Clinical trial results:
A Phase 1, Single- and Multiple-Dose Safety and Pharmacokinetic Study of Oral and IV Tedizolid Phosphate (MK-1986) in Inpatients Under 2 Years Old

Summary

EudraCT number	2017-000953-38
Trial protocol	BG GB NO Outside EU/EEA
Global end of trial date	29 March 2023

Results information

Result version number	v1 (current)
This version publication date	22 October 2023
First version publication date	22 October 2023

Trial information

Trial identification

Sponsor protocol code	MK-1986-014

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03217565
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Merck Sharp & Dohme LLC
Sponsor organisation address	126 East Lincoln Avenue, P.O. Box 2000, Rahway, NJ, United States, 07065
Public contact	Clinical Trials Disclosure, Merck Sharp & Dohme LLC, ClinicalTrialsDisclosure@merck.com
Scientific contact	Clinical Trials Disclosure, Merck Sharp & Dohme LLC, ClinicalTrialsDisclosure@merck.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	Yes
EMA paediatric investigation plan number(s)	EMEA-001379-PIP01-12
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	29 March 2023
Is this the analysis of the primary completion data?	Yes
Primary completion date	18 March 2023
Global end of trial reached?	Yes
Global end of trial date	29 March 2023
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The primary objectives of this study are to describe the single-dose (SD), and multiple dose (MD) pharmacokinetics (PK) of intravenous (IV) tedizolid phosphate, or a single dose oral suspension of tedizolid phosphate, when administered to pediatric participants, full-term (FT) neonates, and preterm (PT) neonates. Part A consists of study arms: Group 1 Cohort 1, Group 1 Cohort 2, Group 2 Cohort 1, Group 2 Cohort 2, Group 3 Cohort 1, Group 3 Cohort 2 and Part B consists of Groups 4, 5 and 6.

Protection of trial subjects:

This study was conducted in conformance with Good Clinical Practice standards and applicable country and/or local statutes and regulations regarding ethical committee review, informed consent, and the protection of human subjects participating in biomedical research.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	06 February 2019
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	Bulgaria: 13
Country: Number of subjects enrolled	Colombia: 19
Country: Number of subjects enrolled	Norway: 5
Country: Number of subjects enrolled	United Kingdom: 5
Country: Number of subjects enrolled	United States: 5
Worldwide total number of subjects	47
EEA total number of subjects	18

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	17
Newborns (0-27 days)	16
Infants and toddlers (28 days-23 months)	14

Children (2-11 years)	0
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:

This study was conducted at 30 centers in 5 countries.

Pre-assignment

Screening details:

Participants were enrolled and allocated to 1 of 9 groups/cohorts to receive either single IV infusion, multiple IV infusions (twice daily for 3 days) or single oral suspension dose of Tedizolid Phosphate (MK-1986).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1 Cohort 1:SD IV Tedizolid Phosphate 28days-<6months

Arm description:

Pediatric participants 28 days to <6 months of age received a single dose (SD) intravenous (IV) infusion of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.

Arm type	Experimental
Investigational medicinal product name	Tedizolid phosphate
Investigational medicinal product code	
Other name	MK-1986
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

2.5 - 3 mg/kg

Arm title	Group 1 Cohort 2: SD IV Tedizolid Phosphate 6-<24months

Arm description:

Pediatric participants 6 months to <24 months of age received an SD IV infusion of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.

Arm type	Experimental
Investigational medicinal product name	Tedizolid Phosphate
Investigational medicinal product code	
Other name	MK-1986
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

2.5 - 3 mg/kg

Arm title	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days

Arm description:

Full term (FT) neonates from birth to 28 days of age received an SD IV infusion of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.

Arm type	Experimental

Investigational medicinal product name	Tedizolid Phosphate
Investigational medicinal product code	
Other name	MK-1986
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

2.5 - 3 mg/kg

Arm title	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days

Arm description:

FT neonates from birth to 28 days of age received multiple dose (MD) IV infusions of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg, administered twice daily for 3 days.

Arm type	Experimental
Investigational medicinal product name	Tedizolid Phosphate
Investigational medicinal product code	
Other name	MK-1986
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

2.5 - 3 mg/kg

Arm title	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days

Arm description:

Preterm (PT) neonates from birth to 28 days of age received an SD IV infusion of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.

Arm type	Experimental
Investigational medicinal product name	Tedizolid Phosphate
Investigational medicinal product code	
Other name	MK-1986
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

2.5 - 3 mg/kg

Arm title	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days

Arm description:

PT neonates from birth to 28 days of age received MD IV infusions of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg, administered twice daily for 3 days.

Arm type	Experimental
Investigational medicinal product name	Tedizolid Phosphate
Investigational medicinal product code	
Other name	MK-1986
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

2.5 - 3 mg/kg

Arm title	Group 4: SD Oral Tedizolid Phosphate 28days-<24months

Arm description:

Pediatric participants 28 days to <24 months of age received an SD oral suspension of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.

Arm type	Experimental

Investigational medicinal product name	Tedizolid Phosphate
Investigational medicinal product code	
Other name	MK-1986
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

2.5 - 3 mg/kg

Arm title	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days

Arm description:

FT neonates from birth to <28 days of age received an SD oral suspension of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.

Arm type	Experimental
Investigational medicinal product name	Tedizolid Phosphate
Investigational medicinal product code	
Other name	MK-1986
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

2.5 - 3 mg/kg

Arm title	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days

Arm description:

PT neonates from birth to <28 days of age received an SD oral suspension of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.

Arm type	Experimental
Investigational medicinal product name	Tedizolid Phosphate
Investigational medicinal product code	
Other name	MK-1986
Pharmaceutical forms	Oral suspension
Routes of administration	Oral use

Dosage and administration details:

2.5 - 3 mg/kg

Number of subjects in period 1	Group 1 Cohort 1:SD IV Tedizolid Phosphate 28days-<6months	Group 1 Cohort 2: SD IV Tedizolid Phosphate 6-<24months	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days
Started	4	6	8
Completed	4	6	8

Number of subjects in period 1	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Started	4	9	4
Completed	4	9	4

Number of subjects in period 1	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days

Started	4	4	4
Completed	4	4	4

Baseline characteristics

Reporting groups

Reporting group title	Group 1 Cohort 1:SD IV Tedizolid Phosphate 28days-<6months
Reporting group description:	
Pediatric participants 28 days to <6 months of age received a single dose (SD) intravenous (IV) infusion of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.	
Reporting group title	Group 1 Cohort 2: SD IV Tedizolid Phosphate 6-<24months
Reporting group description:	
Pediatric participants 6 months to <24 months of age received an SD IV infusion of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.	
Reporting group title	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days
Reporting group description:	
Full term (FT) neonates from birth to 28 days of age received an SD IV infusion of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.	
Reporting group title	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days
Reporting group description:	
FT neonates from birth to 28 days of age received multiple dose (MD) IV infusions of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg, administered twice daily for 3 days.	
Reporting group title	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days
Reporting group description:	
Preterm (PT) neonates from birth to 28 days of age received an SD IV infusion of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.	
Reporting group title	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Reporting group description:	
PT neonates from birth to 28 days of age received MD IV infusions of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg, administered twice daily for 3 days.	
Reporting group title	Group 4: SD Oral Tedizolid Phosphate 28days-<24months
Reporting group description:	
Pediatric participants 28 days to <24 months of age received an SD oral suspension of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.	
Reporting group title	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days
Reporting group description:	
FT neonates from birth to <28 days of age received an SD oral suspension of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.	
Reporting group title	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days
Reporting group description:	
PT neonates from birth to <28 days of age received an SD oral suspension of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.	

Reporting group values	Group 1 Cohort 1:SD IV Tedizolid Phosphate 28days-<6months	Group 1 Cohort 2: SD IV Tedizolid Phosphate 6-<24months	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days
Number of subjects	4	6	8
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	8

Infants and toddlers (28 days-23 months)	4	6	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Units: days			
arithmetic mean	51.3	420.7	8.3
standard deviation	± 9.9	± 167.1	± 9.4
Gender Categorical			
Units: Participants			
Female	2	2	5
Male	2	4	3
Race			
Units: Subjects			
American Indian or Alaskan Native	0	0	0
Black or African American	1	0	0
Multiple	0	1	6
White	3	5	2
Ethnicity			
Units: Subjects			
Hispanic or Latino	0	0	7
Not Hispanic or Latino	4	6	1
Not reported	0	0	0

Reporting group values	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Number of subjects	4	9	4
Age Categorical			
Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	9	4
Newborns (0-27 days)	4	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous			
Units: days			
arithmetic mean	11.8	9.9	2.0
standard deviation	± 11.3	± 7.9	± 1.2
Gender Categorical			
Units: Participants			
Female	1	3	2
Male	3	6	2

Race Units: Subjects			
American Indian or Alaskan Native	1	0	0
Black or African American	0	0	0
Multiple	2	3	2
White	1	6	2
Ethnicity Units: Subjects			
Hispanic or Latino	3	3	2
Not Hispanic or Latino	1	5	2
Not reported	0	1	0

Reporting group values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days
Number of subjects	4	4	4
Age Categorical Units: Subjects			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	4
Newborns (0-27 days)	0	4	0
Infants and toddlers (28 days-23 months)	4	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	0	0	0
From 65-84 years	0	0	0
85 years and over	0	0	0
Age Continuous Units: days			
arithmetic mean	289.0	13.0	6.5
standard deviation	± 165.5	± 11.7	± 6.4
Gender Categorical Units: Participants			
Female	2	0	1
Male	2	4	3
Race Units: Subjects			
American Indian or Alaskan Native	0	0	0
Black or African American	0	0	0
Multiple	0	2	3
White	4	2	1
Ethnicity Units: Subjects			
Hispanic or Latino	0	2	3
Not Hispanic or Latino	4	2	1
Not reported	0	0	0

Reporting group values	Total		
Number of subjects	47		

Age Categorical Units: Subjects			
In utero	0		
Preterm newborn infants (gestational age < 37 wks)	17		
Newborns (0-27 days)	16		
Infants and toddlers (28 days-23 months)	14		
Children (2-11 years)	0		
Adolescents (12-17 years)	0		
Adults (18-64 years)	0		
From 65-84 years	0		
85 years and over	0		
Age Continuous Units: days			
arithmetic mean			
standard deviation	-		
Gender Categorical Units: Participants			
Female	18		
Male	29		
Race Units: Subjects			
American Indian or Alaskan Native	1		
Black or African American	1		
Multiple	19		
White	26		
Ethnicity Units: Subjects			
Hispanic or Latino	20		
Not Hispanic or Latino	26		
Not reported	1		

End points

End points reporting groups

Reporting group title	Group 1 Cohort 1:SD IV Tedizolid Phosphate 28days-<6months
Reporting group description:	
Pediatric participants 28 days to <6 months of age received a single dose (SD) intravenous (IV) infusion of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.	
Reporting group title	Group 1 Cohort 2: SD IV Tedizolid Phosphate 6-<24months
Reporting group description:	
Pediatric participants 6 months to <24 months of age received an SD IV infusion of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.	
Reporting group title	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days
Reporting group description:	
Full term (FT) neonates from birth to 28 days of age received an SD IV infusion of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.	
Reporting group title	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days
Reporting group description:	
FT neonates from birth to 28 days of age received multiple dose (MD) IV infusions of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg, administered twice daily for 3 days.	
Reporting group title	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days
Reporting group description:	
Preterm (PT) neonates from birth to 28 days of age received an SD IV infusion of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.	
Reporting group title	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Reporting group description:	
PT neonates from birth to 28 days of age received MD IV infusions of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg, administered twice daily for 3 days.	
Reporting group title	Group 4: SD Oral Tedizolid Phosphate 28days-<24months
Reporting group description:	
Pediatric participants 28 days to <24 months of age received an SD oral suspension of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.	
Reporting group title	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days
Reporting group description:	
FT neonates from birth to <28 days of age received an SD oral suspension of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.	
Reporting group title	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days
Reporting group description:	
PT neonates from birth to <28 days of age received an SD oral suspension of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.	
Subject analysis set title	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate 28days-<24months
Subject analysis set type	Per protocol
Subject analysis set description:	
Pediatric participants 28 days to <24 months of age received a single dose (SD) intravenous (IV) infusion of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.	

Primary: Part A: Area under the concentration-time curve from time 0 to time of last quantifiable drug concentration (AUC0-last) of tedizolid phosphate (prodrug) after single-dose IV administration

End point title	Part A: Area under the concentration-time curve from time 0 to time of last quantifiable drug concentration (AUC0-last) of tedizolid phosphate (prodrug) after single-dose IV administration[1][2]

End point description:

AUC0-last of tedizolid phosphate was quantified in participants receiving tedizolid phosphate. ”9999” indicates AUC was not calculated due to plasma concentrations below level of quantification (BLOQ), based on protocol. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, according to the underlying scientific model and had data available for this endpoint. Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2). As specified in the protocol, AUC0-last for multiple dose (Part A Group 2 Cohort 2, Group 3 Cohort 2) were not included in this endpoint and have been reported separately in the record. Tedizolid phosphate PK analysis was not planned or conducted in Part B (Groups 4, 5, 6), per protocol.

End point type	Primary

End point timeframe:

1, 1.5, 3, 6, 12 and 24 hours post start of dosing

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 between-arm statistical comparisons were planned for this endpoint.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	0[3]	3	0[4]
Units: hr*µg/mL				
geometric mean (geometric coefficient of variation)	9999 (± 9999)	()	9999 (± 9999)	()

Notes:

[3] - This endpoint is for Part A SD only.

[4] - This endpoint is for Part A SD only.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate 28days-
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[5]	0[6]	0[7]	3
Units: hr*µg/mL				
geometric mean (geometric coefficient of variation)	()	()	()	9999 (± 9999)

Notes:

[5] - Part B not analyzed, per protocol.

[6] - Part B not analyzed, per protocol.

[7] - Part B not analyzed, per protocol.

Statistical analyses

No statistical analyses for this end point

Primary: Part A: Area under the concentration-time curve from time 0 to infinity (AUC0-inf) of tedizolid phosphate (prodrug) after single-dose IV administration

End point title	Part A: Area under the concentration-time curve from time 0 to infinity (AUC0-inf) of tedizolid phosphate (prodrug) after single-dose IV administration[8][9]

End point description:

AUC0-inf of tedizolid phosphate was quantified in participants receiving tedizolid phosphate. ”9999” indicates AUC was not calculated due to plasma concentrations below level of quantification (BLOQ), based on protocol. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, according to the underlying scientific model and had data available for this endpoint. Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2). As specified in the protocol, AUC0-inf for multiple dose (Part A Group 2 Cohort 2, Group 3 Cohort 2) were not included in this endpoint and have been reported separately in the record. Tedizolid phosphate PK analysis was not planned or conducted in Part B (Groups 4, 5, 6), per protocol.

End point type	Primary

End point timeframe:

1, 1.5, 3, 6, 12 and 24 hours post start of dosing

Notes:

[8] - 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 between-arm statistical comparisons were planned for this endpoint.

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	0[10]	3	0[11]
Units: hr*µg/mL				
geometric mean (geometric coefficient of variation)	9999 (± 9999)	()	9999 (± 9999)	()

Notes:

[10] - This endpoint is for Part A SD only.

[11] - This endpoint is for Part A SD only.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate 28days-
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[12]	0[13]	0[14]	3
Units: hr*µg/mL				
geometric mean (geometric coefficient of variation)	()	()	()	9999 (± 9999)

Notes:

[12] - Part B not analyzed, per protocol.

[13] - Part B not analyzed, per protocol.

[14] - Part B not analyzed, per protocol.

Statistical analyses

No statistical analyses for this end point

Primary: Part A: Maximum concentration (Cmax) of tedizolid phosphate (prodrug) after single-dose IV administration

End point title	Part A: Maximum concentration (Cmax) of tedizolid phosphate (prodrug) after single-dose IV administration[15][16]

End point description:

Cmax of tedizolid phosphate was quantified in participants receiving tedizolid phosphate. ”9999” indicates Cmax was not calculated due to plasma concentrations below level of quantification (BLOQ), based on protocol. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, according to the underlying scientific model and had data available for this endpoint. Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2). As specified in the protocol, Cmax for multiple dose (Part A Group 2 Cohort 2, Group 3 Cohort 2) were not included in this endpoint and have been reported separately in the record. Tedizolid phosphate PK analysis was not planned or conducted in Part B (Groups 4, 5, 6), per protocol.

End point type	Primary

End point timeframe:

1, 1.5, 3, 6, 12 and 24 hours post start of dosing

Notes:

[15] - 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 between-arm statistical comparisons were planned for this endpoint.

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	0[17]	3	0[18]
Units: µg/mL				
geometric mean (geometric coefficient of variation)	9999 (± 9999)	()	9999 (± 9999)	()

Notes:

[17] - This endpoint is for Part A SD only.

[18] - This endpoint is for Part A SD only.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate 28days-

Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[19]	0[20]	0[21]	3
Units: µg/mL				
geometric mean (geometric coefficient of variation)	()	()	()	9999 (± 9999)

Notes:

[19] - Part B not analyzed, per protocol.

[20] - Part B not analyzed, per protocol.

[21] - Part B not analyzed, per protocol.

Statistical analyses

No statistical analyses for this end point

Primary: Part A: Time to reach maximum concentration (Tmax) of tedizolid phosphate (prodrug) after single-dose IV administration

End point title	Part A: Time to reach maximum concentration (Tmax) of tedizolid phosphate (prodrug) after single-dose IV administration[22][23]

End point description:

Tmax of tedizolid phosphate was quantified in participants receiving tedizolid phosphate. ”9999” indicates Tmax was not calculated due to plasma concentrations below level of quantification (BLOQ), based on protocol. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, according to the underlying scientific model and had data available for this endpoint. Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2). As specified in the protocol, Tmax for multiple dose (Part A Group 2 Cohort 2, Group 3 Cohort 2) were not included in this endpoint and have been reported separately in the record. Tedizolid phosphate PK analysis was not planned or conducted in Part B (Groups 4, 5, 6), per protocol.

End point type	Primary

End point timeframe:

1, 1.5, 3, 6, 12 and 24 hours post start of dosing

Notes:

[22] - 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 between-arm statistical comparisons were planned for this endpoint.

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	0[24]	3	0[25]
Units: hr				
geometric mean (geometric coefficient of variation)	9999 (± 9999)	()	9999 (± 9999)	()

Notes:

[24] - This endpoint is for Part A SD only.

[25] - This endpoint is for Part A SD only.

End point values	Group 4: SD Oral Tedizolid	Group 5: SD Oral Tedizolid	Group 6: SD Oral Tedizolid	Group 1 Cohorts 1+2:

	Phosphate 28days-<24months	Phosphate FT birth-<28days	Phosphate PT birth-<28days	SD IV Tedizolid Phosphate 28days-<24months
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[26]	0[27]	0[28]	3
Units: hr				
geometric mean (geometric coefficient of variation)	()	()	()	9999 (± 9999)

Notes:

[26] - Part B not analyzed, per protocol.

[27] - Part B not analyzed, per protocol.

[28] - Part B not analyzed, per protocol.

Statistical analyses

No statistical analyses for this end point

Primary: Part A: AUC0-last of tedizolid phosphate (prodrug) after multiple-dose IV administration

End point title	Part A: AUC0-last of tedizolid phosphate (prodrug) after multiple-dose IV administration[29][30]

End point description:

AUC0-last of tedizolid phosphate was quantified in participants receiving tedizolid phosphate. ”9999” indicates AUC was not calculated due to plasma BLOQ, based on protocol. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, according to the underlying scientific model and had data available for this endpoint. As specified in the protocol, AUC0-last for single dose (Part A Group 1 [Cohorts 1 and 2], Group 2 Cohort 1, Group 3 Cohort 1) were not included in this endpoint and have been reported separately in the record. Tedizolid phosphate PK analysis was not planned or conducted in Part B (Groups 4, 5, 6), per protocol. Participants in Group 2 Cohort 2 study arm did not meet the criteria for PK per protocol analysis population for this endpoint and were excluded from this protocol-specified analysis.

End point type	Primary

End point timeframe:

Day 3: pre-dose, 1, 1.5, 3, 6 and 12 hours post start of dosing

Notes:

[29] - 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 between-arm statistical comparisons were planned for this endpoint.

[30] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[31]	0[32]	0[33]	2
Units: hr*µg/mL				
geometric mean (geometric coefficient of variation)	()	()	()	9999 (± 9999)

Notes:

[31] - This endpoint is for Part A MD only.

[32] - Did not meet the criteria for the per protocol population.

[33] - This endpoint is for Part A MD only.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate 28days-
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[34]	0[35]	0[36]	3[37]
Units: hr*µg/mL				
geometric mean (geometric coefficient of variation)	()	()	()	9999 (± 9999)

Notes:

[34] - Part B not analyzed, per protocol.

[35] - Part B not analyzed, per protocol.

[36] - Part B not analyzed, per protocol.

[37] - This endpoint is for Part A MD only.

Statistical analyses

No statistical analyses for this end point

Primary: Part A: Apparent terminal half-life (t½) of tedizolid phosphate (prodrug) after single-dose IV administration

End point title	Part A: Apparent terminal half-life (t½) of tedizolid phosphate (prodrug) after single-dose IV administration[38][39]

End point description:

t½ of tedizolid phosphate was quantified in participants receiving tedizolid phosphate. ”9999” indicates t½ was not calculated due to plasma concentrations below level of quantification (BLOQ), based on protocol. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, according to the underlying scientific model and had data available for this endpoint. Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2). As specified in the protocol, t½ for multiple dose (Part A Group 2 Cohort 2, Group 3 Cohort 2) were not included in this endpoint and have been reported separately in the record. Tedizolid phosphate PK analysis was not planned or conducted in Part B (Groups 4, 5, 6), per protocol.

End point type	Primary

End point timeframe:

1, 1.5, 3, 6, 12 and 24 hours post start of dosing

Notes:

[38] - 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 between-arm statistical comparisons were planned for this endpoint.

[39] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	0[40]	3	0[41]
Units: hr				
geometric mean (geometric coefficient of variation)	9999 (± 9999)	()	9999 (± 9999)	()

Notes:

[40] - This endpoint is for Part A SD only.

[41] - This endpoint is for Part A SD only.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate 28days-
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[42]	0[43]	0[44]	3
Units: hr				
geometric mean (geometric coefficient of variation)	()	()	()	9999 (± 9999)

Notes:

[42] - Part B not analyzed, per protocol.

[43] - Part B not analyzed, per protocol.

[44] - Part B not analyzed, per protocol.

Statistical analyses

No statistical analyses for this end point

Primary: Part A: AUC0-inf of tedizolid phosphate (prodrug) after multiple-dose IV administration

End point title	Part A: AUC0-inf of tedizolid phosphate (prodrug) after multiple-dose IV administration[45][46]

End point description:

AUC0-inf of tedizolid phosphate was quantified in participants receiving tedizolid phosphate. ”9999” indicates AUC was not calculated due to plasma BLOQ, based on protocol. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, according to the underlying scientific model and had data available for this endpoint. As specified in the protocol, AUC0-inf for single dose (Part A Group 1 [Cohorts 1 and 2], Group 2 Cohort 1, Group 3 Cohort 1) were not included in this endpoint and have been reported separately in the record. Tedizolid phosphate PK analysis was not planned or conducted in Part B (Groups 4, 5, 6), per protocol. Participants in Group 2 Cohort 2 study arm did not meet the criteria for PK per protocol analysis population for this endpoint and were excluded from this protocol-specified analysis.

End point type	Primary

End point timeframe:

Day 3: pre-dose, 1, 1.5, 3, 6 and 12 hours post start of dosing

Notes:

[45] - 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 between-arm statistical comparisons were planned for this endpoint.

[46] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline

period.

Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[47]	0[48]	0[49]	2
Units: hr*µg/mL				
geometric mean (geometric coefficient of variation)	()	()	()	9999 (± 9999)

Notes:

[47] - This endpoint is for Part A MD only.

[48] - Did not meet the criteria for the per protocol population.

[49] - This endpoint is for Part A MD only.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate 28days-
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[50]	0[51]	0[52]	0[53]
Units: hr*µg/mL				
geometric mean (geometric coefficient of variation)	()	()	()	()

Notes:

[50] - Part B not analyzed, per protocol.

[51] - Part B not analyzed, per protocol.

[52] - Part B not analyzed, per protocol.

[53] - This endpoint is for Part A MD only.

Statistical analyses

No statistical analyses for this end point

Primary: Part A: Cmax of tedizolid phosphate (prodrug) after multiple-dose IV administration

End point title	Part A: Cmax of tedizolid phosphate (prodrug) after multiple-dose IV administration[54][55]

End point description:

Cmax of tedizolid phosphate was quantified in participants receiving tedizolid phosphate. ”9999” indicates Cmax was not calculated due to plasma BLOQ, based on protocol. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, according to the underlying scientific model and had data available for this endpoint. As specified in the protocol, Cmax for single dose (Part A Group 1 [Cohorts 1 and 2], Group 2 Cohort 1, Group 3 Cohort 1) were not included in this endpoint and have been reported separately in the record. Tedizolid phosphate PK analysis was not planned or conducted in Part B (Groups 4, 5, 6), per protocol. Participants in Group 2 Cohort 2 study arm did not meet the criteria for PK per protocol analysis population for this endpoint and were excluded from this protocol-specified analysis.

End point type	Primary

End point timeframe:

Day 3: pre-dose, 1, 1.5, 3, 6 and 12 hours post start of dosing

Notes:

[54] - 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 between-arm statistical comparisons were planned for this endpoint.

[55] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[56]	0[57]	0[58]	2
Units: µg/mL				
geometric mean (geometric coefficient of variation)	()	()	()	9999 (± 9999)

Notes:

[56] - This endpoint is for Part A MD only.

[57] - Did not meet the criteria for the per protocol population.

[58] - This endpoint is for Part A MD only.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate 28days-
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[59]	0[60]	0[61]	0[62]
Units: µg/mL				
geometric mean (geometric coefficient of variation)	()	()	()	()

Notes:

[59] - Part B not analyzed, per protocol.

[60] - Part B not analyzed, per protocol.

[61] - Part B not analyzed, per protocol.

[62] - This endpoint is for Part A MD only.

Statistical analyses

No statistical analyses for this end point

Primary: Part A: Tmax of tedizolid phosphate (prodrug) after multiple-dose IV administration

End point title	Part A: Tmax of tedizolid phosphate (prodrug) after multiple-dose IV administration[63][64]

End point description:

Tmax of tedizolid phosphate was quantified in participants receiving tedizolid phosphate. ”9999” indicates Tmax was not calculated due to plasma BLOQ, based on protocol. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, according to the underlying scientific model and had data available for this endpoint. As specified in the protocol, Tmax for single dose (Part A Group 1 [Cohorts 1 and 2], Group 2 Cohort 1, Group 3 Cohort 1) were not included in this endpoint and have been reported separately in the record. Tedizolid phosphate PK analysis was not planned or conducted in Part B (Groups 4, 5, 6), per protocol. Participants in Group 2 Cohort 2 study arm did not

meet the criteria for PK per protocol analysis population for this endpoint and were excluded from this protocol-specified analysis.

End point type	Primary

End point timeframe:

Day 3: pre-dose, 1, 1.5, 3, 6 and 12 hours post start of dosing

Notes:

[63] - 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 between-arm statistical comparisons were planned for this endpoint.

[64] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[65]	0[66]	0[67]	2
Units: hr				
geometric mean (geometric coefficient of variation)	()	()	()	9999 (± 9999)

Notes:

[65] - This endpoint is for Part A MD only.

[66] - Did not meet the criteria for the per protocol population.

[67] - This endpoint is for Part A MD only.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate 28days-
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[68]	0[69]	0[70]	0[71]
Units: hr				
geometric mean (geometric coefficient of variation)	()	()	()	()

Notes:

[68] - Part B not analyzed, per protocol.

[69] - Part B not analyzed, per protocol.

[70] - Part B not analyzed, per protocol.

[71] - This endpoint is for Part A MD only.

Statistical analyses

No statistical analyses for this end point

Primary: Part B: Area under the concentration-time curve from time 0 to 24 hours (AUC0-24) of tedizolid after single-dose administration of tedizolid phosphate oral suspension [AUC0-last]

End point title	Part B: Area under the concentration-time curve from time 0 to 24 hours (AUC0-24) of tedizolid after single-dose administration of tedizolid phosphate oral suspension [AUC0-last][72][73]

End point description:

AUC0-last of tedizolid metabolite was quantified in participants receiving tedizolid phosphate. Measure of dispersion couldn’t be estimated due to low number of participants analyzed. The per protocol statistical approach used in this noncompartmental analysis allowed data collected to generate single concentration listing. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, based on the underlying scientific model and had data available for this endpoint. As specified in the protocol, AUC0-last for tedizolid metabolite in Part A (Group 1 [Cohorts 1 and 2], Group 2 Cohort 1, Group 2 Cohort 2, Group 3 Cohort 1, Group 3 Cohort 2) were not included in this endpoint and have been reported separately in the record.

End point type	Primary

End point timeframe:

1, 3, 5, 8, 12, and 24 hours post start of dosing

Notes:

[72] - 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 between-arm statistical comparisons were planned for this endpoint.

[73] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[74]	0[75]	0[76]	0[77]
Units: hr*µg/mL				
number (not applicable)				

Notes:

[74] - This endpoint is for Part B only.

[75] - This endpoint is for Part B only.

[76] - This endpoint is for Part B only.

[77] - This endpoint is for Part B only.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate 28days-
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	1	1	1	0[78]
Units: hr*µg/mL				
number (not applicable)	7.92	9.25	14.9	

Notes:

[78] - This endpoint is for Part B only.

Statistical analyses

No statistical analyses for this end point

Primary: Part A: t½ of tedizolid phosphate (prodrug) after multiple-dose IV administration

End point title	Part A: t½ of tedizolid phosphate (prodrug) after multiple-dose

	IV administration[79][80]

End point description:

t½ of tedizolid phosphate was quantified in participants receiving tedizolid phosphate. ”9999” indicates t½ was not calculated due to plasma BLOQ, based on protocol. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, according to the underlying scientific model and had data available for this endpoint. As specified in the protocol, t½ for single dose (Part A Group 1 [Cohorts 1 and 2], Group 2 Cohort 1, Group 3 Cohort 1) were not included in this endpoint and have been reported separately in the record. Tedizolid phosphate PK analysis was not planned or conducted in Part B (Groups 4, 5, 6), per protocol. Participants in Group 2 Cohort 2 study arm did not meet the criteria for PK per protocol analysis population for this endpoint and were excluded from this protocol-specified analysis.

End point type	Primary

End point timeframe:

Day 3: pre-dose, 1, 1.5, 3, 6 and 12 hours post start of dosing

Notes:

[79] - 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 between-arm statistical comparisons were planned for this endpoint.

[80] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[81]	0[82]	0[83]	2
Units: hr				
geometric mean (geometric coefficient of variation)	()	()	()	9999 (± 9999)

Notes:

[81] - This endpoint is for Part A MD only.

[82] - Did not meet the criteria for the per protocol population.

[83] - This endpoint is for Part A MD only.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate 28days-
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[84]	0[85]	0[86]	0[87]
Units: hr				
geometric mean (geometric coefficient of variation)	()	()	()	()

Notes:

[84] - Part B not analyzed, per protocol.

[85] - Part B not analyzed, per protocol.

[86] - Part B not analyzed, per protocol.

[87] - This endpoint is for Part A MD only.

Statistical analyses

No statistical analyses for this end point

Primary: Part B: AUC0-inf of tedizolid after single-dose administration of tedizolid phosphate oral suspension

End point title	Part B: AUC0-inf of tedizolid after single-dose administration of tedizolid phosphate oral suspension[88][89]

End point description:

AUC0-inf of tedizolid metabolite was quantified in participants receiving tedizolid phosphate. Measure of dispersion couldn't be estimated due to low number of participants analyzed. The per protocol statistical approach used in this noncompartmental analysis allowed data collected to generate single concentration listing. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, based on the underlying scientific model and had data available for this endpoint. As specified in the protocol, AUC0-inf for tedizolid metabolite in Part A (Group 1 [Cohorts 1 and 2], Group 2 Cohort 1, Group 2 Cohort 2, Group 3 Cohort 1, Group 3 Cohort 2) were not included in this endpoint and have been reported separately in the record.

End point type	Primary

End point timeframe:

1, 3, 5, 8, 12, and 24 hours post start of dosing

Notes:

[88] - 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 between-arm statistical comparisons were planned for this endpoint.

[89] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[90]	0[91]	0[92]	0[93]
Units: hr*µg/mL				
number (not applicable)				

Notes:

[90] - This endpoint is for Part B only.

[91] - This endpoint is for Part B only.

[92] - This endpoint is for Part B only.

[93] - This endpoint is for Part B only.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate 28days-
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	1	1	1	0[94]
Units: hr*µg/mL				
number (not applicable)	8.36	9.44	22.1	

Notes:

[94] - This endpoint is for Part B only.

Statistical analyses

No statistical analyses for this end point

Primary: Part B: Cmax of tedizolid after single-dose administration of tedizolid phosphate oral suspension

End point title	Part B: Cmax of tedizolid after single-dose administration of tedizolid phosphate oral suspension[95][96]

End point description:

Cmax of tedizolid metabolite was quantified in participants receiving tedizolid phosphate. Measure of dispersion couldn't be estimated due to low number of participants analyzed. The per protocol statistical approach used in this noncompartmental analysis allowed data collected to generate single concentration listing. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, based on the underlying scientific model and had data available for this endpoint. As specified in the protocol, Cmax for tedizolid metabolite in Part A (Group 1 [Cohorts 1 and 2], Group 2 Cohort 1, Group 2 Cohort 2, Group 3 Cohort 1, Group 3 Cohort 2) were not included in this endpoint and have been reported separately in the record.

End point type	Primary

End point timeframe:

1, 3, 5, 8, 12, and 24 hours post start of dosing

Notes:

[95] - 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 between-arm statistical comparisons were planned for this endpoint.

[96] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[97]	0[98]	0[99]	0[100]
Units: µg/mL				
number (not applicable)				

Notes:

[97] - This endpoint is for Part B only.

[98] - This endpoint is for Part B only.

[99] - This endpoint is for Part B only.

[100] - This endpoint is for Part B only.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate 28days-
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	1	1	1	0[101]
Units: µg/mL				
number (not applicable)	1.32	0.899	1.22	

Notes:

[101] - This endpoint is for Part B only.

Statistical analyses

No statistical analyses for this end point

Primary: Part B: t½ of tedizolid after single-dose administration of tedizolid phosphate oral suspension

End point title	Part B: t½ of tedizolid after single-dose administration of tedizolid phosphate oral suspension[102][103]

End point description:

t½ of tedizolid metabolite was quantified in participants receiving tedizolid phosphate. Measure of dispersion couldn't be estimated due to low number of participants analyzed. The per protocol statistical approach used in this noncompartmental analysis allowed data collected to generate single listing. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, based on the underlying scientific model and had data available for this endpoint. As specified in the protocol, t½ for tedizolid metabolite in Part A (Group 1 [Cohorts 1 and 2], Group 2 Cohort 1, Group 2 Cohort 2, Group 3 Cohort 1, Group 3 Cohort 2) were not included in this endpoint and have been reported separately in the record.

End point type	Primary

End point timeframe:

1, 3, 5, 8, 12, and 24 hours post start of dosing

Notes:

[102] - 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 between-arm statistical comparisons were planned for this endpoint.

[103] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[104]	0[105]	0[106]	0[107]
Units: hr				
number (not applicable)				

Notes:

[104] - This endpoint is for Part B only.

[105] - This endpoint is for Part B only.

[106] - This endpoint is for Part B only.

[107] - This endpoint is for Part B only.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate 28days-

Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	1	1	1	0[108]
Units: hr				
number (not applicable)	5.73	3.82	13.4	

Notes:

[108] - This endpoint is for Part B only.

Statistical analyses

No statistical analyses for this end point

Primary: Part B: Tmax of tedizolid after single-dose administration of tedizolid phosphate oral suspension

End point title	Part B: Tmax of tedizolid after single-dose administration of tedizolid phosphate oral suspension[109][110]

End point description:

Tmax of tedizolid metabolite was quantified in participants receiving tedizolid phosphate. Measure of dispersion couldn't be estimated due to low number of participants analyzed. The per protocol statistical approach used in this noncompartmental analysis allowed data collected to generate single listing. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, based on the underlying scientific model and had data available for this endpoint. As specified in the protocol, Tmax for tedizolid metabolite in Part A (Group 1 [Cohorts 1 and 2], Group 2 Cohort 1, Group 2 Cohort 2, Group 3 Cohort 1, Group 3 Cohort 2) were not included in this endpoint and have been reported separately in the record.

End point type	Primary

End point timeframe:

1, 3, 5, 8, 12, and 24 hours post start of dosing

Notes:

[109] - 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 between-arm statistical comparisons were planned for this endpoint.

[110] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[111]	0[112]	0[113]	0[114]
Units: hr				
number (not applicable)				

Notes:

[111] - This endpoint is for Part B only.

[112] - This endpoint is for Part B only.

[113] - This endpoint is for Part B only.

[114] - This endpoint is for Part B only.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate

				<24months
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	1	1	1	0[115]
Units: hr				
number (not applicable)	1	3.03	8	

Notes:

[115] - This endpoint is for Part B only.

Statistical analyses

No statistical analyses for this end point

Primary: Part A: AUC0-24 of tedizolid (active metabolite) after single-dose IV administration of tedizolid phosphate [AUC0-last]

End point title	Part A: AUC0-24 of tedizolid (active metabolite) after single-dose IV administration of tedizolid phosphate [AUC0-last][116][117]

End point description:

AUC0-last of tedizolid metabolite was quantified in participants receiving tedizolid phosphate. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, according to the underlying scientific model and had data available for this endpoint. Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2). As specified in the protocol, AUC0-last for tedizolid metabolite in multiple dose (Part A Group 2 Cohort 2, Group 3 Cohort 2) and Part B (Groups 4, 5, 6) were not included in this endpoint and have been reported separately in the record.

End point type	Primary

End point timeframe:

1, 1.5, 3, 6, 12 and 24 hours post start of dosing

Notes:

[116] - 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 between-arm statistical comparisons were planned for this endpoint.

[117] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	0[118]	3	0[119]
Units: hr*µg/mL				
geometric mean (geometric coefficient of variation)	8.23 (± 115.9)	()	15.6 (± 17.6)	()

Notes:

[118] - This endpoint is for Part A SD only.

[119] - This endpoint is for Part A SD only.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate

				<24months
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[120]	0[121]	0[122]	10
Units: hr*µg/mL				
geometric mean (geometric coefficient of variation)	()	()	()	13.6 (± 42.4)

Notes:

[120] - This endpoint is for Part A SD only.

[121] - This endpoint is for Part A SD only.

[122] - This endpoint is for Part A SD only.

Statistical analyses

No statistical analyses for this end point

Primary: Part A: AUC0-inf of tedizolid (active metabolite) after single-dose IV administration of tedizolid phosphate

End point title	Part A: AUC0-inf of tedizolid (active metabolite) after single-dose IV administration of tedizolid phosphate[123][124]

End point description:

AUC0-inf of tedizolid metabolite was quantified in participants receiving tedizolid phosphate. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, according to the underlying scientific model and had data available for this endpoint. Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2). As specified in the protocol, AUC0-inf for tedizolid metabolite in multiple dose (Part A Group 2 Cohort 2, Group 3 Cohort 2) and Part B (Groups 4, 5, 6) were not included in this endpoint and have been reported separately in the record.

End point type	Primary

End point timeframe:

1, 1.5, 3, 6, 12 and 24 hours post start of dosing

Notes:

[123] - 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 between-arm statistical comparisons were planned for this endpoint.

[124] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	0[125]	3	0[126]
Units: hr*µg/mL				
geometric mean (geometric coefficient of variation)	9.21 (± 128.2)	()	17.8 (± 20.9)	()

Notes:

[125] - This endpoint is for Part A SD only.

[126] - This endpoint is for Part A SD only.

End point values	Group 4: SD Oral Tedizolid Phosphate	Group 5: SD Oral Tedizolid Phosphate FT	Group 6: SD Oral Tedizolid Phosphate PT	Group 1 Cohorts 1+2:SD IV

	28days-<24months	birth-<28days	birth-<28days	Phosphate 28days-<24months
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[127]	0[128]	0[129]	10
Units: hr*µg/mL				
geometric mean (geometric coefficient of variation)	()	()	()	14.3 (± 40.4)

Notes:

[127] - This endpoint is for Part A SD only.

[128] - This endpoint is for Part A SD only.

[129] - This endpoint is for Part A SD only.

Statistical analyses

No statistical analyses for this end point

Primary: Part A: Cmax of tedizolid (active metabolite) after single-dose IV administration of tedizolid phosphate

End point title	Part A: Cmax of tedizolid (active metabolite) after single-dose IV administration of tedizolid phosphate[130][131]

End point description:

Cmax of tedizolid metabolite was quantified in participants receiving tedizolid phosphate. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, according to the underlying scientific model and had data available for this endpoint. Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2). As specified in the protocol, Cmax for tedizolid metabolite in multiple dose (Part A Group 2 Cohort 2, Group 3 Cohort 2) and Part B (Groups 4, 5, 6) were not included in this endpoint and have been reported separately in the record.

End point type	Primary

End point timeframe:

1, 1.5, 3, 6, 12 and 24 hours post start of dosing

Notes:

[130] - 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 between-arm statistical comparisons were planned for this endpoint.

[131] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	0[132]	3	0[133]
Units: µg/mL				
geometric mean (geometric coefficient of variation)	0.962 (± 71.9)	()	1.35 (± 44.5)	()

Notes:

[132] - This endpoint is for Part A SD only.

[133] - This endpoint is for Part A SD only.

End point values	Group 4: SD Oral Tedizolid	Group 5: SD Oral Tedizolid	Group 6: SD Oral Tedizolid	Group 1 Cohorts 1+2:

	Phosphate 28days-<24months	Phosphate FT birth-<28days	Phosphate PT birth-<28days	SD IV Tedizolid Phosphate 28days-<24months
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[134]	0[135]	0[136]	10
Units: µg/mL				
geometric mean (geometric coefficient of variation)	()	()	()	2.19 (± 51.0)

Notes:

[134] - This endpoint is for Part A SD only.

[135] - This endpoint is for Part A SD only.

[136] - This endpoint is for Part A SD only.

Statistical analyses

No statistical analyses for this end point

Primary: Part A: Tmax of tedizolid (active metabolite) after single-dose IV administration of tedizolid phosphate

End point title	Part A: Tmax of tedizolid (active metabolite) after single-dose IV administration of tedizolid phosphate[137][138]

End point description:

Tmax of tedizolid metabolite was quantified in participants receiving tedizolid phosphate. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, according to the underlying scientific model and had data available for this endpoint. Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2). As specified in the protocol, Tmax for tedizolid metabolite in multiple dose (Part A Group 2 Cohort 2, Group 3 Cohort 2) and Part B (Groups 4, 5, 6) were not included in this endpoint and have been reported separately in the record.

End point type	Primary

End point timeframe:

1, 1.5, 3, 6, 12 and 24 hours post start of dosing

Notes:

[137] - 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 between-arm statistical comparisons were planned for this endpoint.

[138] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	0[139]	3	0[140]
Units: hr				
median (full range (min-max))	1.41 (1.00 to 2.50)	(to)	1.50 (1.08 to 6.53)	(to)

Notes:

[139] - This endpoint is for Part A SD only.

[140] - This endpoint is for Part A SD only.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate 28days-
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[141]	0[142]	0[143]	10
Units: hr				
median (full range (min-max))	(to)	(to)	(to)	1.33 (1.00 to 1.58)

Notes:

[141] - This endpoint is for Part A SD only.

[142] - This endpoint is for Part A SD only.

[143] - This endpoint is for Part A SD only.

Statistical analyses

No statistical analyses for this end point

Primary: Part A: t½ of tedizolid (active metabolite) after single-dose IV administration of tedizolid phosphate

End point title	Part A: t½ of tedizolid (active metabolite) after single-dose IV administration of tedizolid phosphate[144][145]

End point description:

t½ of tedizolid metabolite was quantified in participants receiving tedizolid phosphate. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, according to the underlying scientific model and had data available for this endpoint. Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2). As specified in the protocol, t½ for tedizolid metabolite in multiple dose (Part A Group 2 Cohort 2, Group 3 Cohort 2) and Part B (Groups 4, 5, 6) were not included in this endpoint and have been reported separately in the record.

End point type	Primary

End point timeframe:

1, 1.5, 3, 6, 12 and 24 hours post start of dosing

Notes:

[144] - 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 between-arm statistical comparisons were planned for this endpoint.

[145] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	5	0[146]	3	0[147]
Units: hr				
geometric mean (geometric coefficient of variation)	6.63 (± 38.0)	()	7.08 (± 41.2)	()

Notes:

[146] - This endpoint is for Part A SD only.

[147] - This endpoint is for Part A SD only.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate 28days-
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[148]	0[149]	0[150]	10
Units: hr				
geometric mean (geometric coefficient of variation)	()	()	()	4.17 (± 47.7)

Notes:

[148] - This endpoint is for Part A SD only.

[149] - This endpoint is for Part A SD only.

[150] - This endpoint is for Part A SD only.

Statistical analyses

No statistical analyses for this end point

Primary: Part A: AUC0-12 of tedizolid (active metabolite) after multiple-dose IV administration of tedizolid phosphate [AUC0-last]

End point title	Part A: AUC0-12 of tedizolid (active metabolite) after multiple-dose IV administration of tedizolid phosphate [AUC0-last][151][152]

End point description:

AUC0-last of tedizolid metabolite was quantified in participants receiving tedizolid phosphate. Measure of dispersion couldn't be estimated due to low number of participants analyzed. The per protocol statistical approach used in this noncompartmental analysis allowed data collected to generate single concentration listing. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, based on the underlying scientific model and had data available for this endpoint. As specified in the protocol, AUC0-last for tedizolid metabolite in single dose (Part A Group 1 [Cohorts 1 and 2], Group 2 Cohort 1, Group 3 Cohort 1; Part B [Groups 4, 5, 6]) were not included in this endpoint and have been reported separately in the record.

End point type	Primary

End point timeframe:

Day 3: pre-dose, 1, 1.5, 3, 6 and 12 hours post start of dosing

Notes:

[151] - 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 between-arm statistical comparisons were planned for this endpoint.

[152] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[153]	1	0[154]	1
Units: hr*µg/mL				

number (not applicable)		10.5		7.48

Notes:

[153] - This endpoint is for Part A MD only.

[154] - This endpoint is for Part A MD only.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate 28days-
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[155]	0[156]	0[157]	0[158]
Units: hr*µg/mL				
number (not applicable)				

Notes:

[155] - This endpoint is for Part A MD only.

[156] - This endpoint is for Part A MD only.

[157] - This endpoint is for Part A MD only.

[158] - This endpoint is for Part A MD only.

Statistical analyses

No statistical analyses for this end point

Primary: Part A: Tmax of tedizolid (active metabolite) after multiple-dose IV administration of tedizolid phosphate

End point title	Part A: Tmax of tedizolid (active metabolite) after multiple-dose IV administration of tedizolid phosphate[159][160]

End point description:

Tmax of tedizolid metabolite was quantified in participants receiving tedizolid phosphate. Measure of dispersion couldn’t be estimated due to low number of participants analyzed. The per protocol statistical approach used in this noncompartmental analysis allowed data collected to generate single listing. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, based on the underlying scientific model and had data available for this endpoint. As specified in the protocol, Tmax for tedizolid metabolite in single dose (Part A Group 1 [Cohorts 1 and 2], Group 2 Cohort 1, Group 3 Cohort 1; Part B [Groups 4, 5, 6]) were not included in this endpoint and have been reported separately in the record.

End point type	Primary

End point timeframe:

Day 3: pre-dose, 1, 1.5, 3, 6 and 12 hours post start of dosing

Notes:

[159] - 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 between-arm statistical comparisons were planned for this endpoint.

[160] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[161]	1	0[162]	1
Units: hr				
number (not applicable)		1.60		1.08

Notes:

[161] - This endpoint is for Part A MD only.

[162] - This endpoint is for Part A MD only.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate 28days-
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[163]	0[164]	0[165]	0[166]
Units: hr				
number (not applicable)				

Notes:

[163] - This endpoint is for Part A MD only.

[164] - This endpoint is for Part A MD only.

[165] - This endpoint is for Part A MD only.

[166] - This endpoint is for Part A MD only.

Statistical analyses

No statistical analyses for this end point

Primary: Part A: Cmax of tedizolid (active metabolite) after multiple-dose IV administration of tedizolid phosphate

End point title	Part A: Cmax of tedizolid (active metabolite) after multiple-dose IV administration of tedizolid phosphate[167][168]

End point description:

Cmax of tedizolid metabolite was quantified in participants receiving tedizolid phosphate. Measure of dispersion couldn't be estimated due to low number of participants analyzed. The per protocol statistical approach used in this noncompartmental analysis allowed data collected to generate single concentration listing. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, based on the underlying scientific model and had data available for this endpoint. As specified in the protocol, Cmax for tedizolid metabolite in single dose (Part A Group 1 [Cohorts 1 and 2], Group 2 Cohort 1, Group 3 Cohort 1; Part B [Groups 4, 5, 6]) were not included in this endpoint and have been reported separately in the record.

End point type	Primary

End point timeframe:

Day 3: pre-dose, 1, 1.5, 3, 6 and 12 hours post start of dosing

Notes:

[167] - 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 between-arm statistical comparisons were planned for this endpoint.

[168] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[169]	1	0[170]	1
Units: µg/mL				
number (not applicable)		1.82		1.69

Notes:

[169] - This endpoint is for Part A MD only.

[170] - This endpoint is for Part A MD only.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate 28days-
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[171]	0[172]	0[173]	0[174]
Units: µg/mL				
number (not applicable)				

Notes:

[171] - This endpoint is for Part A MD only.

[172] - This endpoint is for Part A MD only.

[173] - This endpoint is for Part A MD only.

[174] - This endpoint is for Part A MD only.

Statistical analyses

No statistical analyses for this end point

Primary: Part A: AUC0-inf of tedizolid (active metabolite) after multiple-dose IV administration of tedizolid phosphate

End point title	Part A: AUC0-inf of tedizolid (active metabolite) after multiple-dose IV administration of tedizolid phosphate[175][176]

End point description:

AUC0-inf of tedizolid metabolite was quantified in participants receiving tedizolid phosphate. The per protocol statistical approach to be used in this noncompartmental analysis would allow data collected to generate single concentration listing. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol to ensure that these data would likely exhibit treatment effects, based on the underlying scientific model and had data available. However, protocol-specified PK sampling did not characterize the terminal elimination phase; therefore, AUC0-inf of tedizolid metabolite could not be estimated for multiple dose study arms (Part A Group 2 Cohort 2 and Part A Group 3 Cohort 2). As specified in the protocol, AUC0-inf for tedizolid metabolite in single dose (Part A Group 1[Cohorts 1 and 2],Group 2 Cohort 1, Group 3 Cohort 1; Part B[Groups 4, 5, 6]) were not included in this endpoint and have been reported separately in the record.

End point type	Primary

End point timeframe:

Day 3: pre-dose, 1, 1.5, 3, 6 and 12 hours post start of dosing

Notes:

[175] - 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 between-arm statistical comparisons were planned for this endpoint.

[176] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28

days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[177]	0[178]	0[179]	0[180]
Units: hr*µg/mL				
number (not applicable)				

Notes:

[177] - This endpoint is for Part A MD only.

[178] - Could not be estimated per protocol-specified PK sampling scheme.

[179] - This endpoint is for Part A MD only.

[180] - Could not be estimated per protocol-specified PK sampling scheme.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate 28days-
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[181]	0[182]	0[183]	0[184]
Units: hr*µg/mL				
number (not applicable)				

Notes:

[181] - This endpoint is for Part A MD only.

[182] - This endpoint is for Part A MD only.

[183] - This endpoint is for Part A MD only.

[184] - This endpoint is for Part A MD only.

Statistical analyses

No statistical analyses for this end point

Primary: Part A: t½ of tedizolid (active metabolite) after multiple-dose IV administration of tedizolid phosphate

End point title	Part A: t½ of tedizolid (active metabolite) after multiple-dose IV administration of tedizolid phosphate[185][186]

End point description:

t½ of tedizolid metabolite was quantified in participants receiving tedizolid phosphate. The per protocol statistical approach to be used in this noncompartmental analysis would allow data collected to generate single listing. This was analyzed in the per protocol population consisting of the subset of participants who complied with the protocol sufficiently to ensure that these data would be likely to exhibit treatment effects, based on the underlying scientific model and had data available for this endpoint. However, protocol-specified PK sampling did not characterize the terminal elimination phase; therefore, t½ could not be estimated for multiple dose study arms (Part A Group 2 Cohort 2 and Part A Group 3 Cohort 2). As specified in the protocol, t½ for tedizolid metabolite in single dose (Part A Group 1 [Cohorts 1 and 2], Group 2 Cohort 1, Group 3 Cohort 1; Part B [Groups 4, 5, 6]) were not included in this endpoint and have been reported separately in the record.

End point type	Primary

End point timeframe:

Day 3: pre-dose, 1, 1.5, 3, 6 and 12 hours post start of dosing

Notes:

[185] - 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 between-arm statistical comparisons were planned for this endpoint.

[186] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Protocol specified analysis of PK endpoints in Group 1 was done irrespective of age (28 days to <24 months, across ages in Cohorts 1 and 2).

End point values	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	0[187]	0[188]	0[189]	0[190]
Units: hr				
number (not applicable)				

Notes:

[187] - This endpoint is for Part A MD only.

[188] - Could not be estimated per protocol-specified PK sampling scheme.

[189] - This endpoint is for Part A MD only.

[190] - Could not be estimated per protocol-specified PK sampling scheme.

End point values	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 1 Cohorts 1+2:SD IV Tedizolid Phosphate 28days-
Subject group type	Reporting group	Reporting group	Reporting group	Subject analysis set
Number of subjects analysed	0[191]	0[192]	0[193]	0[194]
Units: hr				
number (not applicable)				

Notes:

[191] - This endpoint is for Part A MD only.

[192] - This endpoint is for Part A MD only.

[193] - This endpoint is for Part A MD only.

[194] - This endpoint is for Part A MD only.

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with an Adverse Event (AE)

End point title	Number of participants with an Adverse Event (AE)

End point description:

An AE was defined as any untoward medical occurrence in a participant, temporally associated with the use of study treatment, whether or not considered related to the study treatment. The number of participants experiencing an AE was reported for each arm. All subjects who received at least one dose of the investigational drug were assessed.

End point type	Secondary

End point timeframe:

Up to approximately 21 days

End point values	Group 1 Cohort 1:SD IV Tedizolid Phosphate 28days-<6months	Group 1 Cohort 2: SD IV Tedizolid Phosphate 6-<24months	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	6	8	4
Units: Participants	1	1	0	0

End point values	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	4	4	4
Units: Participants	2	2	1	0

End point values	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: Participants	1			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants that discontinued study treatment due to an AE

End point title	Number of participants that discontinued study treatment due to an AE

End point description:

An AE was defined as any untoward medical occurrence in a participant, temporally associated with the use of study treatment, whether or not considered related to the study treatment. The number of participants that discontinued study treatment due to an AE was reported for each arm. All subjects who received at least one dose of the investigational drug were assessed.

End point type	Secondary

End point timeframe:

Up to approximately 3 days

End point values	Group 1 Cohort 1:SD IV Tedizolid Phosphate 28days-<6months	Group 1 Cohort 2: SD IV Tedizolid Phosphate 6-<24months	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	6	8	4
Units: Participants	0	0	0	0

End point values	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	9	4	4	4
Units: Participants	0	0	0	0

End point values	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days			
Subject group type	Reporting group			
Number of subjects analysed	4			
Units: Participants	0			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to approximately 21 days

Adverse event reporting additional description:

Safety: All participants who received at least one dose of the investigational drug.
All-cause mortality: All allocated participants

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	25.1

Reporting groups

Reporting group title	Group 1 Cohort 1:SD IV Tedizolid Phosphate 28days-<6months

Reporting group description:

Pediatric participants 28 days to <6 months of age received a single dose (SD) intravenous (IV) infusion of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.

Reporting group title	Group 1 Cohort 2: SD IV Tedizolid Phosphate 6-<24months

Reporting group description:

Pediatric participants 6 months to <24 months of age received an SD IV infusion of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.

Reporting group title	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days

Reporting group description:

Full term (FT) neonates from birth to 28 days of age received an SD IV infusion of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.

Reporting group title	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days

Reporting group description:

FT neonates from birth to 28 days of age received multiple dose (MD) IV infusions of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg, administered twice daily for 3 days.

Reporting group title	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days

Reporting group description:

PT neonates from birth to <28 days of age received an SD oral suspension of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.

Reporting group title	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days

Reporting group description:

PT neonates from birth to 28 days of age received MD IV infusions of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg, administered twice daily for 3 days.

Reporting group title	Group 4: SD Oral Tedizolid Phosphate 28days-<24months

Reporting group description:

Pediatric participants 28 days to <24 months of age received an SD oral suspension of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.

Reporting group title	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days

Reporting group description:

FT neonates from birth to <28 days of age received an SD oral suspension of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.

Reporting group title	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days

Reporting group description:

Preterm (PT) neonates from birth to 28 days of age received an SD IV infusion of tedizolid phosphate according to body weight: 3 mg/kg for body weight <10 kg or 2.5 mg/kg for body weight 10 to <30 kg.

Serious adverse events	Group 1 Cohort 1:SD IV Tedizolid Phosphate 28days-<6months	Group 1 Cohort 2: SD IV Tedizolid Phosphate 6-<24months	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
General disorders and administration site conditions			
Therapeutic product effect incomplete			
subjects affected / exposed	1 / 4 (25.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
General disorders and administration site conditions			
Therapeutic product effect incomplete			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
General disorders and administration site conditions			
Therapeutic product effect incomplete			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (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

Frequency threshold for reporting non-serious adverse events: 0 %

Non-serious adverse events	Group 1 Cohort 1:SD IV Tedizolid Phosphate 28days-<6months	Group 1 Cohort 2: SD IV Tedizolid Phosphate 6-<24months	Group 2 Cohort 1: SD IV Tedizolid Phosphate FT birth-28days
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
Investigations			
Immature granulocyte count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
Jaundice neonatal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Swelling of eyelid			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchopulmonary dysplasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 4 (0.00%)	1 / 6 (16.67%)	0 / 8 (0.00%)
occurrences (all)	0	1	0
Infections and infestations			

Conjunctivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0
Serratia sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 6 (0.00%)	0 / 8 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Group 2 Cohort 2: MD IV Tedizolid Phosphate FT birth-28days	Group 6: SD Oral Tedizolid Phosphate PT birth-<28days	Group 3 Cohort 2: MD IV Tedizolid Phosphate PT birth-28days
Total subjects affected by non-serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	2 / 4 (50.00%)
Investigations			
Immature granulocyte count increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 4 (0.00%)
occurrences (all)	0	1	0
Pregnancy, puerperium and perinatal conditions			
Jaundice neonatal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Eye disorders			
Swelling of eyelid			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Bronchopulmonary dysplasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			

Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Conjunctivitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1
Pneumonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 4 (0.00%)
occurrences (all)	0	0	0
Serratia sepsis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 4 (25.00%)
occurrences (all)	0	0	1

Non-serious adverse events	Group 4: SD Oral Tedizolid Phosphate 28days-<24months	Group 5: SD Oral Tedizolid Phosphate FT birth-<28days	Group 3 Cohort 1: SD IV Tedizolid Phosphate PT birth-28days
Total subjects affected by non-serious adverse events			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	2 / 9 (22.22%)
Investigations			
Immature granulocyte count increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
Jaundice neonatal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Swelling of eyelid			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 9 (0.00%)
occurrences (all)	1	0	0
Respiratory, thoracic and mediastinal disorders			

Bronchopulmonary dysplasia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 9 (11.11%) 1
Skin and subcutaneous tissue disorders Rash subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 9 (0.00%) 0
Infections and infestations Conjunctivitis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 9 (0.00%) 0
Pneumonia subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	1 / 9 (11.11%) 1
Serratia sepsis subjects affected / exposed occurrences (all)	0 / 4 (0.00%) 0	0 / 4 (0.00%) 0	0 / 9 (0.00%) 0

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 October 2018	AM1: To ensure an adequate distribution of age and weight among subjects aged 28 days to <24 months, particularly among subjects aged 28 days to <6 months.
31 October 2019	AM2: To update the dose levels following the first interim analysis and to convert the second IV cohort of each neonatal group to receive multiple (not single) doses.
22 July 2021	AM4: To clarify that participants can receive the oral suspension dose via feeding tube.
15 February 2023	AM5: To remove the dependency of enrollment of the second cohorts of Groups 2 and 3 on the availability of safety/tolerability data from Study MK-1986-018.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported