)	35.20 (± 17.156)	37.00 (± 13.652)	40.39 (± 13.371)
Day 1 through Day 14	42.85 (± 24.990)	44.16 (± 25.056)	45.49 (± 21.109)	42.17 (± 19.864)

Notes:

[8] - Days 1-3 N = 25

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Population: AUC of Change From Baseline in RSV RNA Viral Load

End point title	Pooled Population: AUC of Change From Baseline in RSV RNA Viral Load

End point description:

The RSV RNA viral load was measured using RT-qPCR from nasal swabs. The AUC was calculated using the trapezoid rule. The AUC was calculated based on all available assessments collected on Days 1, 3, 5, 9 and 14 and the actual date/time of each assessment was used for the calculation. The model included treatment group (EDP-938, placebo) and Day (3, 5, 9, and 14) as fixed effect, associated baseline, and treatment group by day interaction term as factors. An unstructured covariance matrix was imposed. The Satterthwaite approximation was used to estimate the denominator degrees of freedom.

Efficacy Population: Included all participants who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose.

End point type	Secondary

End point timeframe:

Baseline (Pre-dose on Day 1) through pre-dose on Days 3, 5, 9 and 14

End point values	Combined EDP-938	Combined Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	69	27		
Units: log10 copies/mL*Days				
least squares mean (standard error)				
Day 1 through Day 3	-1.53 (± 0.192)	-1.36 (± 0.331)		
Day 1 through Day 5	-6.00 (± 0.540)	-5.33 (± 0.930)		
Day 1 through Day 9	-21.04 (± 1.319)	-18.32 (± 2.272)		
Day 1 through Day 14	-45.00 (± 2.105)	-41.36 (± 3.619)		

Statistical analyses

Statistical analysis title	Day 1 through Day 3: EDP-938 Versus Placebo

Statistical analysis description:

The model included treatment group (EDP-938, placebo) and Day (3, 5, 9, and 14) as fixed effect, associated baseline, and treatment group by day interaction term as factors. An unstructured covariance matrix was imposed. The Satterthwaite approximation was used to estimate the denominator degrees of freedom.

Comparison groups	Combined EDP-938 v Combined Placebo
Number of subjects included in analysis	96
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6574
Method	Mixed-effect Model of Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.17

Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.93
upper limit	0.59

Statistical analysis title	Day 1 through Day 5: EDP-938 Versus Placebo

Statistical analysis description:

The model included treatment group (EDP-938, placebo) and Day (3, 5, 9, and 14) as fixed effect, associated baseline, and treatment group by day interaction term as factors. An unstructured covariance matrix was imposed. The Satterthwaite approximation was used to estimate the denominator degrees of freedom.

Comparison groups	Combined EDP-938 v Combined Placebo
Number of subjects included in analysis	96
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5359
Method	Mixed-effect Model of Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-0.67
Confidence interval	
level	95 %
sides	2-sided
lower limit	-2.81
upper limit	1.47

Statistical analysis title	Day 1 through Day 9: EDP-938 Versus Placebo

Statistical analysis description:

The model included treatment group (EDP-938, placebo) and Day (3, 5, 9, and 14) as fixed effect, associated baseline, and treatment group by day interaction term as factors. An unstructured covariance matrix was imposed. The Satterthwaite approximation was used to estimate the denominator degrees of freedom.

Comparison groups	Combined EDP-938 v Combined Placebo
Number of subjects included in analysis	96
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3029
Method	Mixed-effect Model of Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-2.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.95
upper limit	2.5

Statistical analysis title	Day 1 through Day 14: EDP-938 Versus Placebo

Statistical analysis description:

The model included treatment group (EDP-938, placebo) and Day (3, 5, 9, and 14) as fixed effect, associated baseline, and treatment group by day interaction term as factors. An unstructured covariance matrix was imposed. The Satterthwaite approximation was used to estimate the denominator degrees of freedom.

Comparison groups	Combined EDP-938 v Combined Placebo
Number of subjects included in analysis	96
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3871
Method	Mixed-effect Model of Repeated Measures
Parameter estimate	Least Squares Mean Difference
Point estimate	-3.64
Confidence interval	
level	95 %
sides	2-sided
lower limit	-11.98
upper limit	4.69

Secondary: Part 1: Daily Change From Baseline in RSV Shedding in Nasal Swab Samples

End point title	Part 1: Daily Change From Baseline in RSV Shedding in Nasal Swab Samples

End point description:

Daily change from baseline in RSV shedding in nasal swab samples was defined as the absolute daily change from baseline in RSV RNA viral load and measured using RT-qPCR from nasal swabs.

Efficacy Population: Included all participants in Part 1 who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose.

End point type	Secondary

End point timeframe:

Baseline to pre-dose on Days 3, 5, 9, and Day 14

End point values	Part 1: EDP-938	Part 1: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34[9]	12[10]		
Units: log10 copies/mL				
arithmetic mean (standard deviation)				
Day 3	-1.68 (± 1.239)	-2.17 (± 1.948)		
Day 5	-2.91 (± 1.634)	-3.44 (± 1.585)		
Day 9	-5.34 (± 2.338)	-4.41 (± 1.897)		
Day 14	-5.11 (± 2.378)	-5.15 (± 2.118)		

Notes:

[9] - Day 5 N = 33
Day 9 N = 32
Day 14 N = 31
[10] - Day 9 N = 11

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 and Part 2: Percentage of Participants With RSV RNA Viral Load Below the Limit of Detection (LOD)

End point title	Part 1 and Part 2: Percentage of Participants With RSV RNA Viral Load Below the Limit of Detection (LOD)

End point description:

The RSV RNA viral load was measured using RT-qPCR from nasal swabs.

Efficacy Population: Included all participants who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose. Included only participants with detectable viral load at baseline and non-missing viral load assessment at the respective visit and was used as a denominator in the percentage population.

End point type	Secondary

End point timeframe:

Pre-dose on Days 3, 5, 9 and 14

End point values	Part 1: EDP-938	Part 1: Placebo	Part 2: EDP-938	Part 2: Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	34[11]	12[12]	28[13]	9[14]
Units: percentage of participants				
number (confidence interval 95%)				
Day 3	0 (0.00 to 10.28)	8.3 (0.21 to 38.48)	3.6 (0.09 to 18.35)	0 (0.00 to 33.63)
Day 5	12.1 (3.40 to 28.20)	16.7 (2.09 to 48.41)	22.2 (8.62 to 42.26)	0 (0.00 to 33.63)
Day 9	62.5 (43.69 to 78.90)	36.4 (10.93 to 69.21)	28.0 (12.07 to 49.39)	25.0 (3.19 to 65.09)
Day 14	61.3 (42.19 to 78.15)	58.3 (27.67 to 84.83)	63.0 (42.37 to 80.60)	88.9 (51.75 to 99.72)

Notes:

[11] - Day 5 N = 33
Day 9 N = 32
Day 14 N = 31
[12] - Day 9 N = 11
[13] - Day 5 N = 27
Day 9 N = 25
Day 14 N = 27
[14] - Day 9 N = 8

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Population: Percentage of Participants With RSV RNA Viral Load Below the LOD

End point title	Pooled Population: Percentage of Participants With RSV RNA Viral Load Below the LOD

End point description:

The RSV RNA viral load was measured using RT-qPCR from nasal swabs.

Efficacy Population: Included all participants who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose. Included only participants with detectable viral load at baseline and non-missing viral load assessment at the respective visit and was used as a denominator in the percentage population.

End point type	Secondary

End point timeframe:

Pre-dose on Days 3, 5, 9 and 14

End point values	Combined EDP-938	Combined Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	62[15]	21[16]		
Units: percentage of participants				
number (confidence interval 95%)				
Day 3	1.6 (0.04 to 8.66)	4.8 (0.12 to 23.82)		
Day 5	16.7 (8.29 to 28.52)	9.5 (1.17 to 30.38)		
Day 9	47.4 (33.98 to 61.03)	31.6 (12.58 to 56.55)		
Day 14	62.1 (48.37 to 74.49)	71.4 (47.82 to 88.72)		

Notes:

[15] - Day 5 N = 60
Day 9 N = 57
Day 14 N = 58
[16] - Day 9 N = 19

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1 and Part 2: Time to RSV RNA Viral Load Being Undetectable

End point title	Part 1 and Part 2: Time to RSV RNA Viral Load Being Undetectable

End point description:

Time to RSV RNA viral load being undetectable was calculated as: first date of RSV RNA viral load target not detected (TND) after which no further samples had detectable RSV RNA viral load - date of first dose.

Efficacy Population: Included all participants who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose.

End point type	Secondary

End point timeframe:

Day 1 to Day 28

End point values	Part 1: EDP-938	Part 1: Placebo	Part 2: EDP-938	Part 2: Placebo
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	34	14	29	9
Units: days				
arithmetic mean (standard deviation)	10.59 (± 3.661)	12.33 (± 3.018)	12.46 (± 3.235)	12.19 (± 3.040)

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Population: Time to RSV RNA Viral Load Being Undetectable

End point title	Pooled Population: Time to RSV RNA Viral Load Being Undetectable

End point description:

Time to RSV RNA viral load being undetectable was calculated as: first date of RSV RNA viral load TND after which no further samples had detectable RSV RNA viral load - date of first dose.

Efficacy Population: Included all participants who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose.

End point type	Secondary

End point timeframe:

Day 1 to Day 28

End point values	Combined EDP-938	Combined Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	63	23		
Units: days				
arithmetic mean (standard deviation)	11.45 (± 3.570)	12.27 (± 2.958)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Number of Participants Who Experienced a TEAE

End point title	Part 2: Number of Participants Who Experienced a TEAE

End point description:

TEAEs were defined as any event, side effect, or untoward medical occurrence in a participant enrolled in a clinical study whether or not it was considered to have a causal relationship to the study drug and first occurred or worsened during the post-baseline phase compared to baseline. Clinically significant

changes from baseline in vital signs and clinical laboratory results were reported as TEAEs.

Safety Population: Included all participants in Part 2 who received any dose (including partial doses) of any study drug. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose.

End point type	Secondary

End point timeframe:

Day 1 to Day 28

End point values	Part 2: EDP-938	Part 2: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	34	10		
Units: participants	14	4		

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Population: Number of Participants Who Experienced a TEAE

End point title	Pooled Population: Number of Participants Who Experienced a TEAE

End point description:

TEAEs were defined as any event, side effect, or untoward medical occurrence in a participant enrolled in a clinical study whether or not it was considered to have a causal relationship to the study drug and first occurred or worsened during the post-baseline phase compared to baseline. Clinically significant changes from baseline in vital signs and clinical laboratory results were reported as TEAEs.

Safety Population: Included all participants who received any dose (including partial doses) of any study drug. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose.

End point type	Secondary

End point timeframe:

Day 1 to Day 28

End point values	Combined EDP-938	Combined Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	70	26		
Units: participants	28	13		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Concentrations of EDP-938 in Plasma

End point title	Part 2: Concentrations of EDP-938 in Plasma

End point description:

Plasma concentrations of EDP-938 were assessed at the designated time points. Values of "99999" indicate N/A.

PK Population: Included all participants in Part 2 who received one full dose of study drug and had samples with quantifiable plasma levels to allow for estimation of PK parameters. Per protocol, data were analyzed per age group and dose received.

End point type	Secondary

End point timeframe:

3 hours post-dose on Day 1 and pre-dose on Day 2 (hospitalized participants only), Day 3, and Day 5

End point values	Part 2: EDP-938 5mg/kg (≥ 28 Days to < 3 Months)	Part 2: EDP-938 5mg/kg (≥ 3 Months to < 6 Months)	Part 2: EDP-938 5mg/kg (≥ 6 Months to < 12 Months)	Part 2: EDP-938 7.5 mg/kg (≥ 12 Months to ≤ 36 Months)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	7[17]	8[18]	7[19]	9[20]
Units: ng/mL				
arithmetic mean (standard deviation)				
Day 1	1116.286 (± 217.9983)	1169.903 (± 802.0744)	1551.429 (± 363.8419)	1368.111 (± 469.7815)
Day 2	585.400 (± 119.6089)	273.500 (± 150.4616)	140.783 (± 73.3099)	200.700 (± 134.3896)
Day 3	194.000 (± 99999)	926.000 (± 57.9828)	112.000 (± 99999)	115.967 (± 84.9347)
Day 5	516.333 (± 247.6697)	519.714 (± 436.8130)	69.110 (± 40.4604)	153.450 (± 102.4372)

Notes:

[17] - Day 2 N = 5
Day 3 N = 1
Day 5 N = 6
[18] - Day 2 N = 6
Day 3 N = 2
Day 5 N = 7
[19] - Day 2 N = 6
Day 3 N = 1
[20] - Day 2 N = 6
Day 3 N = 3
Day 5 N = 8

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Population: Concentrations of EDP-938 in Plasma

End point title	Pooled Population: Concentrations of EDP-938 in Plasma

End point description:

Plasma concentrations of EDP-938 were assessed at the designated time points.

PK Population: Included all participants who received one full dose of study drug and had samples with quantifiable plasma levels to allow for estimation of PK parameters. Per protocol, data were analyzed per age group and dose received.

End point type	Secondary

End point timeframe:

3 hours post-dose on Day 1 and pre-dose on Day 2 (hospitalized participants only), Day 3, and Day 5

End point values	Combined EDP-938 5mg/kg (≥ 28 Days to < 3 Months)	Combined EDP-938 5mg/kg (≥ 3 Months to < 6 Months)	Combined EDP-938 5mg/kg (≥ 6 Months to < 12 Months)	Combined EDP-938 5mg/kg (≥ 12 Months to ≤ 36 Months)
Subject group type	Subject analysis set	Subject analysis set	Subject analysis set	Subject analysis set
Number of subjects analysed	16[21]	12[22]	14[23]	7[24]
Units: ng/mL				
arithmetic mean (standard deviation)				
Day 1	1125.250 (± 321.4278)	1443.102 (± 1027.5197)	1685.357 (± 619.0267)	1420.000 (± 604.8140)
Day 2	458.817 (± 173.0322)	323.800 (± 276.9576)	285.410 (± 293.0727)	249.675 (± 294.5416)
Day 3	363.333 (± 218.5162)	926.000 (± 57.9828)	287.500 (± 125.2478)	97.533 (± 64.9043)
Day 5	522.918 (± 257.0945)	404.091 (± 378.3365)	250.269 (± 472.9799)	252.043 (± 329.2155)

Notes:

[21] - Day 2 N = 12
Day 3 N = 3
Day 5 N = 13
[22] - Day 2 N = 10
Day 3 N = 2
Day 5 N = 11
[23] - Day 2 N = 10
Day 3 N = 4
[24] - Day 1 N = 6
Day 2 N = 4
Day 3 N = 3

End point values	Combined EDP-938 7.5 mg/kg (≥ 12 Months to ≤ 36 Months)			
Subject group type	Subject analysis set			
Number of subjects analysed	18[25]			
Units: ng/mL				
arithmetic mean (standard deviation)				
Day 1	1396.412 (± 635.3537)			
Day 2	221.269 (± 191.0117)			
Day 3	116.080 (± 63.8730)			
Day 5	167.835 (± 131.6054)			

Notes:

[25] - Day 1 N = 17
Day 2 N = 13
Day 3 N = 5
Day 5 N = 17

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Time to First Hospital Discharge for Hospitalized Participants

End point title	Part 2: Time to First Hospital Discharge for Hospitalized Participants

End point description:

Time to first discharge for participants who were hospitalized at randomization was calculated as: date/time of first discharge - date/time of first dose with conversion to days. For participants with continuous hospitalization, the last date of discharge from the continuous hospitalization was used.

Efficacy Population: Included all participants in Part 2 who received one full dose of study drug and had at least one evaluable measurement while on treatment. Only participants who were hospitalized at randomization were included. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose.

End point type	Secondary

End point timeframe:

Day 1 to Day 28

End point values	Part 2: EDP-938	Part 2: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	7		
Units: days				
arithmetic mean (standard deviation)	3.93 (± 1.870)	4.00 (± 3.367)		

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Population: Time to First Hospital Discharge for Hospitalized Participants

End point title	Pooled Population: Time to First Hospital Discharge for Hospitalized Participants

End point description:

Time to first discharge for participants who were hospitalized at randomization was calculated as: date/time of first discharge - date/time of first dose with conversion to days. For participants with continuous hospitalization, the last date of discharge from the continuous hospitalization was used.

Efficacy Population: Included all participants who received one full dose of study drug and had at least one evaluable measurement while on treatment. Only participants who were hospitalized at randomization were included. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose.

End point type	Secondary

End point timeframe:

Day 1 to Day 28

End point values	Combined EDP-938	Combined Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	56	21		
Units: days				
arithmetic mean (standard deviation)	3.71 (± 2.006)	3.57 (± 2.959)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Time to Use of Oxygen for Hospitalized Participants Who Were Not Receiving Oxygen at the Time They Received the First Dose of Study Drug

End point title	Part 2: Time to Use of Oxygen for Hospitalized Participants Who Were Not Receiving Oxygen at the Time They Received the First Dose of Study Drug

End point description:

For participants were were hospitalized at randomization, time to use of oxygen for hospitalization participants who were not receiving oxygen at the time they received the first dose of study drug was calculated as: first date/time of receiving oxygen - date/time of first dose of study drug with conversion to days.

Efficacy Population: Included all participants in Part 2 who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose. As there were no participants in Part 2 in both arms who were hospitalized at randomization who were not receiving oxygen at the time they received the first dose of study drug, no data were collected for this outcome measure.

End point type	Secondary

End point timeframe:

Day 1 to Day 28

End point values	Part 2: EDP-938	Part 2: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[26]	0[27]		
Units: days				
arithmetic mean (standard deviation)	()	()		

Notes:

[26] - No data were collected for this outcome measure.

[27] - No data were collected for this outcome measure.

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Population: Time to Use of Oxygen for Hospitalized Participants Who Were Not Receiving Oxygen at the Time They Received the First Dose of Study Drug

End point title	Pooled Population: Time to Use of Oxygen for Hospitalized Participants Who Were Not Receiving Oxygen at the Time They Received the First Dose of Study Drug

End point description:

For participants were were hospitalized at randomization, time to use of oxygen for hospitalization participants who were not receiving oxygen at the time they received the first dose of study drug was calculated as: first date/time of receiving oxygen - date/time of first dose of study drug with conversion to days. Values of "99999" indicate N/A.

Efficacy Population. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose. Only hospitalized participants who were not receiving oxygen at the time they received the first dose of study drug were included. In the Placebo arm, there were no hospitalized participants who were not receiving oxygen at the time they received the first dose of study drug.

End point type	Secondary

End point timeframe:

Day 1 to Day 28

End point values	Combined EDP-938	Combined Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	1	0[28]		
Units: days				
arithmetic mean (standard deviation)	0.51 (± 99999)	()		

Notes:

[28] - No hospitalized participants who were not receiving oxygen at the time they received study drug.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of Hospitalized Participants Who Required Oxygen Supplementation or Had an Increased Oxygen Requirement After the First Dose of Study Drug

End point title	Part 2: Percentage of Hospitalized Participants Who Required Oxygen Supplementation or Had an Increased Oxygen Requirement After the First Dose of Study Drug

End point description:

The numerator in the percentage calculation was defined by the number of participants who developed a new requirement for oxygen supplementation or new increase in oxygen requirements after the first dose of study drug, based on the response of "yes" to the "Is this an increase of oxygen supplementation compared to previous use?" question on the Oxygen Supplementation case report form (CRF). The 95% confidence interval was reported using the Clopper Pearson confidence interval methods.

Efficacy Population: Included all participants in Part 2 who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose. Only participants who were hospitalized at randomization and/or during the study were included.

End point type	Secondary

End point timeframe:

Day 1 to Day 28

End point values	Part 2: EDP-938	Part 2: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	7		
Units: percentage of participants				
number (confidence interval 95%)	24.1 (10.30 to 43.54)	28.6 (3.67 to 70.96)		

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Population: Percentage of Hospitalized Participants Who Required Oxygen Supplementation or Had an Increased Oxygen Requirement After the First Dose of Study Drug

End point title	Pooled Population: Percentage of Hospitalized Participants Who Required Oxygen Supplementation or Had an Increased Oxygen Requirement After the First Dose of Study Drug

End point description:

The numerator in the percentage calculation was defined by the number of participants who developed a new requirement for oxygen supplementation or new increase in oxygen requirements after the first dose of study drug, based on the response of "yes" to the "Is this an increase of oxygen supplementation compared to previous use?" question on the Oxygen Supplementation CRF. The 95% confidence interval was reported using the Clopper Pearson confidence interval methods.

Efficacy Population: Included all participants who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose. Only participants who were hospitalized at randomization and/or during the study were included.

End point type	Secondary

End point timeframe:

Day 1 to Day 28

End point values	Combined EDP-938	Combined Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	56	21		
Units: percentage of participants				
number (confidence interval 95%)	25.0 (14.39 to 38.37)	19.0 (5.45 to 41.91)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Time to Mechanical Ventilation for Hospitalized Participants

End point title	Part 2: Time to Mechanical Ventilation for Hospitalized Participants

End point description:

Time to mechanical ventilation for participants who were hospitalized at randomization was calculated as: first date/time of mechanical ventilation - date/time of first dose of study drug with conversion to days. Participants who were on mechanical ventilation before their first dose of study drug were excluded from the analysis.

Efficacy Population: Included all participants in Part 2 who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose. As only participants who were hospitalized at baseline and experienced mechanical ventilation were included, no data were collected for this outcome measure.

End point type	Secondary

End point timeframe:

Day 1 to Day 28

End point values	Part 2: EDP-938	Part 2: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[29]	0[30]		
Units: days				
arithmetic mean (standard deviation)	()	()		

Notes:

[29] - No data were collected for this outcome measure.

[30] - No data were collected for this outcome measure.

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Population: Time to Mechanical Ventilation for Hospitalized Participants

End point title	Pooled Population: Time to Mechanical Ventilation for Hospitalized Participants

End point description:

Time to mechanical ventilation for participants who were hospitalized at randomization was calculated as: first date/time of mechanical ventilation - date/time of first dose of study drug with conversion to days. Participants who were on mechanical ventilation before their first dose of study drug were excluded from the analysis.

Efficacy Population: Included all participants who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose. As only participants who were hospitalized at baseline and experienced mechanical ventilation after their first dose of study drug were included, no data were collected for this outcome measure.

End point type	Secondary

End point timeframe:

Day 1 to Day 28

End point values	Combined EDP-938	Combined Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[31]	0[32]		
Units: days				
arithmetic mean (standard deviation)	()	()		

Notes:

[31] - No data were collected for this outcome measure.

[32] - No data were collected for this outcome measure.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of Hospitalized Participants Who Required Mechanical Ventilation

End point title	Part 2: Percentage of Hospitalized Participants Who Required Mechanical Ventilation

End point description:

The numerator in the percentage calculation was defined by the number of participants who developed a new requirement for mechanical ventilation after the first dose of study drug. Participants on mechanical ventilation prior to the first dose of study drug were excluded from analysis. The 95% confidence interval was reported using the Clopper Pearson confidence interval methods.

Efficacy Population: Included all participants in Part 2 who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose. Only hospitalized participants who were not on mechanical ventilation prior to the first dose of study drug were included.

End point type	Secondary

End point timeframe:

Day 1 to Day 28

End point values	Part 2: EDP-938	Part 2: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	7		
Units: percentage of participants				
number (confidence interval 95%)	0 (0.00 to 11.94)	0 (0.00 to 40.96)		

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Population: Percentage of Hospitalized Participants Who Required Mechanical Ventilation

End point title	Pooled Population: Percentage of Hospitalized Participants Who Required Mechanical Ventilation

End point description:

The numerator in the percentage calculation was defined by the number of participants who developed a new requirement for mechanical ventilation after the first dose of study drug. Participants on mechanical

ventilation prior to the first dose of study drug were excluded from analysis. The 95% confidence interval was reported using the Clopper Pearson confidence interval methods.

Efficacy Population: Included all participants who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose. Only hospitalized participants who were not on mechanical ventilation prior to the first dose of study drug were included.

End point type	Secondary

End point timeframe:

Day 1 to Day 28

End point values	Combined EDP-938	Combined Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	56	21		
Units: percentage of participants				
number (confidence interval 95%)	0 (0.00 to 6.38)	0 (0.00 to 16.11)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of Hospitalized Participants Who Died During the Study

End point title	Part 2: Percentage of Hospitalized Participants Who Died During the Study

End point description:

The percentage of hospitalized participants who died during the study included deaths from any cause. The 95% confidence interval was reported using the Clopper Pearson confidence interval methods.

Efficacy Population: Included all participants in Part 2 who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose. Only participants who were hospitalized at randomization and/or during the study were included.

End point type	Secondary

End point timeframe:

Day 1 to Day 28

End point values	Part 2: EDP-938	Part 2: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	29	7		
Units: percentage of participants				
number (confidence interval 95%)	0 (0.00 to 11.94)	0 (0.00 to 40.96)		

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Population: Percentage of Hospitalized Participants Who Died During the Study

End point title	Pooled Population: Percentage of Hospitalized Participants Who Died During the Study

End point description:

The percentage of hospitalized participants who died during the study included deaths from any cause. The 95% confidence interval was reported using the Clopper Pearson confidence interval methods.

Efficacy Population: Included all participants who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose. Only participants who were hospitalized at randomization and/or during the study were included.

End point type	Secondary

End point timeframe:

Day 1 to Day 28

End point values	Combined EDP-938	Combined Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	56	21		
Units: percentage of participants				
number (confidence interval 95%)	0 (0.00 to 6.38)	0 (0.00 to 16.11)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Time to Hospitalization for Initial Outpatients Who Were Subsequently Hospitalized

End point title	Part 2: Time to Hospitalization for Initial Outpatients Who Were Subsequently Hospitalized

End point description:

Time to hospitalization for initial outpatients who are not hospitalized at randomization but subsequently hospitalized was calculated as: first date/time of hospitalization - date/time of first dose with conversion to days.

Efficacy Population: Included all participants in Part 2 who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose. As only participants who were not hospitalized at randomization but subsequently hospitalized were included, no data were collected for this outcome

measure.

End point type	Secondary

End point timeframe:

Day 1 to Day 28

End point values	Part 2: EDP-938	Part 2: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[33]	0[34]		
Units: days				
arithmetic mean (standard deviation)	()	()		

Notes:

[33] - No data were collected for this outcome measure.

[34] - No data were collected for this outcome measure.

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Population: Time to Hospitalization for Initial Outpatients Who Were Subsequently Hospitalized

End point title	Pooled Population: Time to Hospitalization for Initial Outpatients Who Were Subsequently Hospitalized

End point description:

Time to hospitalization for initial outpatients who are not hospitalized at randomization but subsequently hospitalized was calculated as: first date/time of hospitalization - date/time of first dose with conversion to days.

Efficacy Population: Included all participants who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose. As only participants who were not hospitalized at randomization but subsequently hospitalized were included, no data were collected for this outcome measure.

End point type	Secondary

End point timeframe:

Day 1 to Day 28

End point values	Combined EDP-938	Combined Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	0[35]	0[36]		
Units: days				
arithmetic mean (standard deviation)	()	()		

Notes:

[35] - No data were collected for this outcome measure.

[36] - No data were collected for this outcome measure.

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of Outpatients Who Were Subsequently Hospitalized or Died

End point title	Part 2: Percentage of Outpatients Who Were Subsequently Hospitalized or Died

End point description:

Participants who were hospitalized at randomization were excluded from the analysis. The 95% confidence interval was reported using the Clopper Pearson confidence interval methods.

Efficacy Population: Included all participants in Part 2 who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose. Only participants who were not hospitalized at randomization were included.

End point type	Secondary

End point timeframe:

Day 1 to Day 28

End point values	Part 2: EDP-938	Part 2: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	5	3		
Units: percentage of participants				
number (confidence interval 95%)	0 (0.00 to 52.18)	0 (0.00 to 70.76)		

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Population: Percentage of Outpatients Who Were Subsequently Hospitalized or Died

End point title	Pooled Population: Percentage of Outpatients Who Were Subsequently Hospitalized or Died

End point description:

Participants who were hospitalized at randomization were excluded from the analysis. The 95% confidence interval was reported using the Clopper Pearson confidence interval methods.

Efficacy Population: Included all participants who received one full dose of study drug and had at least one evaluable measurement while on treatment. Per the protocol, analyses were planned to be grouped by EDP-938 and placebo, rather than by dose. Only participants who were not hospitalized at randomization were included.

End point type	Secondary

End point timeframe:

Day 1 to Day 28

End point values	Combined EDP-938	Combined Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	13	6		
Units: percentage of participants				
number (confidence interval 95%)	0 (0.00 to 24.71)	0 (0.00 to 45.93)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Time to Resolution of Symptoms for Outpatients Who Were Not Hospitalized

End point title	Part 2: Time to Resolution of Symptoms for Outpatients Who Were Not Hospitalized

End point description:

Resolution of symptoms was defined as the first of 2 consecutive timepoints where each of the seven symptoms assessed by the Parent/Caregiver RSV Foundation (ReSVinet) score was 0 (not present) or 1 (mild). Time to resolution of symptoms for outpatients who were not hospitalized was calculated as: first date/time of resolution of symptoms - date/time of first dose with conversion to days. Participants who did not achieve resolution and had not been followed through the Day 14 visit or completed the Day 14 questionnaire were censored at Day 14.

During the study, the parent(s)/caregiver(s) assessed the severity of RSV-related signs and symptoms. The ReSVinet assessed 7 symptoms, with each symptom being rated from 0 (not present) to 3 (severe), apart from fever which was scored from 0-2. The full range was 0 to 20 with higher scores representing more severe disease.

Efficacy Population. Only participants who were not hospitalized were included.

End point type	Secondary

End point timeframe:

Day 1 to Day 14

End point values	Part 2: EDP-938	Part 2: Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	3	2		
Units: days				
arithmetic mean (standard deviation)	2.60 (± 1.686)	1.49 (± 0.702)		

Statistical analyses

No statistical analyses for this end point

Secondary: Pooled Population: Time to Resolution of Symptoms for Outpatients Who Were Not Hospitalized

End point title	Pooled Population: Time to Resolution of Symptoms for Outpatients Who Were Not Hospitalized

End point description:

Resolution of symptoms was defined as the first of 2 consecutive timepoints where each of the seven symptoms assessed by the Parent/Caregiver ReSVinet score was 0 (not present) or 1 (mild). Time to resolution of symptoms for outpatients who were not hospitalized was calculated as: first date/time of resolution of symptoms - date/time of first dose with conversion to days. Participants who did not achieve resolution and had not been followed through the Day 14 visit or completed the Day 14 questionnaire were censored at Day 14.

During the study, the parent(s)/caregiver(s) assessed the severity of RSV-related signs and symptoms. The ReSVinet assessed 7 symptoms, with each symptom being rated from 0 (not present) to 3 (severe), apart from fever which was scored from 0-2. The full range was 0 to 20 with higher scores representing more severe disease.

Efficacy Population. Only participants who were not hospitalized were included.

End point type	Secondary

End point timeframe:

Day 1 to Day 14

End point values	Combined EDP-938	Combined Placebo		
Subject group type	Subject analysis set	Subject analysis set		
Number of subjects analysed	8	5		
Units: days				
arithmetic mean (standard deviation)	2.42 (± 1.163)	4.20 (± 5.552)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to Day 28

Adverse event reporting additional description:

The analysis population for serious adverse events and other (non-serious) adverse events was the safety population which included all participants who received any dose (including partial doses) of any study drug. Per Section 4.1 of the SAP, analyses were planned to be grouped by treatment, rather than by specific dose.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	Part 1: EDP-938

Reporting group description:

Participants who received oral doses of EDP-938 QD from Day 1 to Day 5 of the study.

Reporting group title	Part 2: EDP-938

Reporting group description:

Participants who received oral doses of EDP-938 QD from Day 1 to Day 5 of the study.

Reporting group title	Part 2: Placebo

Reporting group description:

Participants who received oral doses of placebo matching EDP-938 QD from Day 1 to Day 5 of the study.

Reporting group title	Part 1: Placebo

Reporting group description:

Participants who received oral doses of placebo matching EDP-938 QD from Day 1 to Day 5 of the study.

Serious adverse events	Part 1: EDP-938	Part 2: EDP-938	Part 2: Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 36 (0.00%)	1 / 34 (2.94%)	0 / 10 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 10 (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
Infections and infestations			
Bronchiolitis			

subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 10 (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
Pneumonia			
subjects affected / exposed	0 / 36 (0.00%)	1 / 34 (2.94%)	0 / 10 (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	Part 1: Placebo		
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 16 (12.50%)		
number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Respiratory, thoracic and mediastinal disorders			
Pleural effusion			
subjects affected / exposed	1 / 16 (6.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Bronchiolitis			
subjects affected / exposed	1 / 16 (6.25%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	0 / 16 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Part 1: EDP-938	Part 2: EDP-938	Part 2: Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 36 (19.44%)	9 / 34 (26.47%)	4 / 10 (40.00%)
Investigations			

Myocardial necrosis marker increased			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Thrombocytosis			
subjects affected / exposed	0 / 36 (0.00%)	2 / 34 (5.88%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
General disorders and administration site conditions			
Pyrexia			
subjects affected / exposed	1 / 36 (2.78%)	0 / 34 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Gastrointestinal disorders			
Diarrhoea			
subjects affected / exposed	4 / 36 (11.11%)	3 / 34 (8.82%)	0 / 10 (0.00%)
occurrences (all)	4	3	0
Vomiting			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Nasal congestion			
subjects affected / exposed	0 / 36 (0.00%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Skin and subcutaneous tissue disorders			
Dermatitis diaper			
subjects affected / exposed	1 / 36 (2.78%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Eczema			
subjects affected / exposed	1 / 36 (2.78%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Papule			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rash			

subjects affected / exposed	1 / 36 (2.78%)	2 / 34 (5.88%)	1 / 10 (10.00%)
occurrences (all)	1	2	1
Infections and infestations			
Acarodermatitis			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	0 / 36 (0.00%)	1 / 34 (2.94%)	1 / 10 (10.00%)
occurrences (all)	0	1	1
Otitis media acute			
subjects affected / exposed	1 / 36 (2.78%)	1 / 34 (2.94%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Pneumonia bacterial			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 36 (0.00%)	0 / 34 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 1: Placebo		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 16 (43.75%)		
Investigations			
Myocardial necrosis marker increased			
subjects affected / exposed	0 / 16 (0.00%)		
occurrences (all)	0		
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 16 (0.00%)		
occurrences (all)	0		
Thrombocytosis			
subjects affected / exposed	0 / 16 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Pyrexia			

subjects affected / exposed occurrences (all)	0 / 16 (0.00%) 0		
Gastrointestinal disorders Diarrhoea subjects affected / exposed occurrences (all) Vomiting subjects affected / exposed occurrences (all)	 1 / 16 (6.25%) 1 1 / 16 (6.25%) 1		
Respiratory, thoracic and mediastinal disorders Nasal congestion subjects affected / exposed occurrences (all)	 1 / 16 (6.25%) 1		
Skin and subcutaneous tissue disorders Dermatitis diaper subjects affected / exposed occurrences (all) Eczema subjects affected / exposed occurrences (all) Papule subjects affected / exposed occurrences (all) Rash subjects affected / exposed occurrences (all)	 1 / 16 (6.25%) 1 1 / 16 (6.25%) 1 1 / 16 (6.25%) 1 0 / 16 (0.00%) 0		
Infections and infestations Acarodermatitis subjects affected / exposed occurrences (all) Nasopharyngitis subjects affected / exposed occurrences (all) Otitis media acute subjects affected / exposed occurrences (all)	 1 / 16 (6.25%) 1 1 / 16 (6.25%) 1 1 / 16 (6.25%) 1		

Pneumonia bacterial subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1		
Respiratory tract infection subjects affected / exposed occurrences (all)	1 / 16 (6.25%) 1		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 August 2020	Protocol Version 2.0 (global amendment)
01 June 2021	Protocol Version 4.0 (global amendment)
13 September 2021	Protocol Version 6.0 (global amendment)
28 February 2022	Protocol Version 8.0 (global amendment)
23 August 2022	Protocol Version 10.0 (global amendment)
03 October 2022	Protocol Version 11.0 (global amendment)
03 January 2023	Protocol Version 13.0 (global amendment)
22 September 2023	Protocol Version 15.0 (global amendment; submitted to the United States Food and Drug Administration only)
04 December 2023	Protocol Version 16.0 (global amendment)
09 July 2024	Protocol Version 18.0 (global amendment)

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported