Clinical trial results:
A Multicenter, Open-Label Study to Evaluate the Safety, Efficacy, Pharmacokinetics, and Pharmacodynamics of M281 Administered to Pregnant Women at High Risk for Early Onset Severe Hemolytic Disease of the Fetus and Newborn (HDFN)

Summary

EudraCT number	2017-004958-42
Trial protocol	GB BE NL SE ES
Global end of trial date	05 August 2024

Results information

Result version number	v1 (current)
This version publication date	07 August 2025
First version publication date	07 August 2025

Trial information

Trial identification

Sponsor protocol code	MOM-M281-003

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03842189
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Janssen-Cilag International NV
Sponsor organisation address	Turnhoutseweg 30, Beerse, Belgium, B-2340
Public contact	Clinical Registry Group, Janssen-Cilag International NV, ClinicalTrialsEU@its.jnj.com
Scientific contact	Clinical Registry Group, Janssen-Cilag International NV, ClinicalTrialsEU@its.jnj.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	05 August 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	05 August 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of this trial was to evaluate the safety in maternal subjects and neonate/infant of nipocalimab administered to pregnant women who were at high risk for early onset severe-hemolytic disease of the fetus and newborn (EOS-HDFN) and to evaluate the effectiveness of nipocalimab as measured by percentage of maternal subjects with live birth at or after gestational age Week 32 and without an intrauterine transfusion (IUT) throughout their entire pregnancy.

Protection of trial subjects:

This study was conducted in accordance with the ethical principles that have their origin in the Declaration of Helsinki and that are consistent with Good Clinical Practices and applicable regulatory requirements.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	23 April 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Australia: 3
Country: Number of subjects enrolled	Belgium: 1
Country: Number of subjects enrolled	Germany: 2
Country: Number of subjects enrolled	Netherlands: 2
Country: Number of subjects enrolled	Sweden: 2
Country: Number of subjects enrolled	United Kingdom: 1
Country: Number of subjects enrolled	United States: 2
Worldwide total number of subjects	13
EEA total number of subjects	7

Notes:

Subjects enrolled per age group

In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0

Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	13
From 65 to 84 years	0
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

14 pregnancies (obstetrical history of early onset severe fetal anemia, hydrops or stillbirth related to hemolytic disease of fetus/newborn at GA Week <=24, anti-D>=32 or anti-Kell>=4, pregnant with antigen-positive fetus) enrolled. 1 subject had 2 pregnancies and counted twice; second enrollment data was provided. Results for 13 subjects reported.

Pre-assignment

Screening details:

Initial drug dose was 30 milligrams per kilogram(mg/kg) based on baseline weight (BLW). Per protocol amendments, dose increased to 45 mg/kg BLW, later adjusted to 45 mg/kg based on time-adjusted weight (weight at most recent biweekly visit) to allow dosing interval without loss of receptor occupancy to account for weight increases during pregnancy.

Period 1

Period 1 title	Maternal: GA Week (W)14 to PP W24
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 (Maternal): 30 mg/kg BLW

Arm description:

Maternal subjects received a single dose intravenous (IV) infusion of nipocalimab 30 milligrams per kilograms (mg/kg) based on baseline weight (BLW), once weekly from gestation age (GA) Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes. Maternal subjects were followed up for safety during the safety follow up period of 24 weeks after delivery at approximately GA Week 37 (up to Week 61 [Postpartum {PP} Week 24]).

Arm type	Experimental
Investigational medicinal product name	Nipocalimab
Investigational medicinal product code	JNJ-80202135
Other name	M281
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Maternal subjects received a single dose IV infusions of nipocalimab 30 mg/kg based on BLW, once weekly from GA Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes.

Arm title	Group 2 (Maternal): 30 to 45 mg/kg BLW

Arm description:

Maternal subjects received a single dose of IV infusion of nipocalimab 30 mg/kg initially based on BLW followed by nipocalimab 45 mg/kg with increase in weight, once weekly from GA Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes. Maternal subjects were followed up for safety during the safety follow up period of 24 weeks after delivery at approximately GA Week 37 (up to Week 61 [PP Week 24]).

Arm type	Experimental
Investigational medicinal product name	Nipocalimab
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Dosage and administration details:

Maternal subjects received a single dose of IV infusions of nipocalimab 30 mg/kg initially based on BLW followed by nipocalimab 45 mg/kg with increase in weight, once weekly from GA Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes.

Arm title	Group 3 (Maternal): 45 mg/kg BLW

Arm description:

Maternal subjects received a single dose IV infusion of nipocalimab 45 mg/kg based on BLW, once weekly from GA Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes. Maternal subjects were followed up for safety during the safety follow up period of 24 weeks after delivery at approximately GA Week 37 (up to Week 61 [PP Week 24]).

Arm type	Experimental
Investigational medicinal product name	Nipocalimab
Investigational medicinal product code	JNJ-80202135
Other name	M281
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Maternal subjects received a single dose IV infusions of nipocalimab 45 mg/kg based on BLW, once weekly from GA Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes.

Arm title	Group 4 (Maternal): 45 mg/kg TAW

Arm description:

Maternal subjects received a single dose IV infusion of nipocalimab 45 mg/kg based on time-adjusted weight (TAW), once weekly from GA Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes. Maternal subjects were followed up for safety during the safety follow up period of 24 weeks after delivery at approximately GA Week 37 (up to Week 61 [PP Week 24]).

Arm type	Experimental
Investigational medicinal product name	Nipocalimab
Investigational medicinal product code	JNJ-80202135
Other name	M281
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Maternal subjects received a single dose IV infusions of nipocalimab 45 mg/kg based on TAW, once weekly from GA Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes.

Number of subjects in period 1	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW
Started	3	2	4
Completed	3	2	4

Number of subjects in period 1	Group 4 (Maternal): 45 mg/kg TAW
Started	4
Completed	4

Period 2

Period 2 title	Neonates/Infants: Birth(PP Day 0)-PP W96
Is this the baseline period?	No
Allocation method	Not applicable
Blinding used	Not blinded

Blinding implementation details:

ABC

Arms

Are arms mutually exclusive?	Yes
Arm title	Group 1 (Neonates and Infants): 30 mg/kg BLW

Arm description:

Neonates and infants born to mothers from Group 1 were followed up for safety from PP Day 0 up to 96 weeks. Neonates and infants in this group did not receive any nipocalimab study drug.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Group 2 (Neonates and Infants): 30 to 45 mg/kg BLW

Arm description:

Neonates and infants born to mothers from Group 2 were followed up for safety from PP Day 0 up to 96 weeks. Neonates and infants in this group did not receive any nipocalimab study drug.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Group 3 (Neonates and Infants): 45 mg/kg BLW

Arm description:

Neonates and infants born to mothers from Group 3 were followed up for safety from PP Day 0 up to 96 weeks. Neonates and infants in this group did not receive any nipocalimab study drug.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Arm title	Group 4 (Neonates and Infants): 45 mg/kg TAW

Arm description:

Neonates and infants born to mothers from Group 4 were followed up for safety from PP Day 0 up to 96 weeks. Neonates and infants in this group did not receive any nipocalimab study drug.

Arm type	No intervention

No investigational medicinal product assigned in this arm

Number of subjects in period 2[1]	Group 1 (Neonates and Infants): 30 mg/kg BLW	Group 2 (Neonates and Infants): 30 to 45 mg/kg BLW	Group 3 (Neonates and Infants): 45 mg/kg BLW
Started	3	2	4
Completed	3	2	3
Not completed	0	0	1
Lost to follow-up	-	-	1

Number of subjects in period 2[1]	Group 4 (Neonates and Infants): 45 mg/kg TAW

Started	3
Completed	3
Not completed	0
Lost to follow-up	-

Notes:

[1] - The number of subjects starting the period is not consistent with the number completing the preceding period. It is expected the number of subjects starting the subsequent period will be the same as the number completing the preceding period.
Justification: Only eligible subjects were entered the specified period.

Baseline characteristics

Reporting groups	
Reporting group title	Group 1 (Maternal): 30 mg/kg BLW
Reporting group description:	
Maternal subjects received a single dose intravenous (IV) infusion of nipocalimab 30 milligrams per kilograms (mg/kg) based on baseline weight (BLW), once weekly from gestation age (GA) Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes. Maternal subjects were followed up for safety during the safety follow up period of 24 weeks after delivery at approximately GA Week 37 (up to Week 61 [Postpartum {PP} Week 24]).	
Reporting group title	Group 2 (Maternal): 30 to 45 mg/kg BLW
Reporting group description:	
Maternal subjects received a single dose of IV infusion of nipocalimab 30 mg/kg initially based on BLW followed by nipocalimab 45 mg/kg with increase in weight, once weekly from GA Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes. Maternal subjects were followed up for safety during the safety follow up period of 24 weeks after delivery at approximately GA Week 37 (up to Week 61 [PP Week 24]).	
Reporting group title	Group 3 (Maternal): 45 mg/kg BLW
Reporting group description:	
Maternal subjects received a single dose IV infusion of nipocalimab 45 mg/kg based on BLW, once weekly from GA Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes. Maternal subjects were followed up for safety during the safety follow up period of 24 weeks after delivery at approximately GA Week 37 (up to Week 61 [PP Week 24]).	
Reporting group title	Group 4 (Maternal): 45 mg/kg TAW
Reporting group description:	
Maternal subjects received a single dose IV infusion of nipocalimab 45 mg/kg based on time-adjusted weight (TAW), once weekly from GA Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes. Maternal subjects were followed up for safety during the safety follow up period of 24 weeks after delivery at approximately GA Week 37 (up to Week 61 [PP Week 24]).	

Reporting group values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW
Number of subjects	3	2	4
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	38.7	37.0	38.3
standard deviation	± 1.53	± 1.41	± 4.43
Gender categorical Units: Subjects			
Male	0	0	0
Female	3	2	4
Ethnicity Units: Subjects			
Hispanic or Latino	1	0	0
Not Hispanic or Latino	2	2	4
Race Units: Subjects			
White	2	2	4

Unknown or Not Reported	1	0	0

Reporting group values	Group 4 (Maternal): 45 mg/kg TAW	Total	
Number of subjects	4	13	
Age Categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	30.8		
standard deviation	± 4.19	-	
Gender categorical Units: Subjects			
Male	0	0	
Female	4	13	
Ethnicity Units: Subjects			
Hispanic or Latino	0	1	
Not Hispanic or Latino	4	12	
Race Units: Subjects			
White	4	12	
Unknown or Not Reported	0	1	

Subject analysis sets

Subject analysis set title	All Maternal Subjects
Subject analysis set type	Full analysis

Subject analysis set description:

Maternal subjects of Group 1 (30 milligrams per kilograms [mg/kg] baseline weight [BLW]), Group 2 (30 to 45 mg/kg BLW), Group 3 (45 mg/kg BLW), and Group 4 (45 mg/kg time-adjusted weight [TAW]) who received a single dose of intravenous (IV) infusions of nipocalimab once weekly from gestation age (GA) Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes. Maternal subjects were followed up for safety during the safety follow up period of 24 weeks after delivery at approximately GA Week 37 (up to Week 61 [PP Week 24]).

Subject analysis set title	All Neonates and Infants
Subject analysis set type	Full analysis

Subject analysis set description:

All neonates and infants born to mothers from Group 1 (30 mg/kg BLW), Group 2 (30 to 45 mg/kg BLW), Group 3 (45 mg/kg BLW), and Group 4 (45 mg/kg TAW) were followed up for safety from PP Day 0 up to 96 weeks. Neonates and infants in this group did not receive any study drug.

Reporting group values	All Maternal Subjects	All Neonates and Infants	
Number of subjects	13	12	
Age Categorical Units: Subjects			

Age continuous Units: years arithmetic mean standard deviation	± 	± 	
Gender categorical Units: Subjects			
Male	0	0	
Female	0	0	
Ethnicity Units: Subjects			
Hispanic or Latino	0	0	
Not Hispanic or Latino	0	0	
Race Units: Subjects			
White	0	0	
Unknown or Not Reported	0	0	

End points

End points reporting groups

Reporting group title	Group 1 (Maternal): 30 mg/kg BLW

Reporting group description:

Maternal subjects received a single dose intravenous (IV) infusion of nipocalimab 30 milligrams per kilograms (mg/kg) based on baseline weight (BLW), once weekly from gestation age (GA) Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes. Maternal subjects were followed up for safety during the safety follow up period of 24 weeks after delivery at approximately GA Week 37 (up to Week 61 [Postpartum {PP} Week 24]).

Reporting group title	Group 2 (Maternal): 30 to 45 mg/kg BLW

Reporting group description:

Maternal subjects received a single dose of IV infusion of nipocalimab 30 mg/kg initially based on BLW followed by nipocalimab 45 mg/kg with increase in weight, once weekly from GA Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes. Maternal subjects were followed up for safety during the safety follow up period of 24 weeks after delivery at approximately GA Week 37 (up to Week 61 [PP Week 24]).

Reporting group title	Group 3 (Maternal): 45 mg/kg BLW

Reporting group description:

Maternal subjects received a single dose IV infusion of nipocalimab 45 mg/kg based on BLW, once weekly from GA Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes. Maternal subjects were followed up for safety during the safety follow up period of 24 weeks after delivery at approximately GA Week 37 (up to Week 61 [PP Week 24]).

Reporting group title	Group 4 (Maternal): 45 mg/kg TAW

Reporting group description:

Maternal subjects received a single dose IV infusion of nipocalimab 45 mg/kg based on time-adjusted weight (TAW), once weekly from GA Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes. Maternal subjects were followed up for safety during the safety follow up period of 24 weeks after delivery at approximately GA Week 37 (up to Week 61 [PP Week 24]).

Reporting group title	Group 1 (Neonates and Infants): 30 mg/kg BLW

Reporting group description:

Neonates and infants born to mothers from Group 1 were followed up for safety from PP Day 0 up to 96 weeks. Neonates and infants in this group did not receive any nipocalimab study drug.

Reporting group title	Group 2 (Neonates and Infants): 30 to 45 mg/kg BLW

Reporting group description:

Neonates and infants born to mothers from Group 2 were followed up for safety from PP Day 0 up to 96 weeks. Neonates and infants in this group did not receive any nipocalimab study drug.

Reporting group title	Group 3 (Neonates and Infants): 45 mg/kg BLW

Reporting group description:

Neonates and infants born to mothers from Group 3 were followed up for safety from PP Day 0 up to 96 weeks. Neonates and infants in this group did not receive any nipocalimab study drug.

Reporting group title	Group 4 (Neonates and Infants): 45 mg/kg TAW

Reporting group description:

Neonates and infants born to mothers from Group 4 were followed up for safety from PP Day 0 up to 96 weeks. Neonates and infants in this group did not receive any nipocalimab study drug.

Subject analysis set title	All Maternal Subjects
Subject analysis set type	Full analysis

Subject analysis set description:

Maternal subjects of Group 1 (30 milligrams per kilograms [mg/kg] baseline weight [BLW]), Group 2 (30 to 45 mg/kg BLW), Group 3 (45 mg/kg BLW), and Group 4 (45 mg/kg time-adjusted weight [TAW]) who received a single dose of intravenous (IV) infusions of nipocalimab once weekly from gestation age (GA) Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes. Maternal subjects were followed up for safety during the safety follow up period of 24 weeks after delivery at approximately GA Week 37 (up to Week 61 [PP Week 24]).

Subject analysis set title	All Neonates and Infants
Subject analysis set type	Full analysis

Subject analysis set description:

All neonates and infants born to mothers from Group 1 (30 mg/kg BLW), Group 2 (30 to 45 mg/kg BLW), Group 3 (45 mg/kg BLW), and Group 4 (45 mg/kg TAW) were followed up for safety from PP Day 0 up to 96 weeks. Neonates and infants in this group did not receive any study drug.

Primary: Number of Maternal Subjects With Treatment-emergent Adverse Events (TEAEs)

End point title	Number of Maternal Subjects With Treatment-emergent Adverse Events (TEAEs)[1]

End point description:

An AE was any unfavorable and unintended sign (example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a drug, without any judgment about causality. TEAE was defined as any event occurring after the initiation of the first infusion of nipocalimab. Safety analysis set included all maternal subjects who had received at least 1 dose of nipocalimab.

End point type	Primary

End point timeframe:

From Baseline (GA Week 14) up to PP Week 24

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: Subjects	3	2	4	4

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Subjects	13			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Maternal Subjects With Treatment-emergent Serious Adverse Events (TESAEs)

End point title	Number of Maternal Subjects With Treatment-emergent Serious Adverse Events (TESAEs)[2]

End point description:

SAE was defined as any untoward medical occurrence that resulted in death, a life-threatening AE, inpatient hospitalisation or prolongation of existing hospitalisation, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. An AE was any unfavorable and unintended sign (example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a drug, without any judgment about

causality. TESAEs were any SAEs occurring after the initiation of the first infusion of nipocalimab. Safety analysis set included all maternal subjects who had received at least 1 dose of nipocalimab.

End point type	Primary

End point timeframe:

From Baseline (GA Week 14) up to PP Week 24

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: Subjects	2	0	1	2

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Subjects	5			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Neonates/Infants With Adverse Events (AEs)

End point title	Number of Neonates/Infants With Adverse Events (AEs)[3]

End point description:

An AE was any unfavorable and unintended sign (example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a drug, without any judgment about causality. Neonates or infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy.

End point type	Primary

End point timeframe:

From Birth (PP Day 0) up to PP Week 96

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Neonates and Infants): 30 mg/kg BLW	Group 2 (Neonates and Infants): 30 to 45 mg/kg BLW	Group 3 (Neonates and Infants): 45 mg/kg BLW	Group 4 (Neonates and Infants): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	3
Units: Subjects	3	2	4	3

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Subjects	12			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Maternal Subjects With Treatment-emergent Adverse Events of Special Interest (TEAESIs)

End point title	Number of Maternal Subjects With Treatment-emergent Adverse Events of Special Interest (TEAESIs)[4]

End point description:

Number of maternal subjects with TEAESIs were reported. An AE was any unfavorable and unintended sign (example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a drug, without any judgment about causality. All infections requiring anti-infective (that is, oral or intravenous antibacterial, antiviral, or antifungal) treatment and with hypoalbuminemia greater than or equal to (>=) Grade 3 to less than (<)20 gram per liter (g/L) by the National Cancer Institute of Common Terminology Criteria for Adverse Events (NCI CTCAE) Version 5.0 criteria were considered an AESI for maternal subjects. TEAE was defined as any event occurring after the initiation of the first infusion of nipocalimab. Safety analysis set included all maternal subjects who had received at least 1 dose of nipocalimab.

End point type	Primary

End point timeframe:

From Baseline (GA Week 14) up to PP Week 24

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: Subjects				
Infections: Treatment with Oral /Intravenous	1	1	1	2
Hypoalbuminemia <20 g/L	0	0	0	0
Overall AESIs	1	1	1	2

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	13			

Units: Subjects				
Infections: Treatment with Oral /Intravenous	5			
Hypoalbuminemia <20 g/L	0			
Overall AESIs	5			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Neonates/Infants With Serious Adverse Events (SAEs)

End point title	Number of Neonates/Infants With Serious Adverse Events (SAEs)[5]

End point description:

SAE was defined as any untoward medical occurrence that resulted in death, a life-threatening AE, inpatient hospitalisation or prolongation of existing hospitalisation, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. An AE was any unfavorable and unintended sign (example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a drug, without any judgment about causality. Neonates or infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy.

End point type	Primary

End point timeframe:

From Birth (PP Day 0) up to PP Week 96

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Neonates and Infants): 30 mg/kg BLW	Group 2 (Neonates and Infants): 30 to 45 mg/kg BLW	Group 3 (Neonates and Infants): 45 mg/kg BLW	Group 4 (Neonates and Infants): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	3
Units: Subjects	2	1	1	2

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Subjects	6			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subjects: Absolute Value of Electrocardiogram (ECG) Parameter -

Mean Ventricular Rate at Baseline

End point title	Maternal Subjects: Absolute Value of Electrocardiogram (ECG) Parameter - Mean Ventricular Rate at Baseline[6]

End point description:

Absolute value of ECG parameter - mean ventricular rate at baseline in maternal subjects was reported. Electrocardiogram assessments included comments on whether the tracings were normal or abnormal, rhythm, presence of arrhythmia or conduction defects, morphology, any evidence of myocardial infarction, or ST segment, T Wave, and U Wave abnormalities. The full analysis set (FAS) included all maternal subjects who received any dose of nipocalimab.

End point type	Primary

End point timeframe:

Baseline (GA Week 14)

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: Beats per minute				
arithmetic mean (standard deviation)	77.0 (± 10.58)	77.5 (± 3.54)	63.0 (± 5.35)	76.3 (± 8.42)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Beats per minute				
arithmetic mean (standard deviation)	72.5 (± 9.41)			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Neonates/Infants With Adverse Events of Special Interest (AESIs)

End point title	Number of Neonates/Infants With Adverse Events of Special Interest (AESIs)[7]

End point description:

Number of neonates/infants with TEAESIs were reported. An AE was any unfavorable and unintended sign (example, an abnormal laboratory finding), symptom, or disease temporally associated with the use of a drug, without any judgment about causality. All infections requiring antiinfective (that is, oral or intravenous antibacterial, antiviral, or antifungal) treatment, unexpected/unusual childhood illnesses and Immunoglobulin G (IgG) concentrations <200 milligrams per deciliter (mg/dL) at Week 24 through Week 47 or <300 mg/dL at Week 48 through Week 96 were considered an AESI for neonates and infants. Neonates or infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Per plan, pooled data for all neonates and infants was collected and analyzed for this endpoint.

End point type	Primary

End point timeframe:

From birth (PP Day 0) up to PP Week 96

Notes:

[7] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Subjects				
IgG Concentrations	4			
Infections: Treatment with Oral /Intravenous	2			
Unexpected/Unusual Childhood Illnesses	0			
Overall AESI	4			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subjects: Absolute Value of Electrocardiogram (ECG) Parameter - Mean Ventricular Rate at GA Week 36

End point title	Maternal Subjects: Absolute Value of Electrocardiogram (ECG) Parameter - Mean Ventricular Rate at GA Week 36[8]

End point description:

Absolute value of ECG parameter - mean ventricular rate at GA Week 36 in maternal subjects was reported. Electrocardiogram assessments included comments on whether the tracings were normal or abnormal, rhythm, presence of arrhythmia or conduction defects, morphology, any evidence of myocardial infarction, or ST segment, T Wave, and U Wave abnormalities. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' overall (number of subjects analysed) signifies the number of subjects evaluable for this endpoint. Here, 99999 denotes standard deviation (SD) could not be calculated for a single subject.

End point type	Primary

End point timeframe:

GA Week 36

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: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	3	2
Units: Beats per minute				
arithmetic mean (standard deviation)	89.0 (± 99999)	77.0 (± 21.21)	80.7 (± 7.51)	77.0 (± 21.21)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	8			
Units: Beats per minute				
arithmetic mean (standard deviation)	79.9 (± 12.71)			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subjects: Change From Baseline in ECG Parameter- Mean Ventricular Rate

End point title	Maternal Subjects: Change From Baseline in ECG Parameter- Mean Ventricular Rate[9]

End point description:

Change from baseline in ECG parameter- mean ventricular rate in maternal subjects was reported. Electrocardiogram assessments included comments on whether the tracings were normal or abnormal, rhythm, presence of arrhythmia or conduction defects, morphology, any evidence of myocardial infarction, or ST segment, T Wave, and U Wave abnormalities. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' overall (number of subjects analysed) signifies the number of subjects evaluable for this endpoint. Here, 99999 denotes SD could not be calculated for a single subject.

End point type	Primary

End point timeframe:

Baseline (GA Week 14) and GA Week 36

Notes:

[9] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	3	2
Units: Beats per minute				
arithmetic mean (standard deviation)	8.0 (± 99999)	-0.5 (± 24.75)	16.7 (± 7.37)	8.0 (± 22.63)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	8			
Units: Beats per minute				
arithmetic mean (standard deviation)	9.1 (± 15.08)			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Maternal Subjects With Treatment-emergent (TE) Clinically Important Laboratory and Biomarker Immunoglobulin G (IgG) Values Over Time

End point title	Number of Maternal Subjects With Treatment-emergent (TE) Clinically Important Laboratory and Biomarker Immunoglobulin G (IgG) Values Over Time[10]

End point description:

Laboratory parameters included hematology, chemistry, blood Lipids panel, and Immunoglobulin G (IgG) parameters. TEAE was defined as any event occurring after the initiation of the first infusion of nipocalimab. The safety analysis set included all maternal subjects who had received at least 1 dose of nipocalimab. Here, 'n' (number analysed) signifies the number of subjects evaluable for each category. Only those categories in which at least one subject had data were reported in this endpoint. Here, DP: During pregnancy, Ch: cholesterol, HDL: high-density lipoprotein, LDL: low-density lipoprotein, PB: post birth, Tri: triglycerides, mmol/L: millimoles per litre, and g/L: grams per litre. 99999 signifies no subject available for the analysis.

End point type	Primary

End point timeframe:

From Baseline (GA Week 14) up to PP Week 24

Notes:

[10] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: Subjects				
DP :Ch >9.025 mmol/ L (n=3, 2, 4, 4, 13)	1	2	3	2
DP :LDL >5.793 mmol/ L (n=0, 1, 2, 4, 7)	99999	0	1	2
DP :HDL <1.2413 mmol/L (n=0, 1, 2, 4, 7)	99999	0	0	0
DP : Tri >5.114 mmol/ L (n=3, 2, 4, 4, 13)	0	0	1	1
DP : Albumin <20 g/L (n=3, 2, 4, 4, 13)	0	0	0	1
DP : Ig G <1 g/L (n=3, 2, 4, 4, 13)	1	0	1	0
PB: Ch >5.172 mmol/ L (n=3, 2, 4, 4, 13)	3	2	4	2
PB:LDL >2.586 mmol/ L (n=0, 1, 2, 4, 7)	99999	1	2	3
PB:HDL <1.0344mmol/ L (n=0, 1, 2, 4, 7)	99999	0	1	0
PB: Tri >1.6935 mmol/ L (n=3, 2, 4, 4, 13)	1	1	3	2
PB : Albumin <20 g/L (n=3, 2, 4, 4, 13)	0	0	0	0
PB: IgG < 1 g/L (n=3, 2, 4, 4, 13)	0	0	0	0

End point values	All Maternal Subjects			

Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Subjects				
DP :Ch >9.025 mmol/ L (n=3, 2, 4, 4, 13)	8			
DP :LDL >5.793 mmol/ L (n=0, 1, 2, 4, 7)	3			
DP :HDL <1.2413 mmol/L (n=0, 1, 2, 4, 7)	0			
DP : Tri >5.114 mmol/ L (n=3, 2, 4, 4, 13)	2			
DP : Albumin <20 g/L (n=3, 2, 4, 4, 13)	1			
DP : Ig G <1 g/L (n=3, 2, 4, 4, 13)	2			
PB: Ch >5.172 mmol/ L (n=3, 2, 4, 4, 13)	11			
PB:LDL >2.586 mmol/ L (n=0, 1, 2, 4, 7)	6			
PB:HDL <1.0344mmol/ L (n=0, 1, 2, 4, 7)	1			
PB: Tri >1.6935 mmol/ L (n=3, 2, 4, 4, 13)	7			
PB : Albumin <20 g/L (n=3, 2, 4, 4, 13)	0			
PB: IgG < 1 g/L (n=3, 2, 4, 4, 13)	0			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Neonates or Infants With Clinically Important Laboratory and Biomarker Immunoglobulin G (IgG) Values Over Time

End point title	Number of Neonates or Infants With Clinically Important Laboratory and Biomarker Immunoglobulin G (IgG) Values Over Time[11]

End point description:

Laboratory parameters included total bilirubin and biomarker included immunoglobulin G (IgG). The safety analysis set included all maternal subjects who had received at least 1 dose of nipocalimab. Only those categories in which at least one neonates or Infants had data were reported in this endpoint.

End point type	Primary

End point timeframe:

From Birth (PP Day 0) up to PP Week 96

Notes:

[11] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Neonates and Infants): 30 mg/kg BLW	Group 2 (Neonates and Infants): 30 to 45 mg/kg BLW	Group 3 (Neonates and Infants): 45 mg/kg BLW	Group 4 (Neonates and Infants): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	3
Units: Subjects				
Total Bilirubin >136.8 mmol/ L	1	1	3	3
Immunoglobulin G < 1 g/L	1	0	0	0

Immunoglobulin G < 2 g/L	2	2	4	2

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Subjects				
Total Bilirubin >136.8 mmol/ L	8			
Immunoglobulin G < 1 g/L	1			
Immunoglobulin G < 2 g/L	10			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subjects: Absolute Value of Vital Signs - Body Temperature at Baseline

End point title	Maternal Subjects: Absolute Value of Vital Signs - Body Temperature at Baseline[12]

End point description:

Absolute value of vital signs - body temperature at baseline in maternal subjects was reported. The FAS included all maternal subjects who received any dose of nipocalimab.

End point type	Primary

End point timeframe:

Baseline (GA Week 14)

Notes:

[12] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: Degree Celsius				
arithmetic mean (standard deviation)	36.6 (± 0.1)	37.0 (± 0.5)	37.2 (± 0.5)	36.8 (± 0.8)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Degree Celsius				
arithmetic mean (standard deviation)	36.9 (± 0.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subjects: Absolute Value of Vital Signs - Body Temperature at GA Week 36

End point title	Maternal Subjects: Absolute Value of Vital Signs - Body Temperature at GA Week 36[13]

End point description:

Absolute value of vital signs - body temperature at GA Week 36 in maternal subjects was reported. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' overall (number of subjects analysed) signifies the number of subjects evaluable for this endpoint. Here, 99999 denotes SD could not be calculated for a single subject.

End point type	Primary

End point timeframe:

GA Week 36

Notes:

[13] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	3	1
Units: Degree Celsius				
arithmetic mean (standard deviation)	36.7 (± 99999)	36.8 (± 0.0)	37.1 (± 0.5)	36.0 (± 99999)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	7			
Units: Degree Celsius				
arithmetic mean (standard deviation)	36.8 (± 0.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subjects: Change From Baseline in Vital Sign - Body Temperature

End point title	Maternal Subjects: Change From Baseline in Vital Sign - Body

	Temperature[14]

End point description:

Change from baseline in vital signs- body temperature in maternal subjects was reported. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' (overall number of subjects analysed) signifies number of subjects evaluable for this endpoint. Here, 'n' (number analysed) signifies the number of subjects evaluable for specified timepoints. Here, 99999 denotes SD could not be calculated for a single subject.

End point type	Primary

End point timeframe:

Baseline (GA Week 14), GA Week 36, and PP Week 24

Notes:

[14] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	4
Units: Degree Celsius				
arithmetic mean (standard deviation)				
GA Week 36 (n=1, 2, 3, 1, 7)	0.0 (± 99999)	-0.2 (± 0.5)	-0.2 (± 0.0)	0.2 (± 99999)
PP Week 24 (n= 2, 2, 4, 4, 12)	-0.1 (± 0.1)	-0.2 (± 0.2)	-0.5 (± 0.7)	-0.1 (± 1.0)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Degree Celsius				
arithmetic mean (standard deviation)				
GA Week 36 (n=1, 2, 3, 1, 7)	-0.1 (± 0.3)			
PP Week 24 (n= 2, 2, 4, 4, 12)	-0.2 (± 0.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subjects: Absolute Value of Vital Signs - Body Temperature at PP Week 24

End point title	Maternal Subjects: Absolute Value of Vital Signs - Body Temperature at PP Week 24[15]

End point description:

Absolute value of vital signs - body temperature at PP Week 24 in maternal subjects was reported. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' (overall number of subjects analysed) signifies the number of subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

PP Week 24

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: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	4
Units: Degree Celsius				
arithmetic mean (standard deviation)	36.5 (± 0.1)	36.8 (± 0.3)	36.8 (± 0.3)	36.7 (± 0.5)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Degree Celsius				
arithmetic mean (standard deviation)	36.7 (± 0.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subjects: Absolute Value of Vital Signs - Respiratory Rate at Baseline

End point title	Maternal Subjects: Absolute Value of Vital Signs - Respiratory Rate at Baseline[16]

End point description:

Absolute value of vital signs -respiratory rate at baseline in maternal subjects was reported. The FAS included all maternal subjects who received any dose of nipocalimab.

End point type	Primary

End point timeframe:

Baseline (GA Week 14)

Notes:

[16] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: Breaths per minute				
arithmetic mean (standard deviation)	17.0 (± 1.7)	19.0 (± 1.4)	15.5 (± 3.4)	18.0 (± 2.8)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Breaths per minute				
arithmetic mean (standard deviation)	17.2 (± 2.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subjects: Absolute Value of Vital Signs - Respiratory Rate at PP Week 24

End point title	Maternal Subjects: Absolute Value of Vital Signs - Respiratory Rate at PP Week 24[17]

End point description:

Absolute value of vital signs - respiratory rate at PP Week 24 in maternal subjects was reported. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' (overall number of subjects analysed) signifies the number of subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

PP Week 24

Notes:

[17] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	4
Units: Breaths per minute				
arithmetic mean (standard deviation)	16.5 (± 2.1)	15.5 (± 2.1)	15.8 (± 3.9)	17.3 (± 3.6)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Breaths per minute				
arithmetic mean (standard deviation)	16.3 (± 3.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subjects: Absolute Value of Vital Signs - Respiratory Rate at GA Week 36

End point title	Maternal Subjects: Absolute Value of Vital Signs - Respiratory Rate at GA Week 36[18]

End point description:

Absolute value of vital signs -respiratory rate at GA Week 36 in maternal subjects was reported. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' overall (number of subjects analysed) signifies the number of subjects evaluable for this endpoint. Here, 99999 denotes SD could not be calculated for a single subject.

End point type	Primary

End point timeframe:

GA Week 36

Notes:

[18] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	3	1
Units: Breaths per minute				
arithmetic mean (standard deviation)	20.0 (± 99999)	18.0 (± 0.0)	16.3 (± 3.2)	17.0 (± 99999)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	7			
Units: Breaths per minute				
arithmetic mean (standard deviation)	17.4 (± 2.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subject: Change From Baseline in Vital Sign - Respiratory Rate

End point title	Maternal Subject: Change From Baseline in Vital Sign - Respiratory Rate[19]

End point description:

Change from baseline in vital signs- respiratory rate in maternal subjects was reported. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' (overall number of subjects analysed) signifies the number of subjects evaluable for this endpoint. Here, 'n' (number analysed) signifies the number of subjects evaluable for specified timepoints. Here, 99999 denotes SD could not be calculated for a single subject.

End point type	Primary

End point timeframe:

Baseline (GA Week 14), GA Week 36, and PP Week 24

Notes:

[19] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	4
Units: Breaths per minute				
arithmetic mean (standard deviation)				
GA Week 36 (n=1, 2, 3, 1, 7)	2.0 (± 99999)	-1.0 (± 1.4)	1.0 (± 1.0)	1.0 (± 99999)
PP Week 24 (n=2, 2, 4, 4, 12)	0.0 (± 0.0)	-3.5 (± 0.7)	0.3 (± 1.3)	-0.8 (± 3.0)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Breaths per minute				
arithmetic mean (standard deviation)				
GA Week 36 (n=1, 2, 3, 1, 7)	0.6 (± 1.4)			
PP Week 24 (n=2, 2, 4, 4, 12)	-0.8 (± 2.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subjects: Absolute Value of Vital Signs -Pulse Rate at PP Week 24

End point title	Maternal Subjects: Absolute Value of Vital Signs -Pulse Rate at PP Week 24[20]

End point description:

Absolute value of vital signs -pulse rate at PP Week 24 in maternal subjects was reported. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' (overall number of subjects analysed) signifies the number of subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

PP Week 24

Notes:

[20] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	4
Units: Beats per minute				
arithmetic mean (standard deviation)	73.0 (± 2.8)	75.0 (± 4.2)	69.8 (± 10.2)	77.8 (± 4.1)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Beats per minute				
arithmetic mean (standard deviation)	73.8 (± 6.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subjects: Absolute Value of Vital Signs - Pulse Rate at GA Week 36

End point title	Maternal Subjects: Absolute Value of Vital Signs - Pulse Rate at GA Week 36[21]

End point description:

Absolute value of vital signs -pulse rate at GA Week 36 in maternal subjects was reported. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' overall (number of subjects analysed) signifies the number of subjects evaluable for this endpoint. Here, 99999 denotes SD could not be calculated for a single subject.

End point type	Primary

End point timeframe:

GA Week 36

Notes:

[21] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	3	1
Units: Beats per minute				
arithmetic mean (standard deviation)	88.0 (± 99999)	95.0 (± 17.0)	84.0 (± 9.5)	100.0 (± 99999)

End point values	All Maternal			

	Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	7			
Units: Beats per minute				
arithmetic mean (standard deviation)	90.0 (± 11.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subjects: Absolute Value of Vital Signs - Pulse Rate at Baseline

End point title	Maternal Subjects: Absolute Value of Vital Signs - Pulse Rate at Baseline[22]

End point description:

Absolute value of vital signs - pulse rate at baseline in maternal subjects was reported. The FAS included all maternal subjects who received any dose of nipocalimab.

End point type	Primary

End point timeframe:

Baseline (GA Week 14)

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: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: Beats per minute				
arithmetic mean (standard deviation)	81.3 (± 8.7)	81.0 (± 8.5)	67.5 (± 4.2)	73.5 (± 8.9)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Beats per minute				
arithmetic mean (standard deviation)	74.6 (± 8.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subjects: Change From Baseline in Vital Sign -Pulse Rate

End point title	Maternal Subjects: Change From Baseline in Vital Sign -Pulse

	Rate[23]

End point description:

Change from baseline in vital signs -pulse rate in maternal subjects was reported. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' (overall number of subjects analysed) signifies the number of subjects evaluable for this endpoint. Here, 'n' (number analysed) signifies the number of subjects evaluable for specified timepoints. Here, 99999 denotes SD could not be calculated for a single subject.

End point type	Primary

End point timeframe:

Baseline (GA Week 14), GA Week 36, and PP Week 24

Notes:

[23] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	4
Units: Breaths per minute				
arithmetic mean (standard deviation)				
GA Week 36 (n=1, 2, 3, 1, 7)	-3.0 (± 99999)	14.0 (± 8.5)	15.0 (± 6.1)	29.0 (± 99999)
PP Week 24 (n=2, 2, 4, 4, 12)	-3.5 (± 6.4)	-6.0 (± 4.2)	2.3 (± 8.5)	4.3 (± 11.4)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Breaths per minute				
arithmetic mean (standard deviation)				
GA Week 36 (n=1, 2, 3, 1, 7)	14.1 (± 10.5)			
PP Week 24 (n=2, 2, 4, 4, 12)	0.6 (± 8.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subjects: Absolute Value of Vital Signs - Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at Baseline

End point title	Maternal Subjects: Absolute Value of Vital Signs - Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at Baseline[24]

End point description:

Absolute value of vital signs - SBP and DBP at baseline in maternal subjects was reported. The FAS included all maternal subjects who received any dose of nipocalimab.

End point type	Primary

End point timeframe:

Baseline (GA Week 14)

Notes:

[24] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: Millimeter of mercury (mmHg)				
arithmetic mean (standard deviation)				
SBP	112.0 (± 11.3)	100.5 (± 3.5)	102.3 (± 4.6)	104.8 (± 12.4)
DBP	68.7 (± 3.5)	59.5 (± 3.5)	63.3 (± 6.9)	64.5 (± 10.8)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Millimeter of mercury (mmHg)				
arithmetic mean (standard deviation)				
SBP	105.0 (± 9.2)			
DBP	64.3 (± 7.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subjects: Absolute Value of Vital Signs - Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at GA Week 36

End point title	Maternal Subjects: Absolute Value of Vital Signs - Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at GA Week 36[25]

End point description:

Absolute value of vital signs -SBP and DBP at GA Week 36 in maternal subject was reported. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' (overall number of subjects analysed) signifies the number of subjects evaluable for this endpoint. Here, 99999 denotes SD could not be calculated for a single subject.

End point type	Primary

End point timeframe:

GA Week 36

Notes:

[25] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	3	2
Units: mmHg				
arithmetic mean (standard deviation)				
SBP	134.0 (± 99999)	105.0 (± 8.5)	107.3 (± 9.6)	110.5 (± 7.8)
DBP	70.0 (± 99999)	73.0 (± 5.7)	66.3 (± 4.2)	69.0 (± 5.7)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	8			
Units: mmHg				
arithmetic mean (standard deviation)				
SBP	110.9 (± 11.7)			
DBP	69.1 (± 4.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subjects: Absolute Value of Vital Signs - Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at PPWeek 24

End point title	Maternal Subjects: Absolute Value of Vital Signs - Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at PPWeek 24[26]

End point description:

Absolute value of vital signs - SBP and DBP at PP Week 24 in maternal subjects was reported. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' (overall number of subjects analysed) signifies the number of subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

PP Week 24

Notes:

[26] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	4
Units: mmHg				
arithmetic mean (standard deviation)				
SBP	117.5 (± 14.8)	110.5 (± 14.8)	112.3 (± 4.0)	118.8 (± 9.9)

DBP	73.5 (± 10.6)	69.5 (± 6.4)	71.3 (± 6.2)	71.8 (± 1.7)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: mmHg				
arithmetic mean (standard deviation)				
SBP	115.0 (± 9.2)			
DBP	71.5 (± 5.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subjects: Change From Baseline in Vital Sign - Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP)

End point title	Maternal Subjects: Change From Baseline in Vital Sign - Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP)[27]

End point description:

Change from baseline in vital signs - SBP and DBP in maternal subjects was reported. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' (overall number of subjects analysed) signifies the number of subjects evaluable for this endpoint. Here, 'n' (number analysed) signifies the number of subjects evaluable for specified categories and timepoints. Here, 99999 denotes SD could not be calculated for a single subject.

End point type	Primary

End point timeframe:

Baseline (GA Week 14), GA Week 36, and PP Week 24

Notes:

[27] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	4
Units: mmHg				
arithmetic mean (standard deviation)				
SBP: GA Week 36 (n=1, 2, 3, 2, 8)	15.0 (± 99999)	4.5 (± 4.9)	5.0 (± 13.0)	5.0 (± 22.6)
SBP: PP Week 24 (n=2, 2, 4, 4, 12)	9.0 (± 1.4)	10.0 (± 11.3)	10.0 (± 4.2)	14.0 (± 7.0)
DBP: GA Week 36 (n=1, 2, 3, 2, 8)	-2.0 (± 99999)	13.5 (± 2.1)	3.0 (± 9.8)	6.5 (± 23.3)
DBP: PP Week 24 (n=2, 2, 4, 4, 12)	6.5 (± 7.8)	10.0 (± 2.8)	8.0 (± 10.2)	7.3 (± 11.8)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: mmHg				
arithmetic mean (standard deviation)				
SBP: GA Week 36 (n=1, 2, 3, 2, 8)	6.1 (± 11.7)			
SBP: PP Week 24 (n=2, 2, 4, 4, 12)	11.2 (± 5.9)			
DBP: GA Week 36 (n=1, 2, 3, 2, 8)	5.9 (± 11.6)			
DBP: PP Week 24 (n=2, 2, 4, 4, 12)	7.8 (± 8.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subjects: Absolute Value of Vital Signs - Body Weight at GA Week 36

End point title	Maternal Subjects: Absolute Value of Vital Signs - Body Weight at GA Week 36[28]

End point description:

Absolute value of vital signs -body weight at GA Week 36 in maternal subjects was reported. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' overall (number of subjects analysed) signifies the number of subjects evaluable for this endpoint. Here, 99999 denotes SD could not be calculated for a single subject.

End point type	Primary

End point timeframe:

GA Week 36

Notes:

[28] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	3	2
Units: Kilograms				
arithmetic mean (standard deviation)	130.6 (± 99999)	77.6 (± 15.6)	80.8 (± 7.9)	87.3 (± 14.9)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	8			
Units: Kilograms				
arithmetic mean (standard deviation)	87.8 (± 19.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subjects: Absolute Value of Vital Signs - Body Weight at Baseline

End point title	Maternal Subjects: Absolute Value of Vital Signs - Body Weight at Baseline[29]

End point description:

Absolute value of vital signs - body weight at baseline in maternal subjects was reported. The FAS included all maternal subjects who received any dose of nipocalimab.

End point type	Primary

End point timeframe:

Baseline (GA Week 14)

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: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: Kilograms (kg)				
arithmetic mean (standard deviation)	76.0 (± 29.7)	64.0 (± 12.7)	71.8 (± 8.8)	75.8 (± 18.0)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Kilograms (kg)				
arithmetic mean (standard deviation)	72.8 (± 16.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subject: Change From Baseline in Vital Sign -Body Weight

End point title	Maternal Subject: Change From Baseline in Vital Sign -Body Weight[30]

End point description:

Change from baseline in vital signs- body weight in maternal subjects was reported. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' (overall number of subjects analysed) signifies the number of subjects evaluable for this endpoint. Here, 'n' (number analysed) signifies the number of subjects evaluable for specified timepoints. Here, 99999 denotes SD could not be calculated for a single subject.

End point type	Primary

End point timeframe:

Baseline (GA Week 14), GA Week 36, and PP Week 24

Notes:

[30] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	4
Units: Kilograms				
arithmetic mean (standard deviation)				
GA Week 36 (n=1, 2, 3, 2, 8)	20.6 (± 99999)	13.6 (± 3.0)	8.6 (± 2.9)	7.7 (± 1.4)
PP Week 24 (n=2, 2, 4, 4, 12)	1.0 (± 2.4)	5.6 (± 0.8)	-0.5 (± 4.6)	2.2 (± 2.9)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Kilograms				
arithmetic mean (standard deviation)				
GA Week 36 (n=1, 2, 3, 2, 8)	11.1 (± 5.0)			
PP Week 24 (n=2, 2, 4, 4, 12)	1.7 (± 3.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Maternal Subjects: Absolute Value of Vital Signs -Body Weight at PP Week 24

End point title	Maternal Subjects: Absolute Value of Vital Signs -Body Weight at PP Week 24[31]

End point description:

Absolute value of vital signs - body weight at PP Week 24 in maternal subjects was reported. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' (overall number of subjects analysed) signifies the number of subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

PP Week 24

Notes:

[31] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	4
Units: Kilograms				
arithmetic mean (standard deviation)	60.1 (± 8.0)	69.5 (± 13.4)	71.3 (± 11.1)	78.0 (± 20.1)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Kilograms				
arithmetic mean (standard deviation)	71.4 (± 14.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Neonates/Infants: Absolute Value in Vital Signs - Body Temperature at PP Week 1

End point title	Neonates/Infants: Absolute Value in Vital Signs - Body Temperature at PP Week 1[32]

End point description:

Absolute value in vital signs parameter -body temperature at PP Week 1 was reported for all neonates/infants. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Here, 'N' (overall number of subjects analysed) signifies the number of neonates or infants evaluable for this endpoint. Per plan, pooled data for all neonates and infants was collected and analysed for this endpoint.

End point type	Primary

End point timeframe:

PP Week 1

Notes:

[32] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	8			
Units: Degree Celsius				
arithmetic mean (standard deviation)	37.0 (± 0.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Neonates/Infants: Absolute Value in Vital Signs - Body Temperature at Baseline

End point title	Neonates/Infants: Absolute Value in Vital Signs - Body Temperature at Baseline [33]

End point description:

Absolute value in vital signs parameter -body temperature at baseline was reported for all neonates/infants. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Here, 'N' (overall number of subjects analysed) signifies the number of neonates or infants evaluable for this endpoint. Per plan, pooled data for all neonates and infants was collected and analysed for this endpoint.

End point type	Primary

End point timeframe:

Baseline (PP Day 0)

Notes:

[33] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	10			
Units: Degree Celsius				
arithmetic mean (standard deviation)	36.7 (± 0.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Neonates/Infants: Absolute Value in Vital Signs - Body Temperature at PP Week 4

End point title	Neonates/Infants: Absolute Value in Vital Signs - Body Temperature at PP Week 4[34]

End point description:

Absolute value in vital signs parameter -body temperature at PP Week 4 was reported for all neonates/infants. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Here, 'N' (overall number of subjects analysed) signifies the number of neonates or infants evaluable for this endpoint. Per plan, pooled data for all neonates and infants was collected and analysed for this endpoint.

End point type	Primary

End point timeframe:

PP Week 4

Notes:

[34] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	10			
Units: Degree Celsius				
arithmetic mean (standard deviation)	37.0 (± 0.4)			

Statistical analyses

No statistical analyses for this end point

Primary: Neonates/Infants: Absolute Value in Vital Signs - Body Temperature at PP Week 24

End point title	Neonates/Infants: Absolute Value in Vital Signs - Body Temperature at PP Week 24[35]

End point description:

Absolute value in vital signs parameter -body temperature at PP Week 24 was reported for all neonates/infants. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Here, 'N' (overall number of subjects analysed) signifies the number of neonates or infants evaluable for this endpoint. Per plan, pooled data for all neonates and infants was collected and analysed for this endpoint.

End point type	Primary

End point timeframe:

PP Week 24

Notes:

[35] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	10			
Units: Degree Celsius				
arithmetic mean (standard deviation)	37.0 (± 0.5)			

Statistical analyses

No statistical analyses for this end point

Primary: Neonates/Infants: Change From Baseline in Vital Signs - Body Temperature

End point title	Neonates/Infants: Change From Baseline in Vital Signs - Body Temperature[36]

End point description:

Change from baseline in vital signs parameter- body temperature was reported for all neonates/ infants. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Here, 'N' (overall number of subjects analysed) signifies the number of neonates or infants evaluable for this endpoint and 'n' (number analysed) signifies the number of neonates or infants evaluable for specified timepoints. Per plan, pooled data for all neonates and infants was collected and analysed for this endpoint.

End point type	Primary

End point timeframe:

Baseline (PP Day 0), PP Weeks 1, 4, and 24

Notes:

[36] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	8			
Units: Degree Celsius				
arithmetic mean (standard deviation)				
PP Week 1 (n=6)	0.2 (± 0.2)			
PP Week 4 (n=8)	0.5 (± 0.4)			
PP Week 24 (n=8)	0.3 (± 0.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Neonates/Infants: Absolute Value of Vital Signs - Body Weight at PP Week 4

End point title	Neonates/Infants: Absolute Value of Vital Signs - Body Weight at PP Week 4[37]

End point description:

Absolute value of vital signs parameter - body weight at PP Week 4 was reported for all neonates/infants. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Per plan, pooled data for all neonates and infants was collected and analysed for this endpoint.

End point type	Primary

End point timeframe:

PP Week 4

Notes:

[37] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Kilograms				
arithmetic mean (standard deviation)	3.3 (± 0.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Neonates/Infants: Absolute Value of Vital Signs - Body Weight at PP Week 1

End point title	Neonates/Infants: Absolute Value of Vital Signs - Body Weight at PP Week 1[38]

End point description:

Absolute value of vital signs parameter - body weight at PP Week 1 was reported for all neonates/infants. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Here, 'N' (overall number of subjects analysed) signifies the number of neonates or infants evaluable for this endpoint. Per plan, pooled data for all neonates and infants was collected and analysed for this endpoint.

End point type	Primary

End point timeframe:

PP Week 1

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: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	10			
Units: Kilograms				
arithmetic mean (standard deviation)	2.5 (± 0.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Neonates/Infants: Absolute Value of Vital Signs - Body Weight at Baseline

End point title	Neonates/Infants: Absolute Value of Vital Signs - Body Weight at Baseline[39]

End point description:

Absolute value of vital signs parameter - body weight at baseline was reported for all neonates/infants. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Per plan, pooled data for all neonates and infants was collected and analysed for this endpoint.

End point type	Primary

End point timeframe:

Baseline (PP Day 0)

Notes:

[39] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Kilograms				
arithmetic mean (standard deviation)	2.7 (± 0.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Neonates/Infants: Absolute Value of Vital Signs - Respiratory Rate at PP Week 4

End point title	Neonates/Infants: Absolute Value of Vital Signs - Respiratory Rate at PP Week 4[40]

End point description:

Absolute value of vital signs parameter included respiratory rate at PP Week 4 was reported for all neonates/infants. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Here, 'N' (overall number of subjects analysed) signifies the number of neonates or infants evaluable for this endpoint. Per plan, pooled data for all neonates and infants was collected and analyzed for this endpoint.

End point type	Primary

End point timeframe:

PP Week 4

Notes:

[40] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	8			
Units: Breaths per minute				
arithmetic mean (standard deviation)	54.0 (± 14.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Neonates/Infants: Change From Baseline in Vital Signs -Body Weight

End point title	Neonates/Infants: Change From Baseline in Vital Signs -Body Weight[41]

End point description:

Change from baseline in vital signs included body weight was reported for all neonates/infants.

Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Here, 'n' (number analysed) signifies the number of neonates or infants evaluable for specified timepoints. Per plan, pooled data for all neonates and infants was collected and analyzed for this endpoint.

End point type	Primary

End point timeframe:

Baseline (PP Day 0), PP Weeks 1, 4, and 24

Notes:

[41] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Kilograms				
arithmetic mean (standard deviation)				
PP Week 1 (n=10)	-0.1 (± 0.1)			
PP Week 4 (n=12)	0.6 (± 0.4)			
PP Week 24 (n=12)	4.7 (± 0.9)			

Statistical analyses

No statistical analyses for this end point

Primary: Neonates/Infants: Absolute Value of Vital Signs - Respiratory Rate at Baseline

End point title	Neonates/Infants: Absolute Value of Vital Signs - Respiratory Rate at Baseline[42]

End point description:

Absolute value of vital signs parameter included respiratory rate at baseline was reported for all neonates/infants. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Here, 'N' (overall number of subjects analysed) signifies the number of neonates or infants evaluable for this endpoint. Per plan, pooled data for all neonates and infants was collected and analyzed for this endpoint.

End point type	Primary

End point timeframe:

Baseline (PP Day 0)

Notes:

[42] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	10			
Units: breaths per minute				
arithmetic mean (standard deviation)	43.9 (± 8.1)			

Statistical analyses

No statistical analyses for this end point

Primary: Neonates/Infants: Absolute Value of Vital Signs - Respiratory Rate at PP Week 1

End point title	Neonates/Infants: Absolute Value of Vital Signs - Respiratory Rate at PP Week 1[43]

End point description:

Absolute value of vital signs parameter included respiratory rate at PP Week 1 was reported for all neonates/infants. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Here, 'N' (overall number of subjects analysed) signifies the number of neonates or infants evaluable for this endpoint. Per plan, pooled data for all neonates and infants was collected and analyzed for this endpoint.

End point type	Primary

End point timeframe:

PP Week 1

Notes:

[43] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	8			
Units: breaths per minute				
arithmetic mean (standard deviation)	42.3 (± 12.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Neonates/Infants: Absolute Value of Vital Signs - Body Weight at PP Week 24

End point title	Neonates/Infants: Absolute Value of Vital Signs - Body Weight at PP Week 24[44]

End point description:

Absolute value of vital signs parameter - body weight at PP Week 24 was reported for all neonates/infants. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Per plan, pooled data for all neonates and infants was collected and analysed for this endpoint.

End point type	Primary

End point timeframe:

PP Week 24

Notes:

[44] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Kilograms				
arithmetic mean (standard deviation)	7.4 (± 1.2)			

Statistical analyses

No statistical analyses for this end point

Primary: Neonates/Infants: Absolute Value of Vital Sign - Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at PP Week 1

End point title	Neonates/Infants: Absolute Value of Vital Sign - Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at PP Week 1[45]

End point description:

Absolute value of vital signs parameter included SBP and DBP at PP Week 1 were reported for all neonates/infants. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Here, 'N' (overall number of subjects analysed) signifies the number of neonates or infants evaluable for this endpoint. Per plan, pooled data for all neonates and infants was collected and analyzed for this endpoint.

End point type	Primary

End point timeframe:

PP Week 1

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: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	4			
Units: milliliter of mercury				
arithmetic mean (standard deviation)				
SBP	66.3 (± 6.1)			
DBP	42.5 (± 9.3)			

Statistical analyses

No statistical analyses for this end point

Primary: Neonates/Infants: Absolute Value of Vital Sign - Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at Baseline

End point title	Neonates/Infants: Absolute Value of Vital Sign - Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at Baseline[46]

End point description:

Absolute value of vital signs parameter included systolic blood pressure (SBP) and diastolic blood pressure (DBP) at baseline were reported for all neonates/infants. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Here, 'N' (overall number of subjects analysed) signifies the number of neonates or infants evaluable for this endpoint. Per plan, pooled data for all neonates and infants was collected and analyzed for this endpoint.

End point type	Primary

End point timeframe:

Baseline (PP Day 0)

Notes:

[46] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	7			
Units: milliliter of mercury				
arithmetic mean (standard deviation)				
SBP	66.7 (± 11.2)			
DBP	34.9 (± 5.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Neonates/Infants: Change From Baseline in Vital Signs - Respiratory Rate

End point title	Neonates/Infants: Change From Baseline in Vital Signs - Respiratory Rate[47]

End point description:

Change from baseline in vital signs -respiratory rate up to PP Week 24 were reported for all neonates/infants. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Here, 'N' (overall number of subjects analysed) signifies the number of neonates or infants evaluable for this endpoint and 'n' (number analysed) signifies the number of neonates or infants evaluable for specified timepoints. Per plan, pooled data for all neonates and infants was collected and analyzed for this endpoint.

End point type	Primary

End point timeframe:

Baseline (PP Day 0), PP Weeks 1, 4, and 24

Notes:

[47] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	8			
Units: breaths per minute				
arithmetic mean (standard deviation)				
PP Week 1 (n=6) PP Week 4 (n=8) PP Week 24 (n=8)	-3.8 (± 8.0) 13.0 (± 16.9) -5.6 (± 17.6)			

Statistical analyses

No statistical analyses for this end point

Primary: Neonates/Infants: Absolute Value of Vital Signs - Respiratory Rate at PP Week 24

End point title	Neonates/Infants: Absolute Value of Vital Signs - Respiratory Rate at PP Week 24[48]

End point description:

Absolute value of vital signs parameter included respiratory rate at PP Week 24 was reported for all neonates/infants. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Here, 'N' (overall number of subjects analysed) signifies the number of neonates or infants evaluable for this endpoint. Per plan, pooled data for all neonates and infants was collected and analyzed for this endpoint.

End point type	Primary

End point timeframe:

PP Week 24

Notes:

[48] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	10			
Units: Breaths per minute				
arithmetic mean (standard deviation)	37.6 (± 11.1)			

Statistical analyses

No statistical analyses for this end point

Primary: Neonates/Infants: Absolute Value of Vital Sign - Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at PP Week 24

End point title	Neonates/Infants: Absolute Value of Vital Sign - Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at PP Week 24[49]

End point description:

Absolute value of vital signs parameter included SBP and DBP at PP Week 24 were reported for all

neonates/infants. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Here, 'N' (overall number of subjects analysed) signifies the number of neonates or infants evaluable for this endpoint. Per plan, pooled data for all neonates and infants was collected and analyzed for this endpoint.

End point type	Primary

End point timeframe:

PP Week 24

Notes:

[49] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	5			
Units: milliliter of mercury				
arithmetic mean (standard deviation)				
SBP	106.8 (± 19.8)			
DBP	73.8 (± 22.4)			

Statistical analyses

No statistical analyses for this end point

Primary: Neonates/Infants: Absolute Value of Vital Sign - Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at PP Week 4

End point title	Neonates/Infants: Absolute Value of Vital Sign - Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP) at PP Week 4[50]

End point description:

Absolute value of vital signs parameter included SBP and DBP at PP Week 4 were reported for all neonates/infants. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Here, 'N' (overall number of subjects analysed) signifies the number of neonates or infants evaluable for this endpoint. Per plan, pooled data for all neonates and infants was collected and analyzed for this endpoint.

End point type	Primary

End point timeframe:

PP Week 4

Notes:

[50] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	4			
Units: milliliter of mercury				
arithmetic mean (standard deviation)				
SBP	83.3 (± 18.3)			
DBP	44.8 (± 17.7)			

Statistical analyses

No statistical analyses for this end point

Primary: Neonates/Infants: Change From Baseline in Vital Signs - Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP)

End point title	Neonates/Infants: Change From Baseline in Vital Signs - Systolic Blood Pressure (SBP) and Diastolic Blood Pressure (DBP)[51]

End point description:

Change from baseline in vital signs included SBP and DBP were reported for all neonates/infants. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Here, 'N' (overall number of subjects analysed) signifies the number of neonates or infants evaluable for this endpoint and 'n' (number analysed) signifies the number of neonates or infants evaluable for specified categories and timepoints. Per plan, pooled data for all neonates and infants was collected and analyzed for this endpoint.

End point type	Primary

End point timeframe:

Baseline (PP Day 0), PP Weeks 1, 4, and 24

Notes:

[51] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	4			
Units: milliliter of mercury				
arithmetic mean (standard deviation)				
SBP: PP Week 1 (n=4)	3.3 (± 16.4)			
SBP: PP Week 4 (n=4)	22.8 (± 22.8)			
SBP: PP Week 24 (n=3)	41.3 (± 9.7)			
DBP: PP Week 1 (n=4)	7.0 (± 9.1)			
DBP: PP Week 4 (n=4)	11.8 (± 21.8)			
DBP: PP Week 24 (n=3)	39.0 (± 7.0)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Maternal Subjects With Intrauterine Growth Restriction (IUGR) Based on Ultrasound Assessments

End point title	Percentage of Maternal Subjects With Intrauterine Growth Restriction (IUGR) Based on Ultrasound Assessments[52]

End point description:

Percentage of maternal subjects with intrauterine growth restriction (IUGR) based on ultrasound assessments and guidelines from American College of Obstetricians and Gynecologists, and Society for Maternal-Fetal Medicine was reported. This endpoint provided the incidence of fetus with IUGR at delivery. IUGR was defined as weight below the 10th percentile for gestational age based on the World Health Organization (WHO) fetal growth curve. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'n' (number analysed) signifies the number of subjects evaluable for specified timepoints and 99999 signifies that no subjects were available for the analysis.

End point type	Primary

End point timeframe:

Baseline (GA Week 14), GA Weeks 16, 18, 22, 24, 26, 28, 30, 32, 34, and 36

Notes:

[52] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: Percentage of maternal subjects				
number (not applicable)				
Baseline (n= 2, 0, 3, 3, 8)	0	99999	0	0
GA Week 16 (n= 1, 2, 3, 4, 10)	0	0	0	0
GA Week 18 (n= 1, 2, 4, 4, 11)	0	0	0	0
GA Week 20 (n= 2, 1, 4, 4, 11)	50.0	0	0	0
GA Week 22 (n= 2, 1, 4, 3, 10)	0	0	0	0
GA Week 24 (n= 3, 1, 4, 3, 11)	0	0	0	0
GA Week 26 (n= 3, 2, 4, 3, 12)	0	50.0	0	0
GA Week 28 (n= 3, 2, 4, 3, 12)	0	50.0	0	0
GA Week 30 (n= 2, 2, 3, 3, 10)	0	0	0	0
GA Week 32 (n= 2, 1, 4, 3, 10)	0	100.0	0	0
GA Week 34 (n= 2, 1, 4, 2, 9)	0	0	0	0
GA Week 36 (n= 1, 2, 3, 2, 8)	0	0	0	0

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Percentage of maternal subjects				
number (not applicable)				
Baseline (n= 2, 0, 3, 3, 8)	0			
GA Week 16 (n= 1, 2, 3, 4, 10)	0			
GA Week 18 (n= 1, 2, 4, 4, 11)	0			
GA Week 20 (n= 2, 1, 4, 4, 11)	9.1			
GA Week 22 (n= 2, 1, 4, 3, 10)	0			
GA Week 24 (n= 3, 1, 4, 3, 11)	0			
GA Week 26 (n= 3, 2, 4, 3, 12)	8.3			
GA Week 28 (n= 3, 2, 4, 3, 12)	8.3			
GA Week 30 (n= 2, 2, 3, 3, 10)	0			

GA Week 32 (n= 2, 1, 4, 3, 10)	10.0			
GA Week 34 (n= 2, 1, 4, 2, 9)	0			
GA Week 36 (n= 1, 2, 3, 2, 8)	0			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Maternal Subjects with Abnormal Amniotic Fluid Values: Amniotic Fluid Index (AFI) at Baseline

End point title	Percentage of Maternal Subjects with Abnormal Amniotic Fluid Values: Amniotic Fluid Index (AFI) at Baseline[53]

End point description:

Percentage of maternal subjects with abnormal amniotic fluid values: amniotic fluid index (AFI) at baseline was reported. The amniotic fluid volume abnormality was categorized as an AFI <5 centimeter (cm) or >24 cm. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' (overall number of subjects analysed) signifies the number of subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Baseline (GA Week 14)

Notes:

[53] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	3
Units: Percentage of maternal subjects				
number (not applicable)	0	50.0	50.0	0

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Percentage of maternal subjects				
number (not applicable)	25.0			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Maternal Subjects with Abnormal Amniotic Fluid Values: AFI at GA Week 26

End point title	Percentage of Maternal Subjects with Abnormal Amniotic Fluid Values: AFI at GA Week 26[54]

End point description:

Percentage of maternal subjects with abnormal amniotic fluid values: AFI at GA Week 26 was reported. The amniotic fluid volume abnormality was categorized as an AFI <5 cm or >24 cm. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' (overall number of subjects analysed) signifies the number of subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

GA Week 26

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: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	0[55]	4	3
Units: Percentage of maternal subjects				
number (not applicable)	0		25.0	0

Notes:

[55] - Data was not collected and analysed as no subject was available for the analysis.

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	8			
Units: Percentage of maternal subjects				
number (not applicable)	25.0			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Maternal Subjects with Abnormal Amniotic Fluid Values: AFI at GA Week 36

End point title	Percentage of Maternal Subjects with Abnormal Amniotic Fluid Values: AFI at GA Week 36[56]

End point description:

Percentage of maternal subjects with abnormal amniotic fluid values: AFI at GA Week 36 was reported. The amniotic fluid volume abnormality was categorized as an AFI <5 cm or >24 cm. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' (overall number of subjects analysed) signifies the number of subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

GA Week 36

Notes:

[56] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	3	2
Units: Percentage of maternal subjects				
number (not applicable)	0	0	33.3	0

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	7			
Units: Percentage of maternal subjects				
number (not applicable)	14.3			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Maternal Subjects with Abnormal Amniotic Fluid Values: Max Vertical Pocket (MVP) at Baseline

End point title	Percentage of Maternal Subjects with Abnormal Amniotic Fluid Values: Max Vertical Pocket (MVP) at Baseline[57]

End point description:

Percentage of maternal subjects with abnormal amniotic fluid values: max vertical pocket (MVP) at baseline was reported. The amniotic fluid volume abnormality was categorized as MVP <2 cm or >8 cm. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' (overall number of subjects analysed) signifies the number of subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

Baseline (GA Week 14)

Notes:

[57] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	1	4	3
Units: Percentage of maternal subjects				
number (not applicable)	0	0	0	0

End point values	All Maternal Subjects			

Subject group type	Subject analysis set			
Number of subjects analysed	9			
Units: Percentage of maternal subjects				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Maternal Subjects with Abnormal Amniotic Fluid Values: MVP at GA Week 18

End point title	Percentage of Maternal Subjects with Abnormal Amniotic Fluid Values: MVP at GA Week 18[58]

End point description:

Percentage of maternal subjects with abnormal amniotic fluid values: MVP at GA Week 18 was reported. The amniotic fluid volume abnormality was categorized as MVP <2 cm or >8 cm. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' (overall number of subjects analysed) signifies the number of subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

GA Week 18

Notes:

[58] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	2	2	4	4
Units: Percentage of maternal subjects				
number (not applicable)	0	0	0	25.0

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Percentage of maternal subjects				
number (not applicable)	8.3			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Maternal Subjects with Abnormal Amniotic Fluid Values:

MVP at GA Week 22

End point title	Percentage of Maternal Subjects with Abnormal Amniotic Fluid Values: MVP at GA Week 22[59]

End point description:

Percentage of maternal subjects with abnormal amniotic fluid values: MVP at GA Week 22 was reported. The amniotic fluid volume abnormality was categorized as MVP <2 cm or >8 cm. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' (overall number of subjects analysed) signifies the number of subjects evaluable for this endpoint.

End point type	Primary

End point timeframe:

GA Week 22

Notes:

[59] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	3
Units: Percentage of maternal subjects				
number (not applicable)	0	0	0	0

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Percentage of maternal subjects				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Neonates/Infants with Appearance, Pulse, Grimace Response, Activity, Respiration (Apgar) Score

End point title	Number of Neonates/Infants with Appearance, Pulse, Grimace Response, Activity, Respiration (Apgar) Score [60]

End point description:

Number of neonates/infants with Apgar score from 1 to 10 minutes of life were reported. The system provided a standardized assessment for infants after delivery. The Apgar score comprises five components: 1) color, 2) heart rate, 3) reflexes, 4) muscle tone, and 5) respiration, each of which is given a score of 0, 1, or 2. The score is reported at 1 minute and 5 minutes after birth for all infants, and at 5-minute intervals thereafter until 20 minutes for infants with a score less than 7. This is using an Apgar scale which ranges from minimum total score of 0 and maximum total score of 10, with higher score representing a better outcome. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Here, 'n' (number analysed) signifies the number of neonates or infants evaluable for specified timepoints. Per plan, pooled data for all neonates and infants was collected and analyzed for this endpoint.

End point type	Primary

End point timeframe:

1, 5, and 10 minutes after birth at PP Day 0

Notes:

[60] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Subjects				
1 minute: <5 Score (n=12)	2			
1 minute: 5-7 Score (n=12)	1			
1 minute: 8-10 Score (n=12)	9			
5 minute: <5 Score (n=12)	0			
5 minute: 5-7 Score (n=12)	1			
5 minute: 8-10 Score (n=12)	11			
5 minute: <5 Score (n=7)	0			
10 minute: 5-7 Score (n=7)	1			
10 minute: 8-10 Score (n=7)	6			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Maternal Subjects With Live Birth at or After Gestational Age (GA) Week 32 and Without an Intrauterine Transfusion (IUT) Throughout Their Entire Pregnancies

End point title	Percentage of Maternal Subjects With Live Birth at or After Gestational Age (GA) Week 32 and Without an Intrauterine Transfusion (IUT) Throughout Their Entire Pregnancies[61]

End point description:

Percentage of maternal subjects with live birth at or after GA Week 32 and without an IUT throughout their entire pregnancies were reported. The FAS included all maternal subjects who received any dose of nipocalimab.

End point type	Primary

End point timeframe:

From baseline (GA Week 14) up to GA Week 37

Notes:

[61] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: Percentage of Maternal Subjects				
number (confidence interval 95%)	33.3 (0.8 to 90.6)	50.0 (1.3 to 98.7)	75.0 (19.4 to 99.4)	50.0 (6.8 to 93.2)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Percentage of Maternal Subjects				
number (confidence interval 95%)	53.8 (25.1 to 80.8)			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Maternal Subjects With Concomitant Medications and Therapies

End point title	Number of Maternal Subjects With Concomitant Medications and Therapies[62]

End point description:

Number of maternal subjects with concomitant medications and therapies were reported. Safety analysis set included all maternal subjects who received at least 1 dose of nipocalimab.

End point type	Primary

End point timeframe:

Baseline (GA Week 14) up to PP Week 24

Notes:

[62] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.
Justification: Only descriptive data was planned to be reported for this endpoint.

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: Subjects	3	2	4	4

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Subjects	13			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Neonates/Infants With Concomitant Medications and Therapies

End point title	Number of Neonates/Infants With Concomitant Medications and Therapies[63]

End point description:

Number of neonates/infants with concomitant medications and therapies were reported.
Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy.

End point type	Primary

End point timeframe:

From birth (PP Day 0) up to PP Week 96

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: Only descriptive data was planned to be reported for this endpoint.

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Subjects	12			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Maternal Subjects With Live Birth

End point title	Percentage of Maternal Subjects With Live Birth

End point description:

Percentage of maternal subjects with live birth were reported. The FAS included all maternal subjects who received any dose of nipocalimab.

End point type	Secondary

End point timeframe:

From baseline (GA Week 14) up to GA Week 37

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: Percentage of maternal subjects				
number (not applicable)	100	100	100	75

End point values	All Maternal Subjects			

Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Percentage of maternal subjects				
number (not applicable)	92.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Maternal Subjects Without an Intrauterine Transfusion (IUT) Before Gestational Age (GA) Week 24

End point title	Percentage of Maternal Subjects Without an Intrauterine Transfusion (IUT) Before Gestational Age (GA) Week 24

End point description:

Percentage of maternal subjects without an IUT before GA Week 24 were reported. The FAS included all maternal subjects who received any dose of nipocalimab.

End point type	Secondary

End point timeframe:

Baseline (GA Week 14) up to GA Week 24

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: Percentage of maternal subjects				
number (not applicable)	100	100	100	75

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Percentage of maternal subjects				
number (not applicable)	92.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Median Number of Intrauterine Transfusion (IUT) Per Maternal Subjects

End point title	Median Number of Intrauterine Transfusion (IUT) Per Maternal Subjects

End point description:

Median number of intrauterine transfusion (IUT) per maternal subjects were reported. The FAS included all maternal subjects who received any dose of nipocalimab.

End point type	Secondary

End point timeframe:

From baseline (GA Week 14) up to GA Week 37

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: IUTs per maternal subject				
median (full range (min-max))	4 (3 to 5)	5 (5 to 5)	3 (3 to 3)	1 (1 to 1)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: IUTs per maternal subject				
median (full range (min-max))	3 (1 to 5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Maternal Subjects : Gestational Age (GA) at First Intrauterine Transfusion (IUT)

End point title	Maternal Subjects : Gestational Age (GA) at First Intrauterine Transfusion (IUT)

End point description:

Gestational age (GA) at first IUT for maternal subjects were reported. The FAS included all maternal subjects who received any dose of nipocalimab. Per plan, pooled data for all maternal subjects was collected and analysed for this endpoint.

End point type	Secondary

End point timeframe:

From baseline (GA Week 14) up to GA Week 37

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: weeks				
median (full range (min-max))	27 (22 to 31)			

Statistical analyses

No statistical analyses for this end point

Secondary: Frequency of Intrauterine Transfusions (IUTs) on Maternal Subjects

End point title	Frequency of Intrauterine Transfusions (IUTs) on Maternal Subjects

End point description:

Frequency of intrauterine transfusions (IUTs) on maternal subjects were reported. Frequency of IUTs was defined as total number of IUTs divided by the (date of delivery – date of first IUT +1)/7. The FAS included all maternal subjects who received any dose of nipocalimab.

End point type	Secondary

End point timeframe:

From baseline (GA Week 14) up to GA Week 37

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: IUT/week				
median (full range (min-max))	0.52 (0.48 to 0.57)	0.56 (0.56 to 0.56)	0.43 (0.43 to 0.43)	0.70 (0.64 to 0.78)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: IUT/week				
median (full range (min-max))	0.56 (0.43 to 0.78)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Maternal Subjects With Fetal Hydrops in Utero or Post Birth

End point title	Percentage of Maternal Subjects With Fetal Hydrops in Utero or Post Birth

End point description:

Percentage of maternal subjects with fetal hydrops in utero or post birth were reported. The FAS included all maternal subjects who received any dose of nipocalimab. Here, 'N' overall (number of subjects analysed) signifies the number of subjects evaluable for this endpoint.

End point type	Secondary

End point timeframe:

From birth (PP Day 0) up to PP Week 24

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: Percentage of maternal subjects				
number (not applicable)	0	0	0	0

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: Percentage of maternal subjects				
number (not applicable)	0			

Statistical analyses

No statistical analyses for this end point

Secondary: Maternal Subjects: Gestational Age at Time of Delivery

End point title	Maternal Subjects: Gestational Age at Time of Delivery

End point description:

Gestational age at time of delivery for maternal subjects were reported. The FAS included all maternal subjects who received any dose of nipocalimab.

End point type	Secondary

End point timeframe:

From baseline (GA Week 14) up to GA Week 37

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: weeks				
median (full range (min-max))	36 (29 to 37)	36 (35 to 37)	36 (36 to 37)	35 (23 to 37)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: weeks				
median (full range (min-max))	36 (23 to 37)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Neonates Who Required Phototherapy

End point title	Percentage of Neonates Who Required Phototherapy

End point description:

Percentage of neonates who required phototherapy were reported. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy.

End point type	Secondary

End point timeframe:

From birth (PP Day 0) up to PP Week 24

End point values	Group 1 (Neonates and Infants): 30 mg/kg BLW	Group 2 (Neonates and Infants): 30 to 45 mg/kg BLW	Group 3 (Neonates and Infants): 45 mg/kg BLW	Group 4 (Neonates and Infants): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	3
Units: Percentage of neonates				
number (not applicable)	100	50	100	100

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Percentage of neonates				

number (not applicable)	91.7			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Neonates Who Required Exchange Transfusions

End point title	Percentage of Neonates Who Required Exchange Transfusions

End point description:

Percentage of neonates who required exchange transfusions were reported. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy.

End point type	Secondary

End point timeframe:

From birth (PP Day 0) up to PP Week 24

End point values	Group 1 (Neonates and Infants): 30 mg/kg BLW	Group 2 (Neonates and Infants): 30 to 45 mg/kg BLW	Group 3 (Neonates and Infants): 45 mg/kg BLW	Group 4 (Neonates and Infants): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	3
Units: Percentage of neonates				
number (not applicable)	0	0	0	33.3

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Percentage of neonates				
number (not applicable)	8.3			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Postnatal Phototherapy Required by Neonates

End point title	Duration of Postnatal Phototherapy Required by Neonates

End point description:

Duration of postnatal phototherapy required by neonates were reported. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study

pregnancy.

End point type	Secondary

End point timeframe:

From birth (PP Day 0) up to PP Week 24

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	3
Units: hours				
median (full range (min-max))	96.0 (84.00 to 301.07)	46.68 (46.68 to 46.68)	100.88 (12.00 to 173.95)	86.98 (72.00 to 127.33)

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: hours				
median (full range (min-max))	86.98 (12.00 to 301.07)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Neonates Who Required Simple Transfusions in the First 12 Weeks of Life

End point title	Percentage of Neonates Who Required Simple Transfusions in the First 12 Weeks of Life

End point description:

Percentage of neonates who required simple transfusions in the first 12 weeks of life were reported. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy.

End point type	Secondary

End point timeframe:

From birth (PP Day 0) up to PP Week 12

End point values	Group 1 (Neonates and Infants): 30 mg/kg BLW	Group 2 (Neonates and Infants): 30 to 45 mg/kg BLW	Group 3 (Neonates and Infants): 45 mg/kg BLW	Group 4 (Neonates and Infants): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	3
Units: Percentage of neonates				
number (not applicable)	66.7	50.0	50.0	33.3

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Percentage of neonates				
number (not applicable)	50.0			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of Simple Transfusions Required by Neonate in the First 12 Weeks of Life

End point title	Number of Simple Transfusions Required by Neonate in the First 12 Weeks of Life

End point description:

Number of simple transfusions required by neonates in the first 12 weeks of life were reported. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy.

End point type	Secondary

End point timeframe:

From birth (PP Day 0) up to PP Week 12

End point values	Group 1 (Neonates and Infants): 30 mg/kg BLW	Group 2 (Neonates and Infants): 30 to 45 mg/kg BLW	Group 3 (Neonates and Infants): 45 mg/kg BLW	Group 4 (Neonates and Infants): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	3
Units: simple transfusions				
median (full range (min-max))	4.5 (3 to 6)	4.0 (4 to 4)	1.0 (1 to 1)	1.0 (1 to 1)

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	12			

Units: simple transfusions				
median (full range (min-max))	2.0 (1 to 6)			

Statistical analyses

No statistical analyses for this end point

Secondary: Maternal Serum Unoccupied Neonatal Concentration of Subjects Fc Receptor [FcRn] Receptor Occupancy (RO) in Monocytes by Nipocalimab

End point title	Maternal Serum Unoccupied Neonatal Concentration of Subjects Fc Receptor [FcRn] Receptor Occupancy (RO) in Monocytes by Nipocalimab

End point description:

Maternal serum unoccupied neonatal concentration of subjects Fc receptor [FcRn] receptor occupancy (RO) in monocytes by nipocalimab were reported. The pharmacodynamics (PD) evaluable analysis set included all maternal subjects who received at least 1 dose of nipocalimab and had at least 1 valid post-dose PD (RO or IgG) assessment. Here, 'n' (number analysed) signifies the number of subjects evaluable for specified timepoints. Here, n=0 signifies that no subjects were available for the analysis. Here, 99999 denoted for SD could not be calculated for a single subject. 9999 signifies no subject available for the analysis at that timepoint.

End point type	Secondary

End point timeframe:

Baseline (GA Week 14), GA Week 16, GA Week 36, PP Day 0, PP Week 4, and PP Week 24

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: percentage of receptors unoccupied				
arithmetic mean (standard deviation)				
Baseline (n= 3, 2, 4, 4, 13)	100.00 (± 0.000)	100.00 (± 0.000)	100.00 (± 0.000)	100.00 (± 0.000)
GA Week 16 (n= 3, 2, 3, 4, 12)	2.80 (± 0.346)	2.50 (± 1.556)	4.20 (± 3.816)	-0.15 (± 6.276)
GA Week 36 (n= 1, 1, 2, 2, 6)	12.20 (± 99999)	3.80 (± 99999)	5.40 (± 1.838)	3.75 (± 1.202)
PP Day 0 (n= 2, 2, 4, 4, 12)	126.75 (± 6.859)	21.00 (± 22.486)	68.83 (± 43.253)	39.30 (± 43.856)
PP Week 4 (n= 2, 0, 4, 4, 10)	107.55 (± 68.943)	9999 (± 9999)	130.78 (± 49.901)	121.55 (± 54.002)
PP Week 24 (n= 2, 2, 4, 4, 12)	99.60 (± 5.091)	98.45 (± 15.486)	114.15 (± 28.333)	117.20 (± 29.816)

End point values	All Maternal Subjects			

Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: percentage of receptors unoccupied				
arithmetic mean (standard deviation)				
Baseline (n= 3, 2, 4, 4, 13)	100.00 (± 0.000)			
GA Week 16 (n= 3, 2, 3, 4, 12)	2.12 (± 4.103)			
GA Week 36 (n= 1, 1, 2, 2, 6)	5.72 (± 3.420)			
PP Day 0 (n= 2, 2, 4, 4, 12)	60.67 (± 48.532)			
PP Week 4 (n= 2, 0, 4, 4, 10)	122.44 (± 49.09)			
PP Week 24 (n= 2, 2, 4, 4, 12)	110.13 (± 23.549)			

Statistical analyses

No statistical analyses for this end point

Secondary: Maternal Subjects: Change From Baseline in Serum Concentration of Total Immunoglobulin G (IgG) and Subclasses (IgG1, IgG2, IgG3, IgG4), IgA, IgM, and IgE

End point title	Maternal Subjects: Change From Baseline in Serum Concentration of Total Immunoglobulin G (IgG) and Subclasses (IgG1, IgG2, IgG3, IgG4), IgA, IgM, and IgE

End point description:

Change from baseline in serum concentration of total immunoglobulin G (IgG) and subclasses (IgG1, IgG2, IgG3, IgG4), IgA, IgM, and IgE were reported. The PD evaluable analysis set included all maternal subjects who received at least 1 dose of nipocalimab and had at least 1 valid post-dose PD (RO or IgG) assessment. Here, 'n' (number analysed) signifies the number of subjects evaluable for specified categories and timepoints. Here, 99999 signifies that no subjects were available for the analysis.

End point type	Secondary

End point timeframe:

IgG: Baseline (GA Week 14), GA Week 16, GA Week 36, birth (PP Day 0), PP Week 4, and PP Week 24; IgG1, IgG2, IgG3, IgG4, IgA, IgM, and IgE: baseline (GA Week 14), GA Week 36

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: grams/liter (g/L)				
arithmetic mean (standard deviation)				
IgG: GA Week 16 (n=3, 2, 4, 4,13)	-8.12 (± 2.235)	-7.31 (± 0.813)	-6.51 (± 1.285)	-8.19 (± 1.018)
IgG: GA Week 36 (n=2, 2. 4, 3, 11)	-7.52 (± 1.549)	-5.26 (± 2.574)	-5.83 (± 2.380)	-8.34 (± 1.305)
IgG: birth (PP Day 0)(n=2, 2, 4, 4, 12)	-0.40 (± 0.884)	-2.64 (± 0.148)	-2.45 (± 1.016)	-4.38 (± 2.771)
IgG: PP Week4 (n=2, 0, 4, 4, 10)	1.88 (± 1.803)	99999 (± 99999)	-0.17 (± 0.638)	1.10 (± 3.455)

IgG: PP Week 24 (n=2, 2, 4, 4, 12)	2.56 (± 0.255)	2.02 (± 0.622)	1.34 (± 0.411)	2.61 (± 1.101)
IgG1: GA Week 36 (n=2, 2, 3, 3, 10)	-4.35 (± 1.386)	-3.94 (± 1.464)	-3.45 (± 1.421)	-5.46 (± 1.006)
IgG2: GA Week 36 (n=2, 2, 3, 3, 10)	-2.48 (± 0.085)	-1.29 (± 0.629)	-1.91 (± 1.013)	-2.31 (± 1.192)
IgG3: GA Week 36 (n=2, 2, 3, 3, 10)	-0.25 (± 0.045)	-0.23 (± 0.228)	-0.24 (± 0.195)	-0.38 (± 0.124)
IgG4: GA Week 36 (n=2, 2, 3, 3, 10)	-0.39 (± 0.209)	-0.06 (± 0.045)	-0.13 (± 0.066)	-0.28 (± 0.140)
IgA: GA Week 36 (n=2, 2, 3, 3, 10)	0.17 (± 0.163)	0.11 (± 0.191)	0.20 (± 0.382)	0.05 (± 0.015)
IgM: GA Week 36 (n=2, 2, 3, 3, 10)	0.01 (± 0.120)	-0.06 (± 0.049)	0.01 (± 0.072)	-0.12 (± 0.075)
IgE: GA Week 36 (n=2, 2, 3, 3, 10)	-0.31 (± 0.420)	0.00 (± 0.003)	0.01 (± 0.012)	0.00 (± 0.086)

End point values	All Maternal Subjects			
Subject group type	Subject analysis set			
Number of subjects analysed	13			
Units: grams/liter (g/L)				
arithmetic mean (standard deviation)				
IgG: GA Week 16 (n=3, 2, 4, 4,13)	-7.52 (± 1.464)			
IgG: GA Week 36 (n=2, 2. 4, 3, 11)	-6.72 (± 2.146)			
IgG: birth (PP Day 0)(n=2, 2, 4, 4, 12)	-2.78 (± 2.111)			
IgG: PP Week4 (n=2, 0, 4, 4, 10)	0.75 (± 2.277)			
IgG: PP Week 24 (n=2, 2, 4, 4, 12)	2.08 (± 0.873)			
IgG1: GA Week 36 (n=2, 2, 3, 3, 10)	-4.33 (± 1.356)			
IgG2: GA Week 36 (n=2, 2, 3, 3, 10)	-2.02 (± 0.888)			
IgG3: GA Week 36 (n=2, 2, 3, 3, 10)	-0.28 (± 0.151)			
IgG4: GA Week 36 (n=2, 2, 3, 3, 10)	-0.21 (± 0.163)			
IgA: GA Week 36 (n=2, 2, 3, 3, 10)	0.13 (± 0.208)			
IgM: GA Week 36 (n=2, 2, 3, 3, 10)	-0.04 (± 0.087)			
IgE: GA Week 36 (n=2, 2, 3, 3, 10)	-0.06 (± 0.197)			

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Unoccupied Concentration of Subjects Fc Receptor [FcRn] Receptor Occupancy (RO) in Monocytes of Neonate by Nipocalimab

End point title	Serum Unoccupied Concentration of Subjects Fc Receptor [FcRn] Receptor Occupancy (RO) in Monocytes of Neonate by Nipocalimab

End point description:

Serum unoccupied FcRn RO in monocytes of neonate by Nipocalimab were reported. The PD evaluable set neonates included all neonate/infant subjects who had at least 1 valid PD (RO or IgG) assessment. Here, 'N' overall (number of subjects analysed) signifies the number of subjects evaluable for this endpoint. Here, 99999 denoted for SD could not be calculated for a single neonate/infant.

End point type	Secondary

End point timeframe:

From birth (PP Day 0) up to PP Week 24

End point values	Group 1 (Neonates and Infants): 30 mg/kg BLW	Group 2 (Neonates and Infants): 30 to 45 mg/kg BLW	Group 3 (Neonates and Infants): 45 mg/kg BLW	Group 4 (Neonates and Infants): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	1	2	3	2
Units: percentage of receptor unoccupied				
arithmetic mean (standard deviation)	118.20 (± 99999)	70.60 (± 19.233)	80.87 (± 18.029)	74.50 (± 33.093)

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	8			
Units: percentage of receptor unoccupied				
arithmetic mean (standard deviation)	81.38 (± 23.295)			

Statistical analyses

No statistical analyses for this end point

Secondary: Neonates/Infants: Change From Baseline in Serum Concentration of Total IgG, IgA, IgM, and IgE

End point title	Neonates/Infants: Change From Baseline in Serum Concentration of Total IgG, IgA, IgM, and IgE

End point description:

Change from baseline in serum concentration of total IgG, IgA, IgM, and IgE in neonates/infants were reported. PD evaluable set - neonates included all neonate/infant subjects who had at least 1 valid PD (RO or IgG) assessment. Here, 'n' (number analysed) signifies the number of subjects evaluable for specified categories and timepoints. Here, 9999 signifies that no subjects were available for the analysis and '99999' signifies that SD could not be calculated for a single subject.

End point type	Secondary

End point timeframe:

Baseline (PP Day 0) up to PP Week 96

End point values	Group 1 (Neonates and Infants): 30 mg/kg BLW	Group 2 (Neonates and Infants): 30 to 45 mg/kg BLW	Group 3 (Neonates and Infants): 45 mg/kg BLW	Group 4 (Neonates and Infants): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	3
Units: grams/liter (g/L)				
arithmetic mean (standard deviation)				
IgG: PP Week 4 (n=1, 1, 3, 2, 7)	4.61 (± 99999)	-2.16 (± 99999)	0.37 (± 2.521)	-0.87 (± 0.559)
IgG: PP Week 24 (n=1, 1, 4, 1, 7)	-7.59 (± 99999)	-0.09 (± 99999)	0.78 (± 2.675)	1.68 (± 99999)
IgG: PP Week 96 (n=0, 1, 3, 2, 6)	9999 (± 9999)	-1.41 (± 99999)	5.55 (± 2.866)	4.62 (± 1.683)
IgA: PP Week 4 (n=1, 0, 2, 1, 4)	0.00 (± 99999)	9999 (± 9999)	0.00 (± 0.000)	0.03 (± 99999)
IgA: PP Week 24 (n=1, 1, 3, 1, 6)	0.02 (± 99999)	0.07 (± 99999)	0.23 (± 0.127)	-0.87 (± 99999)
IgA: PP Week 96 (n=0, 1, 2 , 2, 5)	9999 (± 9999)	0.28 (± 99999)	0.47 (± 0.297)	0.29 (± 0.035)
IgM: PP Week 4 (n=1, 0, 2, 2, 5)	0.10 (± 99999)	9999 (± 9999)	0.17 (± 0.092)	0.34 (± 0.071)
IgM: PP Week 24 (n=1, 1, 3, 1, 6)	0.32 (± 99999)	0.26 (± 99999)	0.61 (± 0.078)	0.44 (± 99999)
IgM: PP Week 96 (n=0, 1, 2, 2, 5)	9999 (± 9999)	0.53 (± 99999)	1.04 (± 0.014)	0.86 (± 0.368)
IgE: PP Week 4 (n=1, 0, 3, 2, 6)	0.00 (± 99999)	-2.16 (± 99999)	0.00 (± 0.007)	0.00 (± 0.000)
IgE: PP Week 24 (n=1, 1, 3, 1, 6)	0.01 (± 99999)	0.00 (± 99999)	0.37 (± 0.059)	0.02 (± 99999)
IgE: PP Week 96 (n=0, 1, 2, 2, 5)	9999 (± 9999)	0.02 (± 99999)	0.02 (± 0.008)	0.03 (± 0.027)

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: grams/liter (g/L)				
arithmetic mean (standard deviation)				
IgG: PP Week 4 (n=1, 1, 3, 2, 7)	0.26 (± 2.594)			
IgG: PP Week 24 (n=1, 1, 4, 1, 7)	-0.41 (± 3.723)			
IgG: PP Week 96 (n=0, 1, 3, 2, 6)	4.08 (± 3.361)			
IgA: PP Week 4 (n=1, 0, 2, 1, 4)	0.01 (± 0.015)			
IgA: PP Week 24 (n=1, 1, 3, 1, 6)	0.15 (± 0.121)			
IgA: PP Week 96 (n=0, 1, 2 , 2, 5)	0.36 (± 0.181)			
IgM: PP Week 4 (n=1, 0, 2, 2, 5)	0.22 (± 0.125)			
IgM: PP Week 24 (n=1, 1, 3, 1, 6)	0.48 (± 0.166)			
IgM: PP Week 96 (n=0, 1, 2, 2, 5)	0.87 (± 0.278)			
IgE: PP Week 4 (n=1, 0, 3, 2, 6)	0.00 (± 0.004)			
IgE: PP Week 24 (n=1, 1, 3, 1, 6)	0.02 (± 0.040)			
IgE: PP Week 96 (n=0, 1, 2, 2, 5)	0.02 (± 0.016)			

Statistical analyses

No statistical analyses for this end point

Secondary: Serum Concentrations of Nipocalimab in Maternal Subjects

End point title	Serum Concentrations of Nipocalimab in Maternal Subjects

End point description:

Serum concentrations of nipocalimab in maternal subjects were reported. Pharmacokinetic evaluable analysis set included all maternal subjects who received at least 1 dose of nipocalimab and had at least 1 valid post-dose blood sample drawn for PK analysis. Here, 'n' (number analysed) signifies the number of subjects evaluable for specifie timepoints. Here, '9999' signifies that no subjects were available for the analysis and '99999' signifies that SD could not be calculated for a single subject.

End point type	Secondary

End point timeframe:

Pre dose and post dose: GA Week 14 and GA Week 24; Birth (PP Day 0), PP Week 4 and PP Week 24

End point values	Group 1 (Maternal): 30 mg/kg BLW	Group 2 (Maternal): 30 to 45 mg/kg BLW	Group 3 (Maternal): 45 mg/kg BLW	Group 4 (Maternal): 45 mg/kg TAW
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	2	4	4
Units: mcg/mL				
arithmetic mean (standard deviation)				
GA Week 14: Pre-dose (n=3, 2, 4, 4)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)
GA Week 14: Post-dose (n=3, 2, 4, 4)	726.00 (± 138.01)	577.00 (± 110.31)	947.75 (± 193.17)	928.50 (± 159.05)
GA Week 24: Pre-dose (n=2, 2, 4, 3)	58.25 (± 43.63)	71.15 (± 19.87)	197.25 (± 73.27)	205.00 (± 82.18)
GA Week 24: Post-dose (n=2, 2, 4, 3)	736.50 (± 101.12)	629.00 (± 90.51)	1051.25 (± 196.49)	1246.67 (± 202.32)
PP Day 0 (n=2, 1, 3, 4)	0.01 (± 0.02)	100.0 (± 99999)	14.54 (± 25.16)	278.96 (± 547.41)
PP Week 4 (n=2, 0, 4, 4)	0.00 (± 0.00)	9999 (± 9999)	0.00 (± 0.00)	0.00 (± 0.00)
PP Week 24 (n=2, 2, 4, 3)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)	0.00 (± 0.00)

Statistical analyses

No statistical analyses for this end point

Secondary: Pediatric Quality of Life Inventory (PedsQL) Total and Sub Scale Score in Neonates/Infants

End point title	Pediatric Quality of Life Inventory (PedsQL) Total and Sub Scale Score in Neonates/Infants

End point description:

The 45-item PedsQL infant Scales (ages 13-24 months) included physical functioning, physical symptoms, emotional functioning, social functioning, and cognitive functioning. Health summary score for psychosocial (sum of all items over number of items: emotional, social, cognitive functioning scales) and physical (sum of the items over number of items: physical functioning and symptoms scales), as well as a total score (sum of all items over number of items answered on all scales). Items were reverse-scored and linearly transformed to 0-100 scale (0=100, 1=75, 2=50, 3=25, 4=0). PedsQL a validated scale ranging from 0 -100, higher scores = a better quality of life. Neonates/ infants analysis

set included all live births to maternal subjects who received at least 1 dose of nipocalimab in study pregnancy. Per plan, pooled data for all neonates and infants was collected and analysed for this endpoint.

End point type	Secondary

End point timeframe:

PP Week 96

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Score on a scale				
arithmetic mean (standard deviation)				
Overall Total Score	86.39 (± 8.35)			
Psychosocial Health Total Score	82.69 (± 10.47)			
Physical Health Total Score	91.45 (± 8.78)			
Physical Functioning Score	93.75 (± 9.59)			
Physical Symptoms Score	89.38 (± 10.07)			
Emotional Functioning Score	76.82 (± 14.50)			
Social Functioning Score	95.00 (± 9.64)			
Cognitive Functioning Score	83.68 (± 12.90)			

Statistical analyses

No statistical analyses for this end point

Secondary: Ages and Stages Questionnaires, Third Edition (ASQ-3) Total Domain Score in Neonates/Infants

End point title	Ages and Stages Questionnaires, Third Edition (ASQ-3) Total Domain Score in Neonates/Infants

End point description:

The ASQ-3 assesses child's development based on age and included 6 questions in each area of child development: communication, gross motor, fine motor, problem solving, and personal-social skills. Parents answered either yes (10 points), sometimes (5 points) or not yet (0 points) to each question to complete ASQ-3 and each domain score could range from 0 to 60 points which higher score signifying stronger development. Neonates/infants analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy. Here, 'n' (number analysed) signifies the number of subjects evaluable for specified categories and timepoints. Per plan, pooled data for all neonates and infants was collected and analysed for this endpoint.

End point type	Secondary

End point timeframe:

At PP 6 month, PP 12 month, and PP 24 month

End point values	All Neonates and Infants			
Subject group type	Subject analysis set			
Number of subjects analysed	12			
Units: Score on a scale				
arithmetic mean (standard deviation)				
Communication Total Score: 6-month (n=12)	45.0 (± 8.0)			
Communication Total Score: 12-month (n=11)	42.3 (± 10.1)			
Communication Total Score: 24-month (n=11)	39.5 (± 13.9)			
Gross Motor Total Score: 6-month (n=12)	28.8 (± 9.8)			
Gross Motor Total Score: 12-month (n=11)	28.2 (± 19.4)			
Gross Motor Total Score: 24-month (n=11)	51.8 (± 11.0)			
Fine Motor Total Score: 6-month (n=12)	35.8 (± 13.3)			
Fine Motor Total Score: 12-month (n=11)	46.8 (± 8.4)			
Fine Motor Total Score: 24-month (n=11)	50.9 (± 7.0)			
Problem Solving Total Score: 6-month (n=12)	35.8 (± 11.4)			
Problem Solving Total Score: 12-month (n=11)	33.2 (± 12.1)			
Problem Solving Total Score: 24-month (n=11)	40.9 (± 9.4)			
Personal-Social Total Score: 6-month (n=12)	34.2 (± 12.9)			
Personal-Social Total Score: 12-month (n=11)	30.5 (± 11.3)			
Personal-Social Total Score: 24-month (n=11)	48.6 (± 10.5)			

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

All-cause mortality: Maternal: Screening (GA Week 8) up to PP Week 24, Neonates/Infants: Birth (PP Day 0) up to PP Week 96; SAE and other AEs: Maternal: From baseline (GA Week 14) up to PP Week 24, Neonates/Infants: From birth (PP Day 0) up to PP Week 96

Adverse event reporting additional description:

Maternal: Safety analysis set included all maternal subjects who have received at least 1 dose of nipocalimab. Neonates/Infants: SAEs/other AEs: Safety analysis set included all live births to maternal subjects who received at least 1 dose of nipocalimab in the study pregnancy.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	26.1

Reporting groups

Reporting group title	Group 1 (Maternal): 30mg/kg BLW

Reporting group description:

Maternal subjects received a single dose intravenous (IV) infusion of nipocalimab 30 milligrams per kilograms (mg/kg) based on baseline weight (BLW), once weekly from gestation age (GA) Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes. Maternal subjects were followed up for safety during the safety follow up period of 24 weeks after delivery at approximately GA Week 37 (up to Week 61 [PP Week 24]).

Reporting group title	Group 3 (Maternal): 45mg/kg BLW

Reporting group description:

Maternal subjects received a single dose IV infusion of nipocalimab 45 mg/kg based on BLW, once weekly from GA Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes. Maternal subjects were followed up for safety during the safety follow up period of 24 weeks after delivery at approximately GA Week 37 (up to Week 61 [PP Week 24]).

Reporting group title	Group 2 (Maternal): 30 to45 mg/kg BLW

Reporting group description:

Maternal participants received a single dose IV infusion of nipocalimab 30 mg/kg initially based on BLW followed by nipocalimab 45 mg/kg with increase in weight, once weekly from GA Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes. Maternal participants were followed up for safety during the safety follow up period of 24 weeks after delivery at approximately GA Week 37 (up to Week 61 [PP Week 24]).

Reporting group title	Group 3 (Neonates and Infants): 45 mg/kg BLW

Reporting group description:

Neonates and infants born to mothers from Group 3 were followed up for safety from PP Day 0 up to 96 weeks. Neonates and infants in this group did not receive any study drug.

Reporting group title	Group 2 (Neonates and Infants): 30 to 45 mg/kg BLW

Reporting group description:

Neonates and infants born to mothers from Group 2 were followed up for safety from PP Day 0 up to 96 weeks. Neonates and infants in this group did not receive any study drug.

Reporting group title	Group 1 (Neonates and Infants): 30 mg/kg BLW

Reporting group description:

Neonates and infants born to mothers from Group 1 were followed up for safety from PP Day 0 up to 96 weeks. Neonates and infants in this group did not receive any study drug.

Reporting group title	Group 4 (Neonates and Infants): 45 mg/kg TAW

Reporting group description:

Neonates and infants born to mothers from Group 4 were followed up for safety from PP Day 0 up to 96 weeks. Neonates and infants in this group did not receive any study drug.

Reporting group title	Group 4 (Maternal): 45mg/kg TAW

Reporting group description:

Maternal subjects received a single dose IV infusion of nipocalimab 45 mg/kg based on time-adjusted weight (TAW), once weekly from GA Week 14 to GA Week 35. The first infusion of nipocalimab was administered over 60 minutes, subsequent infusions were administered over 30 minutes. Maternal subjects were followed up for safety during the safety follow up period of 24 weeks after delivery at approximately GA Week 37 (up to Week 61 [PP Week 24]).

Serious adverse events	Group 1 (Maternal): 30mg/kg BLW	Group 3 (Maternal): 45mg/kg BLW	Group 2 (Maternal): 30 to45 mg/kg BLW
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	1 / 4 (25.00%)	0 / 2 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Cardiac disorders			
Foetal Heart Rate Deceleration Abnormality			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pregnancy, puerperium and perinatal conditions			
Foetal Growth Restriction			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Foetal Death			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (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
Premature Separation of Placenta			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subchorionic Haematoma			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Retained Placenta or Membranes			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (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
Blood and lymphatic system disorders			
Foetal Anaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia Neonatal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hyperbilirubinaemia Neonatal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (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
Jaundice			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (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
Respiratory, thoracic and mediastinal disorders			
Neonatal Respiratory Distress Syndrome			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Respiratory Syncytial Virus Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (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
Upper Respiratory Tract Infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (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 3 (Neonates and Infants): 45 mg/kg BLW	Group 2 (Neonates and Infants): 30 to 45 mg/kg BLW	Group 1 (Neonates and Infants): 30 mg/kg BLW
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 4 (25.00%)	1 / 2 (50.00%)	2 / 3 (66.67%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Cardiac disorders			
Foetal Heart Rate Deceleration Abnormality			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (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
Pregnancy, puerperium and perinatal conditions			
Foetal Growth Restriction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (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
Foetal Death			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (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
Premature Separation of Placenta			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (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
Subchorionic Haematoma			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (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
Retained Placenta or Membranes			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (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
Blood and lymphatic system disorders			
Foetal Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (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
Anaemia Neonatal			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hyperbilirubinaemia Neonatal			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	1 / 4 (25.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Neonatal Respiratory Distress Syndrome			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Respiratory Syncytial Virus Infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (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
Upper Respiratory Tract Infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (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 (Neonates and Infants): 45 mg/kg TAW	Group 4 (Maternal): 45mg/kg TAW	
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 3 (66.67%)	2 / 4 (50.00%)	
number of deaths (all causes)	0	0	
number of deaths resulting from adverse events	0	0	
Cardiac disorders			
Foetal Heart Rate Deceleration Abnormality			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pregnancy, puerperium and perinatal conditions			
Foetal Growth Restriction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Foetal Death			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Premature Separation of Placenta			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subchorionic Haematoma			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Retained Placenta or Membranes			

subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Foetal Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anaemia Neonatal			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Hyperbilirubinaemia Neonatal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Neonatal Respiratory Distress Syndrome			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Respiratory Syncytial Virus Infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper Respiratory Tract Infection			

subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Group 1 (Maternal): 30mg/kg BLW	Group 3 (Maternal): 45mg/kg BLW	Group 2 (Maternal): 30 to45 mg/kg BLW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	4 / 4 (100.00%)	2 / 2 (100.00%)
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Superficial Vein Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Varicose Vein			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Surgical and medical procedures			
Caesarean Section			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Epidural Anaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
Premature Separation of Placenta			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Premature Baby			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Postpartum Haemorrhage			

subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Polyhydramnios			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Gestational Diabetes			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Foetal Hypokinesia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Small for Dates Baby			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Uterine Contractions During Pregnancy			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
General disorders and administration site conditions			
Catheter Site Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chest Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Chest Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Chills			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infusion Site Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Puncture Site Pain			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Peripheral Swelling			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Oedema Peripheral			
subjects affected / exposed	2 / 3 (66.67%)	1 / 4 (25.00%)	1 / 2 (50.00%)
occurrences (all)	2	1	2
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Pyrexia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Breast Mass			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Nasal Congestion			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Snoring			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Social Anxiety Disorder			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Investigations			
Blood Bilirubin Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Protein Total Decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Reticulocyte Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood Immunoglobulin G Decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Blood Potassium Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Haemoglobin Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Infusion Related Reaction			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Procedural Hypotension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Procedural Pain			

subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Wound Complication			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Palpitations			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Hypotonia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Syncope			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	1	1	0
Anaemia Neonatal			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Thrombocytopenia			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Foetal Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Ear and labyrinth disorders			
Ear Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Otorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Photopsia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Conjunctival Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Retinopathy of Prematurity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Distension			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Paraesthesia Oral			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	2 / 2 (100.00%)
occurrences (all)	0	1	18
Haemorrhoids			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Dyspepsia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 2 (50.00%)
occurrences (all)	0	1	2
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Umbilical Hernia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Biliary Colic			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Jaundice			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Non-Alcoholic Fatty Liver			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Eczema			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hidradenitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Night Sweats			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	2	0	0
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	0 / 2 (0.00%)
occurrences (all)	0	2	0
Pruritus Allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Rash			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Scar Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Telangiectasia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pyelocaliectasis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Musculoskeletal and connective tissue disorders			

Muscle Spasms			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Pain in Extremity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Back Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	1 / 2 (50.00%)
occurrences (all)	0	1	1
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Asymptomatic Bacteriuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bacterial Vaginosis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Candida Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bacteriuria			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Bacterial Vulvovaginitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	1 / 2 (50.00%)
occurrences (all)	0	0	1
Conjunctivitis Bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Ear Infection			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Covid-19			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Streptococcal Urinary Tract Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	1	0	0
Respiratory Syncytial Virus Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Mastitis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	0 / 2 (0.00%)
occurrences (all)	0	1	0
Nasopharyngitis			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	1 / 2 (50.00%)
occurrences (all)	0	3	1
Otitis Media Acute			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Urinary Tract Infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	1 / 2 (50.00%)
occurrences (all)	1	0	2
Varicella			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Vulvovaginal Candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Fluid Intake Reduced			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoalbuminaemia			
subjects affected / exposed	1 / 3 (33.33%)	2 / 4 (50.00%)	0 / 2 (0.00%)
occurrences (all)	1	2	0
Hyperglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	0 / 2 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Group 3 (Neonates and Infants): 45 mg/kg BLW	Group 2 (Neonates and Infants): 30 to 45 mg/kg BLW	Group 1 (Neonates and Infants): 30 mg/kg BLW
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	2 / 2 (100.00%)	3 / 3 (100.00%)
Vascular disorders			
Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Superficial Vein Thrombosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Varicose Vein			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Surgical and medical procedures			
Caesarean Section			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Epidural Anaesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pregnancy, puerperium and perinatal conditions			
Premature Separation of Placenta			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Premature Baby			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Postpartum Haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Polyhydramnios			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gestational Diabetes			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Foetal Hypokinesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Small for Dates Baby			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Uterine Contractions During Pregnancy			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Catheter Site Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chest Discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chills			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infusion Site Discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Puncture Site Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral Swelling			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema Peripheral			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Reproductive system and breast disorders			
Breast Mass			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasal Congestion			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Snoring			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Dyspnoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Social Anxiety Disorder			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Blood Bilirubin Increased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Protein Total Decreased			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reticulocyte Count Decreased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Blood Immunoglobulin G Decreased			
subjects affected / exposed	1 / 4 (25.00%)	2 / 2 (100.00%)	1 / 3 (33.33%)
occurrences (all)	1	2	1
Blood Potassium Increased			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Haemoglobin Decreased			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Injury, poisoning and procedural complications			

Infusion Related Reaction			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural Hypotension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Wound Complication			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac disorders			
Bradycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tachycardia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Palpitations			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Headache			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypotonia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Syncope			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	3 / 3 (100.00%)
occurrences (all)	1	0	13
Anaemia Neonatal			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	5	0
Thrombocytopenia			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Foetal Anaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Ear Discomfort			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Otorrhoea			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Vertigo			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Photopsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctival Haemorrhage			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retinopathy of Prematurity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal Distension			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia Oral			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Haemorrhoids			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspepsia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Abdominal Pain			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Constipation			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Umbilical Hernia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	2 / 3 (66.67%)
occurrences (all)	1	0	4
Biliary Colic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Jaundice			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0

Non-Alcoholic Fatty Liver			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Alopecia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hidradenitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Night Sweats			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pruritus Allergic			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Scar Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Telangiectasia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pyelocaliectasis			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Muscle Spasms			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain in Extremity			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Back Pain			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Arthralgia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Asymptomatic Bacteriuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bacterial Vaginosis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Candida Infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Bacteriuria			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Bacterial Vulvovaginitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis Bacterial			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal Infection			

subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear Infection			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	2	0
Covid-19			
subjects affected / exposed	0 / 4 (0.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Streptococcal Urinary Tract Infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sinusitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory Syncytial Virus Infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Mastitis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Otitis Media Acute			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary Tract Infection			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Varicella			
subjects affected / exposed	1 / 4 (25.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Vulvovaginal Candidiasis			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			

Fluid Intake Reduced			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyponatraemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hypoalbuminaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hyperglycaemia			
subjects affected / exposed	0 / 4 (0.00%)	0 / 2 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoglycaemia			
subjects affected / exposed	1 / 4 (25.00%)	1 / 2 (50.00%)	0 / 3 (0.00%)
occurrences (all)	1	1	0

Non-serious adverse events	Group 4 (Neonates and Infants): 45 mg/kg TAW	Group 4 (Maternal): 45mg/kg TAW	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	4 / 4 (100.00%)	
Vascular disorders			
Hypotension			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	
occurrences (all)	1	1	
Superficial Vein Thrombosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Varicose Vein			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Surgical and medical procedures			
Caesarean Section			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Epidural Anaesthesia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	

Pregnancy, puerperium and perinatal conditions			
Premature Separation of Placenta			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Premature Baby			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Postpartum Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Polyhydramnios			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Gestational Diabetes			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Foetal Hypokinesia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Small for Dates Baby			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Uterine Contractions During Pregnancy			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Catheter Site Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Chest Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	2	
Chest Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	

Chills			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Infusion Site Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Puncture Site Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Peripheral Swelling			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Oedema Peripheral			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	
occurrences (all)	0	4	
Oedema			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Non-Cardiac Chest Pain			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	2 / 3 (66.67%)	0 / 4 (0.00%)	
occurrences (all)	2	0	
Reproductive system and breast disorders			
Breast Mass			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Nasal Congestion			

subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	
occurrences (all)	1	1	
Oropharyngeal Pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	
occurrences (all)	0	2	
Snoring			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Dyspnoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Psychiatric disorders			
Social Anxiety Disorder			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Investigations			
Blood Bilirubin Increased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Protein Total Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Reticulocyte Count Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Blood Immunoglobulin G Decreased			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Blood Potassium Increased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Haemoglobin Decreased			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			

Infusion Related Reaction subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0	
Procedural Hypotension subjects affected / exposed occurrences (all)	1 / 3 (33.33%) 1	1 / 4 (25.00%) 1	
Procedural Pain subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1	
Wound Complication subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1	
Cardiac disorders Bradycardia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1	
Tachycardia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0	
Palpitations subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0	
Nervous system disorders Headache subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1	
Hypotonia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1	
Paraesthesia subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	1 / 4 (25.00%) 1	
Syncope subjects affected / exposed occurrences (all)	0 / 3 (0.00%) 0	0 / 4 (0.00%) 0	
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Anaemia Neonatal			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	
occurrences (all)	2	0	
Thrombocytopenia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Foetal Anaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Ear and labyrinth disorders			
Ear Discomfort			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	2	
Otorrhoea			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Vertigo			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Photopsia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Conjunctival Haemorrhage			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Retinopathy of Prematurity			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Abdominal Distension			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Paraesthesia Oral			

subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Nausea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Haemorrhoids			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Dyspepsia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Diarrhoea			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	2	
Abdominal Pain			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Constipation			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Vomiting			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	3	
Umbilical Hernia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Hepatobiliary disorders			
Hyperbilirubinaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Biliary Colic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Jaundice			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	
occurrences (all)	1	0	

Non-Alcoholic Fatty Liver			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Skin and subcutaneous tissue disorders			
Eczema			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Alopecia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Hidradenitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Night Sweats			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Pruritus			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Pruritus Allergic			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Scar Pain			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Telangiectasia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	
occurrences (all)	0	2	
Pyelocaliectasis			

subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Musculoskeletal and connective tissue disorders			
Muscle Spasms			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Pain in Extremity			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Back Pain			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	
occurrences (all)	0	2	
Arthralgia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Infections and infestations			
Asymptomatic Bacteriuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	3	
Bacterial Vaginosis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Candida Infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Bacteriuria			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Bacterial Vulvovaginitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Conjunctivitis Bacterial			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal Infection			

subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Ear Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Covid-19			
subjects affected / exposed	0 / 3 (0.00%)	2 / 4 (50.00%)	
occurrences (all)	0	3	
Streptococcal Urinary Tract Infection			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Sinusitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Respiratory Syncytial Virus Infection			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Mastitis			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Nasopharyngitis			
subjects affected / exposed	1 / 3 (33.33%)	1 / 4 (25.00%)	
occurrences (all)	1	1	
Otitis Media Acute			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Urinary Tract Infection			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Varicella			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Vulvovaginal Candidiasis			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	3	
Metabolism and nutrition disorders			

Fluid Intake Reduced			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Hyponatraemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	
Hypoalbuminaemia			
subjects affected / exposed	0 / 3 (0.00%)	1 / 4 (25.00%)	
occurrences (all)	0	1	
Hyperglycaemia			
subjects affected / exposed	1 / 3 (33.33%)	0 / 4 (0.00%)	
occurrences (all)	1	0	
Hypoglycaemia			
subjects affected / exposed	0 / 3 (0.00%)	0 / 4 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
05 October 2018	The purpose of this amendment was to add gestational age at delivery as a secondary endpoint Criteria for dose adjustment was changed to be based on M281 (nipocalimab) blood concentration in conjunction with an adverse fetal event caused by severe fetal anemia
09 January 2019	The purpose of this amendment was to changed eligibility criterion for anti-Kell alloantibody to titers >=4, based on evidence that titers as low as 4 could be associated with EOS-HDFN.
22 February 2019	The purpose of this amendment was to exclusion criteria were revised to better ensure subject safety.
22 April 2019	The purpose of this amendment was to clarified that DSMB would review all available data including data from MOM-281-103. Modified justification for study design in accordance with regulatory agency requests.
18 December 2019	The purpose of this amendment was to changed the name of the study drug to the US adopted name for the product.
20 January 2020	The purpose of this amendment was to changed IUT stopping rule to allow for continued nipocalimab in the event of IUT until fetal sampling at a subsequent IUT indicated no fetal red blood cells remaining in the fetal circulation, confirmed by laboratory assessment.
12 August 2020	The purpose of this amendment was to modified inclusion criterion #7 to clarify procedures to be followed if Screening serologies for measles mumps, rubella, and varicella are borderline or negative.
29 January 2021	The purpose of this amendment was to amended to include additional assessments for monitoring IgG, IgM, IgA, and IgE concentrations in infants at Weeks 48 and 96 due to an unexpected finding of immunoglobulin (IgG, IgM, IgA) serum concentrations below normal range or at low normal range in infants with available data at 6 months and 1-year post birth.
21 March 2021	The purpose of this amendment was to amended to due to drug-related elevations in total cholesterol and low-density lipoprotein (LDL) observed, the protocol was amended to include lipid monitoring for all participants(mothers and infants), and an exclusion criterion for participants with a recent significant cardiovascular event was added.
21 March 2022	The purpose of this amendment was to amended to the exclusion criteria were amended to exclude participants with any history of major adverse cardiovascular events, and any such events that occurred during the study were to be adjudicated.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported