Clinical trial results:
Multicenter, Randomized, Double-blind, Placebo Controlled Study to Assess the Efficacy, Safety, Pharmacokinetics, and Pharmacodynamics of GZ/SAR402671 in Patients with Early-stage Parkinson's Disease Carrying a GBA Mutation or Other Pre-specified Variant.

Summary

EudraCT number	2016-000657-12
Trial protocol	SE DE AT ES PT IT GR
Global end of trial date	27 May 2021

Results information

Result version number	v1
This version publication date	21 April 2022
First version publication date	21 April 2022

Trial information

Trial identification

Sponsor protocol code	ACT14820

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02906020
WHO universal trial number (UTN)	U1111-1180-6918

Notes:

Sponsors

Sponsor organisation name	Genzyme Corporation, A Sanofi company
Sponsor organisation address	50 Binney Street, Cambridge, MA, United States, 02142
Public contact	Trial Transparency Team, Sanofi aventis recherche & développement, Contact-US@sanofi.com
Scientific contact	Trial Transparency Team, Sanofi aventis recherche & développement, Contact-US@sanofi.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	06 August 2021
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	27 May 2021
Was the trial ended prematurely?	Yes

Notes:

General information about the trial

Main objective of the trial:

To determine the safety and tolerability of 4, 8, and 15 milligrams (mg) of GZ/SAR402671, as compared to placebo, when administered orally daily for 4 weeks in early-stage Parkinson’s disease subjects carrying a glucocerebrosidase gene (GBA) mutation or other prespecified sequence variants (from now on both mutation types are referred to as ‘GBA mutation’). This allowed selection of the dose for the second part of this study (this did not apply to Japanese subjects).

Protection of trial subjects:

Subjects were fully informed of all pertinent aspects of the clinical trial as well as the possibility to discontinue at any time in language and terms appropriate for the subject and considering the local culture. During the course of the trial, subjects were provided with individual subject cards indicating the nature of the trial the subject is participating, contact details and any information needed in the event of a medical emergency. Collected personal data and human biological samples were processed in compliance with the Sanofi-Aventis Group Personal Data Protection Charter ensuring that the Group abides by the laws governing personal data protection in force in all countries in which it operates.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 December 2016
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	36 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 2
Country: Number of subjects enrolled	Italy: 32
Country: Number of subjects enrolled	Japan: 22
Country: Number of subjects enrolled	Sweden: 8
Country: Number of subjects enrolled	Greece: 2
Country: Number of subjects enrolled	Singapore: 4
Country: Number of subjects enrolled	Canada: 14
Country: Number of subjects enrolled	Israel: 34
Country: Number of subjects enrolled	Austria: 3
Country: Number of subjects enrolled	Norway: 5
Country: Number of subjects enrolled	United States: 83
Country: Number of subjects enrolled	Germany: 15
Country: Number of subjects enrolled	Taiwan: 3

Country: Number of subjects enrolled	United Kingdom: 6
Country: Number of subjects enrolled	Spain: 13
Country: Number of subjects enrolled	Portugal: 4
Worldwide total number of subjects	250
EEA total number of subjects	84

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)	182
From 65 to 84 years	68
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Study was conducted at 52 sites in 16 countries. A total of 273 subjects were enrolled from 15-Dec-2016 to 18-Dec-2019. Study consisted of 2 Parts: Part 1 (dose escalation period) & Part 2 (double-blind [DB] treatment period + long-term follow-up [LTFU]) period.

Pre-assignment

Screening details:

Post part 1 completion, 23 eligible & willing subjects were re-randomised in Part 2 and were counted again in total enrollment number (273) i.e.,250 unique subjects (29 in Part 1+221 in Part 2)+23 re-randomised in Part 2; these 23 subjects are displayed only in 'subject disposition' & 'adverse events' sections but not in any other section.

Period 1

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

Arms

Are arms mutually exclusive?	No
Arm title	Part 1: Placebo (ROW)

Arm description:

Subjects from rest of world (ROW, except Japan), received placebo (matched to venglustat) capsule orally once daily (QD) for up to 36 weeks in Part 1.

Arm type	Placebo
Investigational medicinal product name	Placebo for Part 1 (ROW)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Placebo (matched to venglustat; per protocol) capsule orally QD in Part 1 up to 36 weeks for ROW.

Arm title	Part 1: Venglustat 4 mg (ROW)

Arm description:

Subjects from ROW (except Japan), received venglustat 4 milligrams (mg) capsule orally QD for up to 36 weeks in Part 1.

Arm type	Experimental
Investigational medicinal product name	Venglustat for Part 1 (ROW)
Investigational medicinal product code	GZ/SAR402671
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Venglustat 4 mg (per protocol) capsule orally QD in Part 1, up to 36 weeks for ROW.

Arm title	Part 1: Venglustat 8 mg (ROW)

Arm description:

Subjects from ROW (except Japan), received venglustat 8 mg capsule orally QD for up to 36 weeks in Part 1.

Arm type	Experimental

Investigational medicinal product name	Venglustat for Part 1 (ROW)
Investigational medicinal product code	GZ/SAR402671
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Venglustat 8 mg (per protocol) capsule orally QD in Part 1, up to 36 weeks for ROW.

Arm title	Part 1: Venglustat 15 mg (ROW)

Arm description:

Subjects from ROW (except Japan), received venglustat 15 mg capsule orally QD for up to 36 weeks in Part 1.

Arm type	Experimental
Investigational medicinal product name	Venglustat for Part 1 (ROW)
Investigational medicinal product code	GZ/SAR402671
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Venglustat 15 mg (per protocol) capsule orally QD in Part 1, up to 36 weeks for ROW.

Arm title	Part 1: Placebo (Japan only)

Arm description:

Japanese subjects received placebo (matched to venglustat) capsule orally QD for up to 52 weeks in Part 1.

Arm type	Placebo
Investigational medicinal product name	Placebo for Part 1 (Japan only)
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Placebo (matched to venglustat; per protocol) capsule orally QD in Part 1, up to 52 weeks for Japanese subjects.

Arm title	Part 1: Venglustat 4 mg (Japan only)

Arm description:

Japanese subjects received venglustat 4 mg capsule orally QD for up to 52 weeks in Part 1.

Arm type	Experimental
Investigational medicinal product name	Venglustat for Part 1
Investigational medicinal product code	GZ/SAR402671
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Venglustat 4 mg (per protocol) capsule orally QD in Part 1, up to 52 weeks for Japanese subjects.

Arm title	Part 1: Venglustat 8 mg (Japan only)

Arm description:

Japanese subjects received venglustat 8 mg capsule orally QD for up to 52 weeks in Part 1.

Arm type	Experimental

Investigational medicinal product name	Venglustat for Part 1
Investigational medicinal product code	GZ/SAR402671
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Venglustat 8 mg (per protocol) capsule orally QD in Part 1, up to 52 weeks for Japanese subjects.

Arm title	Part 1: Venglustat 15 mg (Japan only)

Arm description:

Japanese subjects received venglustat 15 mg capsule orally QD for up to 52 weeks in Part 1.

Arm type	Experimental
Investigational medicinal product name	Venglustat for Part 1
Investigational medicinal product code	GZ/SAR402671
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Venglustat 15 mg (per protocol) capsule orally QD in Part 1, up to 52 weeks for Japanese subjects.

Arm title	Part 2, DB period: Placebo

Arm description:

Subjects received placebo (matched to venglustat) capsule orally QD for 52 weeks in Part 2 DB period.

Arm type	Placebo
Investigational medicinal product name	Placebo for Part 2 DB period
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Placebo (matched to venglustat; per protocol) capsule orally QD in Part 2 DB period for 52 weeks.

Arm title	Part 2, DB period: Venglustat 15 mg

Arm description:

Subjects received venglustat 15 mg capsule orally QD for 52 weeks in Part 2 DB period.

Arm type	Experimental
Investigational medicinal product name	Venglustat for Part 2 DB period
Investigational medicinal product code	GZ/SAR402671
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Venglustat 15 mg (per protocol) capsule orally QD in Part 2 DB period for 52 weeks.

Arm title	Part 2, DB period: Placebo (Re-randomised from Part 1)

Arm description:

Subjects who completed Part 1 with placebo (matched to venglustat) or venglustat 4/8/15 mg, met eligibility criteria for Part 2 and agreed to continue in the study, were re-randomised to receive placebo (matched to venglustat) capsule orally QD for 52 weeks in Part 2 DB period.

Arm type	Placebo

Investigational medicinal product name	Placebo for Part 2 DB period
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Placebo (matched to venglustat; per protocol) capsule orally QD in Part 2 DB period for 52 weeks.

Arm title	Part 2, DB Period: Venglustat 15mg (Re-randomised From Part 1)

Arm description:

Subjects who completed Part 1 with placebo (matched to venglustat) or venglustat 4/8/15 mg, met eligibility criteria for Part 2 and agreed to continue in the study, were re-randomised to receive venglustat 15 mg capsule orally QD for 52 weeks in Part 2 DB period.

Arm type	Experimental
Investigational medicinal product name	Venglustat for Part 2 DB period
Investigational medicinal product code	GZ/SAR402671
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Venglustat 15 mg (per protocol) capsule orally QD in Part 2 DB period for 52 weeks.

Arm title	Part 2, LTFU Period: Placebo Then Venglustat 15 mg

Arm description:

Subjects who were enrolled in the study in Part 2, received placebo (matched to venglustat), completed Part 2 DB period, entered long-term follow-up (LTFU) period to receive venglustat 15 mg capsule orally QD for 156 weeks.

Arm type	Experimental
Investigational medicinal product name	Venglustat for Part 2 LTFU period
Investigational medicinal product code	GZ/SAR402671
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Venglustat 15 mg (per protocol) capsule orally QD in Part 2 LTFU for 156 weeks.

Arm title	Part 2, LTFU Period: Venglustat 15 mg

Arm description:

Subjects who were enrolled in the study in Part 2, received venglustat 15 mg, completed Part 2 DB period, entered LTFU period to receive venglustat 15 mg capsule orally QD for 156 weeks.

Arm type	Experimental
Investigational medicinal product name	Venglustat for Part 2 LTFU period
Investigational medicinal product code	GZ/SAR402671
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Venglustat 15 mg (per protocol) capsule orally QD in Part 2 LTFU period for 156 weeks.

Arm title	Part 2,LTFU:Placebo Then Veng 15mg (Re-randomised From Part 1)

Arm description:

Subjects from Part 1 who were re-randomised in the study in Part 2, received placebo (matched to venglustat) and completed Part 2 DB period, entered LTFU period to receive venglustat (Veng) 15 mg capsule orally QD for 156 weeks.

Arm type	Experimental

Investigational medicinal product name	Venglustat for Part 2 LTFU period
Investigational medicinal product code	GZ/SAR402671
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Venglustat 15 mg (per protocol) capsule orally QD in Part 2 LTFU for 156 weeks.

Arm title	Part 2, LTFU: Venglustat 15 mg (Re-randomised From Part 1)

Arm description:

Subjects from Part 1 who were re-randomised in the study in Part 2, received venglustat 15 mg and completed Part 2 DB period, entered LTFU period to receive venglustat 15 mg capsule orally QD for 156 weeks.

Arm type	Experimental
Investigational medicinal product name	Venglustat for Part 2 LTFU period
Investigational medicinal product code	GZ/SAR402671
Other name	
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

Venglustat 15 mg (per protocol) capsule orally QD in Part 2 LTFU period for 156 weeks.

Number of subjects in period 1	Part 1: Placebo (ROW)	Part 1: Venglustat 4 mg (ROW)	Part 1: Venglustat 8 mg (ROW)
Started	4	4	5
Treated	4	4	5
Completed	4	3	5
Not completed	0	1	0
Other	-	-	-
Progressive Disease	-	-	-
Adverse event	-	1	-
Study terminated by sponsor	-	-	-
Poor Compliance to Protocol	-	-	-
Lack of efficacy	-	-	-

Number of subjects in period 1	Part 1: Venglustat 15 mg (ROW)	Part 1: Placebo (Japan only)	Part 1: Venglustat 4 mg (Japan only)
Started	4	3	3
Treated	4	3	3
Completed	3	3	3
Not completed	1	0	0
Other	-	-	-
Progressive Disease	-	-	-
Adverse event	1	-	-
Study terminated by sponsor	-	-	-
Poor Compliance to Protocol	-	-	-

Lack of efficacy	-	-	-

Number of subjects in period 1	Part 1: Venglustat 8 mg (Japan only)	Part 1: Venglustat 15 mg (Japan only)	Part 2, DB period: Placebo
Started	3	3	111
Treated	3	3	111
Completed	3	3	99
Not completed	0	0	12
Other	-	-	6
Progressive Disease	-	-	-
Adverse event	-	-	6
Study terminated by sponsor	-	-	-
Poor Compliance to Protocol	-	-	-
Lack of efficacy	-	-	-

Number of subjects in period 1	Part 2, DB period: Venglustat 15 mg	Part 2, DB period: Placebo (Re-randomised from Part 1)	Part 2, DB Period: Venglustat 15mg (Re-randomised From Part 1)
Started	110	10	13
Treated	110	10	13
Completed	85	10	13
Not completed	25	0	0
Other	10	-	-
Progressive Disease	-	-	-
Adverse event	15	-	-
Study terminated by sponsor	-	-	-
Poor Compliance to Protocol	-	-	-
Lack of efficacy	-	-	-

Number of subjects in period 1	Part 2, LTFU Period: Placebo Then Venglustat 15 mg	Part 2, LTFU Period: Venglustat 15 mg	Part 2,LTFU:Placebo Then Veng 15mg (Re-randomised From Part 1)
Started	99	85	10
Treated	87	75	10
Completed	0	0	0
Not completed	99	85	10
Other	13	8	3
Progressive Disease	7	4	-
Adverse event	10	4	-
Study terminated by sponsor	67	64	7
Poor Compliance to Protocol	1	4	-
Lack of efficacy	1	1	-

Number of subjects in period 1	Part 2, LTFU: Venglustat 15 mg

	(Re-randomised From Part 1)
Started	11
Treated	11
Completed	0
Not completed	11
Other	2
Progressive Disease	1
Adverse event	-
Study terminated by sponsor	8
Poor Compliance to Protocol	-
Lack of efficacy	-

Baseline characteristics

Reporting groups	
Reporting group title	Overall Study

Reporting group description: -

Reporting group values	Overall Study	Total	
Number of subjects	250	250	
Age categorical Units: Subjects			
Age continuous Units: years			
arithmetic mean	58.7		
standard deviation	± 9.1	-	
Gender categorical Units: Subjects			
Female	97	97	
Male	153	153	
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	
Asian	29	29	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	0	0	
White	221	221	
More than one race	0	0	
Unknown or Not Reported	0	0	

End points

End points reporting groups

Reporting group title	Part 1: Placebo (ROW)
Reporting group description:	
Subjects from rest of world (ROW, except Japan), received placebo (matched to venglustat) capsule orally once daily (QD) for up to 36 weeks in Part 1.	
Reporting group title	Part 1: Venglustat 4 mg (ROW)
Reporting group description:	
Subjects from ROW (except Japan), received venglustat 4 milligrams (mg) capsule orally QD for up to 36 weeks in Part 1.	
Reporting group title	Part 1: Venglustat 8 mg (ROW)
Reporting group description:	
Subjects from ROW (except Japan), received venglustat 8 mg capsule orally QD for up to 36 weeks in Part 1.	
Reporting group title	Part 1: Venglustat 15 mg (ROW)
Reporting group description:	
Subjects from ROW (except Japan), received venglustat 15 mg capsule orally QD for up to 36 weeks in Part 1.	
Reporting group title	Part 1: Placebo (Japan only)
Reporting group description:	
Japanese subjects received placebo (matched to venglustat) capsule orally QD for up to 52 weeks in Part 1.	
Reporting group title	Part 1: Venglustat 4 mg (Japan only)
Reporting group description:	
Japanese subjects received venglustat 4 mg capsule orally QD for up to 52 weeks in Part 1.	
Reporting group title	Part 1: Venglustat 8 mg (Japan only)
Reporting group description:	
Japanese subjects received venglustat 8 mg capsule orally QD for up to 52 weeks in Part 1.	
Reporting group title	Part 1: Venglustat 15 mg (Japan only)
Reporting group description:	
Japanese subjects received venglustat 15 mg capsule orally QD for up to 52 weeks in Part 1.	
Reporting group title	Part 2, DB period: Placebo
Reporting group description:	
Subjects received placebo (matched to venglustat) capsule orally QD for 52 weeks in Part 2 DB period.	

Reporting group title	Part 2, DB period: Venglustat 15 mg
Reporting group description:	
Subjects received venglustat 15 mg capsule orally QD for 52 weeks in Part 2 DB period.	

Reporting group title	Part 2, DB period: Placebo (Re-randomised from Part 1)
Reporting group description:	
Subjects who completed Part 1 with placebo (matched to venglustat) or venglustat 4/8/15 mg, met eligibility criteria for Part 2 and agreed to continue in the study, were re-randomised to receive placebo (matched to venglustat) capsule orally QD for 52 weeks in Part 2 DB period.	
Reporting group title	Part 2, DB Period: Venglustat 15mg (Re-randomised From Part 1)
Reporting group description:	
Subjects who completed Part 1 with placebo (matched to venglustat) or venglustat 4/8/15 mg, met eligibility criteria for Part 2 and agreed to continue in the study, were re-randomised to receive venglustat 15 mg capsule orally QD for 52 weeks in Part 2 DB period.	
Reporting group title	Part 2, LTFU Period: Placebo Then Venglustat 15 mg
Reporting group description:	
Subjects who were enrolled in the study in Part 2, received placebo (matched to venglustat), completed Part 2 DB period, entered long-term follow-up (LTFU) period to receive venglustat 15 mg capsule orally	

QD for 156 weeks.

Reporting group title	Part 2, LTFU Period: Venglustat 15 mg

Reporting group description:

Subjects who were enrolled in the study in Part 2, received venglustat 15 mg, completed Part 2 DB period, entered LTFU period to receive venglustat 15 mg capsule orally QD for 156 weeks.

Reporting group title	Part 2,LTFU:Placebo Then Veng 15mg (Re-randomised From Part 1)

Reporting group description:

Subjects from Part 1 who were re-randomised in the study in Part 2, received placebo (matched to venglustat) and completed Part 2 DB period, entered LTFU period to receive venglustat (Veng) 15 mg capsule orally QD for 156 weeks.

Reporting group title	Part 2, LTFU: Venglustat 15 mg (Re-randomised From Part 1)

Reporting group description:

Subjects from Part 1 who were re-randomised in the study in Part 2, received venglustat 15 mg and completed Part 2 DB period, entered LTFU period to receive venglustat 15 mg capsule orally QD for 156 weeks.

Primary: Part 1: Number of Subjects With Treatment-Emergent Adverse Events (TEAEs), and Treatment-Emergent Serious Adverse Events (TESAEs)

End point title	Part 1: Number of Subjects With Treatment-Emergent Adverse Events (TEAEs), and Treatment-Emergent Serious Adverse Events (TESAEs)[1][2]

End point description:

Adverse event (AE): defined as any untoward medical occurrence in a subject who received study drug and does not necessarily had to have a causal relationship with treatment. Serious AEs (SAEs): any untoward medical occurrence that resulted in any of the following outcomes: death, life-threatening, required initial or prolonged in-patient hospitalisation, persistent or significant disability/incapacity, congenital anomaly/birth defect, or considered as medically important event. TEAEs were the AEs that developed or worsened or became serious during the TEAE period (defined as period from the time of 1st investigational medicinal product [IMP] administration up of 6 weeks after last administration of IMP). Analysed on safety population which included both non-Japanese (ROW) and Japanese subjects who received at least 1 dose of study medication in Part 1 of study. This endpoint was planned to be analysed and reported for Part 1 only and not for Part 2, as pre-specified in the protocol.

End point type	Primary

End point timeframe:

From the first IMP administration up to 6 weeks after the last administration of the IMP (i.e., up to 42 weeks for ROW and up to 58 weeks for Japanese subjects)

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: As the endpoint was descriptive in nature, no statistical analysis was provided.

[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was reported for all applicable arms in the study.

End point values	Part 1: Placebo (ROW)	Part 1: Venglustat 4 mg (ROW)	Part 1: Venglustat 8 mg (ROW)	Part 1: Venglustat 15 mg (ROW)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	4
Units: subjects				
Any TEAE	4	4	4	4
Any TESAE	0	0	0	0

End point values	Part 1: Placebo (Japan only)	Part 1: Venglustat 4 mg (Japan only)	Part 1: Venglustat 8 mg (Japan only)	Part 1: Venglustat 15 mg (Japan only)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: subjects				
Any TEAE	2	3	3	2
Any TESAE	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of Subjects With Abnormal Physical Examination Findings

End point title	Part 1: Number of Subjects With Abnormal Physical Examination Findings[3][4]

End point description:

Physical examination included following observations/measurements: general appearance; heart, skin, respiratory auscultation; head, eyes, ears, nose, and throat, extremities/joints, and abdomen. New onset of abnormal physical examination was defined as a normal physical examination at Baseline and an abnormal physical examination during the treatment-emergent (TE) period (defined as the period from the time of first IMP administration up of 6 weeks after the last administration of the IMP). Abnormalities in physical examination were based on investigator's evaluation. Analysis was performed on safety population. This endpoint was planned to be analysed and reported for Part 1 only and not for Part 2, as pre-specified in the protocol.

End point type	Primary

End point timeframe:

From the first IMP administration up to 6 weeks after the last administration of the IMP (i.e., up to 42 weeks for ROW and up to 58 weeks for Japanese subjects)

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: As the endpoint was descriptive in nature, no statistical analysis was provided.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was reported for all applicable arms in the study.

End point values	Part 1: Placebo (ROW)	Part 1: Venglustat 4 mg (ROW)	Part 1: Venglustat 8 mg (ROW)	Part 1: Venglustat 15 mg (ROW)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	4
Units: subjects	0	0	1	2

End point values	Part 1: Placebo (Japan only)	Part 1: Venglustat 4 mg (Japan only)	Part 1: Venglustat 8 mg (Japan only)	Part 1: Venglustat 15 mg (Japan only)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: subjects	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of Subjects With Abnormal Neurological Examination Findings

End point title	Part 1: Number of Subjects With Abnormal Neurological Examination Findings[5][6]

End point description:

Neurological examination included at least assessments of the subject's cranial nerves, motor system (including muscle atrophy, tone, and power), mental status, deep tendon reflex, sensation, and cerebellar function. Abnormalities in neurological examination were based on investigator's evaluation. Analysis was performed on safety population. This endpoint was planned to be analysed and reported for Part 1 only and not for Part 2, as pre-specified in the protocol.

End point type	Primary

End point timeframe:

From the first IMP administration up to 6 weeks after the last administration of the IMP (i.e., up to 42 weeks for ROW and up to 58 weeks for Japanese subjects)

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: As the endpoint was descriptive in nature, no statistical analysis was provided.

[6] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was reported for all applicable arms in the study.

End point values	Part 1: Placebo (ROW)	Part 1: Venglustat 4 mg (ROW)	Part 1: Venglustat 8 mg (ROW)	Part 1: Venglustat 15 mg (ROW)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	4
Units: subjects				
Abnormal cranial nerve examination	1	1	1	2
Abnormal motor examination	3	4	4	3
Abnormal strength examination	1	4	3	3
Abnormal reflex examination	0	1	1	1
Abnormal sensory examination	0	2	0	1
Abnormal coordination examination	2	1	1	3
Abnormal gait and coordination	3	4	4	2

End point values	Part 1: Placebo (Japan only)	Part 1: Venglustat 4 mg (Japan only)	Part 1: Venglustat 8 mg (Japan only)	Part 1: Venglustat 15 mg (Japan only)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: subjects				

Abnormal cranial nerve examination	1	3	3	2
Abnormal motor examination	3	3	3	3
Abnormal strength examination	1	2	2	1
Abnormal reflex examination	0	2	2	0
Abnormal sensory examination	0	1	0	0
Abnormal coordination examination	1	0	1	2
Abnormal gait and coordination	3	2	2	2

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of Subjects With Potentially Clinically Significant Laboratory Abnormalities: Hematology

End point title	Part 1: Number of Subjects With Potentially Clinically Significant Laboratory Abnormalities: Hematology[7][8]

End point description:

Criteria for potentially clinically significant abnormalities (PCSA): Hemoglobin: less than or equal to (<=) 115 grams per litre (g/L) (Male[M]) or <=95 g/L (Female[F]), greater than or equal to (>=) 185 g/L (M) or >=165 g/L (F), Decrease from baseline (DFB) >=20 g/L; Hematocrit: <=0.37 v/v (M) or <=0.32 v/v (F), >=0.55 v/v (M) or >=0.5 v/v (F); Red blood cells (RBC): >=6 Tera/L; Platelets: less than (<) 100 Giga/L, >=700 Giga/L; White blood cells (WBC): <3.0 Giga/L (Non-Black [NB]) or <2.0 Giga/L (Black [B]), >=16.0 Giga/L; Neutrophils: <1.5 Giga/L (NB) or <1.0 Giga/L (B); Lymphocytes: <lower limit of normal (LLN), greater than (>) 4.0 Giga/L; Monocytes: <LLN, >0.7 Giga/L; Basophils: >0.1 Giga/L; Eosinophils: >0.5 Giga/L or >upper limit of normal (ULN) (if ULN >=0.5 Giga/L). Analysis was performed on safety population. This endpoint was planned to be analysed and reported for Part 1 only and not for Part 2, as pre-specified in the protocol.

End point type	Primary

End point timeframe:

From the first IMP administration up to 6 weeks after the last administration of the IMP (i.e., up to 42 weeks for ROW and up to 58 weeks for Japanese subjects)

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: As the endpoint was descriptive in nature, no statistical analysis was provided.

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was reported for all applicable arms in the study.

End point values	Part 1: Placebo (ROW)	Part 1: Venglustat 4 mg (ROW)	Part 1: Venglustat 8 mg (ROW)	Part 1: Venglustat 15 mg (ROW)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	4
Units: subjects				
Hemoglobin <= 115 g/L (M); <=95 g/L (F)	0	0	0	0
Hemoglobin >=185 g/L (M) or >=165 g/L (F)	0	0	0	0
Hemoglobin DFB >=20 g/L	1	0	1	1
Hematocrit: <=0.37 v/v (M) or <=0.32 v/v (F)	0	0	1	2
Hematocrit: >=0.55 v/v (M); >=0.5 v/v (F)	0	0	0	0
RBC: >=6 Tera/L	0	0	0	0

Platelets: <100 Giga/L	0	0	1	0
Platelets: >=700 Giga/L	0	0	0	0
WBC: <3.0 Giga/L (NB) or <2.0 Giga/L (B)	0	0	0	0
WBC: >=16.0 Giga/L	0	0	0	0
Neutrophils <1.5 Giga/L (NB) or <1.0 Giga/L (B)	0	0	0	0
Lymphocytes: <LLN	0	1	0	0
Lymphocytes: >4.0 Giga/L	0	0	0	0
Monocytes: <LLN	0	0	0	0
Monocytes: >0.7 Giga/L	0	0	2	0
Basophils: >0.1 Giga/L	0	0	0	0
Eosinophils >0.5 Giga/L or >ULN (ULN >=0.5Giga/L)	0	0	0	0

End point values	Part 1: Placebo (Japan only)	Part 1: Venglustat 4 mg (Japan only)	Part 1: Venglustat 8 mg (Japan only)	Part 1: Venglustat 15 mg (Japan only)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: subjects				
Hemoglobin <= 115 g/L (M); <=95 g/L (F)	0	0	0	0
Hemoglobin >=185 g/L (M) or >=165 g/L (F)	0	0	0	0
Hemoglobin DFB >=20 g/L	0	0	0	1
Hematocrit: <=0.37 v/v (M) or <=0.32 v/v (F)	0	0	0	0
Hematocrit: >=0.55 v/v (M); >=0.5 v/v (F)	0	0	0	0
RBC: >=6 Tera/L	0	0	0	0
Platelets: <100 Giga/L	0	0	0	0
Platelets: >=700 Giga/L	0	0	0	0
WBC: <3.0 Giga/L (NB) or <2.0 Giga/L (B)	0	0	0	0
WBC: >=16.0 Giga/L	0	0	0	0
Neutrophils <1.5 Giga/L (NB) or <1.0 Giga/L (B)	0	0	0	0
Lymphocytes: <LLN	0	0	1	0
Lymphocytes: >4.0 Giga/L	0	0	0	0
Monocytes: <LLN	0	0	0	0
Monocytes: >0.7 Giga/L	0	0	0	0
Basophils: >0.1 Giga/L	0	0	0	0
Eosinophils >0.5 Giga/L or >ULN (ULN >=0.5Giga/L)	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of Subjects With Potentially Clinically Significant Laboratory Abnormalities: Liver Function Parameters

End point title	Part 1: Number of Subjects With Potentially Clinically Significant Laboratory Abnormalities: Liver Function Parameters[9][10]

End point description:

Criteria for PCSA: Alanine Aminotransferase (ALT): >3 ULN, >5 ULN; Aspartate aminotransferase (AST): >3*ULN; Alkaline phosphatase (ALP): >1.5*ULN; Total Bilirubin: >1.5 ULN; ALT and Bilirubin: >3 ULN and >2 ULN; Direct Bilirubin (DB) and Bilirubin: >35% and >1.5 ULN. Analysis was performed on safety population. This endpoint was planned to be analysed and reported for Part 1 only and not for Part 2, as pre-specified in the protocol.

End point type	Primary

End point timeframe:

From the first IMP administration up to 6 weeks after the last administration of the IMP (i.e., up to 42 weeks for ROW and up to 58 weeks for Japanese subjects)

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: As the endpoint was descriptive in nature, no statistical analysis was provided.

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was reported for all applicable arms in the study.

End point values	Part 1: Placebo (ROW)	Part 1: Venglustat 4 mg (ROW)	Part 1: Venglustat 8 mg (ROW)	Part 1: Venglustat 15 mg (ROW)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	4
Units: subjects				
ALT >3 ULN	0	0	0	0
ALT >5 ULN	0	0	0	0
AST >3 ULN	0	0	0	0
AST >5 ULN	0	0	0	0
ALP >1.5 ULN	0	0	0	0
Total Bilirubin > 1.5 ULN	0	0	0	0
ALT and Bilirubin: >3 ULN and >2 ULN	0	0	0	0
DB and B: >35% and >1.5 ULN	0	0	0	0

End point values	Part 1: Placebo (Japan only)	Part 1: Venglustat 4 mg (Japan only)	Part 1: Venglustat 8 mg (Japan only)	Part 1: Venglustat 15 mg (Japan only)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: subjects				
ALT >3 ULN	1	0	1	0
ALT >5 ULN	0	0	0	0
AST >3 ULN	1	0	0	0
AST >5 ULN	0	0	0	0
ALP >1.5 ULN	1	0	0	0
Total Bilirubin > 1.5 ULN	0	0	0	0
ALT and Bilirubin: >3 ULN and >2 ULN	0	0	0	0
DB and B: >35% and >1.5 ULN	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of Subjects With Potentially Clinically Significant Laboratory Abnormalities: Renal Parameters

End point title	Part 1: Number of Subjects With Potentially Clinically Significant Laboratory Abnormalities: Renal Parameters[11][12]

End point description:

Criteria for PCSA: Creatinine: >=150 micromoles per litre (mcmol/L) (adults [A]), >=30% change from baseline, >=100% change from baseline; Blood urea nitrogen (BUN): >=17 millimoles (mmol)/L. Analysis was performed on safety population. This endpoint was planned to be analysed and reported for Part 1 only and not for Part 2, as pre-specified in the protocol.

End point type	Primary

End point timeframe:

From the first IMP administration up to 6 weeks after the last administration of the IMP (i.e., up to 42 weeks for ROW and up to 58 weeks for Japanese subjects)

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: As the endpoint was descriptive in nature, no statistical analysis was provided.

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was reported for all applicable arms in the study.

End point values	Part 1: Placebo (ROW)	Part 1: Venglustat 4 mg (ROW)	Part 1: Venglustat 8 mg (ROW)	Part 1: Venglustat 15 mg (ROW)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	4
Units: subjects				
Creatinine >=150 mcmol/L (A)	0	0	0	0
Creatinine >=30% change from baseline	0	0	0	0
Creatinine >=100% change from baseline	0	0	0	0
BUN >=17 mmol/L	0	0	0	0

End point values	Part 1: Placebo (Japan only)	Part 1: Venglustat 4 mg (Japan only)	Part 1: Venglustat 8 mg (Japan only)	Part 1: Venglustat 15 mg (Japan only)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: subjects				
Creatinine >=150 mcmol/L (A)	0	0	0	0

Creatinine >=30% change from baseline	0	0	1	0
Creatinine >=100% change from baseline	0	0	0	0
BUN >=17 mmol/L	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of Subjects With Potentially Clinically Significant Laboratory Abnormalities: Metabolic Parameters

End point title	Part 1: Number of Subjects With Potentially Clinically Significant Laboratory Abnormalities: Metabolic Parameters[13][14]

End point description:

Criteria for PCSA: Glucose: <=3.9 mmol/L and <LLN; >=11.1 mmol/L (unfasted [unfas]) or >=7 mmol/L (fasted [fas]); Albumin: <=25 g/L. Analysis was performed on safety population. This endpoint was planned to be analysed and reported for Part 1 only and not for Part 2, as pre-specified in the protocol.

End point type	Primary

End point timeframe:

From the first IMP administration up to 6 weeks after the last administration of the IMP (i.e., up to 42 weeks for ROW and up to 58 weeks for Japanese subjects)

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: As the endpoint was descriptive in nature, no statistical analysis was provided.

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was reported for all applicable arms in the study.

End point values	Part 1: Placebo (ROW)	Part 1: Venglustat 4 mg (ROW)	Part 1: Venglustat 8 mg (ROW)	Part 1: Venglustat 15 mg (ROW)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	4
Units: subjects				
Glucose <=3.9 mmol/L and <LLN	0	0	0	0
Glucose >=11.1 mmol/L (unfas) or >=7 mmol/L (fas)	0	0	0	0
Albumin <=25 g/L	0	0	0	0

End point values	Part 1: Placebo (Japan only)	Part 1: Venglustat 4 mg (Japan only)	Part 1: Venglustat 8 mg (Japan only)	Part 1: Venglustat 15 mg (Japan only)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: subjects				
Glucose <=3.9 mmol/L and <LLN	0	0	0	0

Glucose >=11.1 mmol/L (unfas) or >=7 mmol/L (fas)	0	1	0	0
Albumin <=25 g/L	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of Subjects With Potentially Clinically Significant Laboratory Abnormalities: Electrolytes Parameters

End point title	Part 1: Number of Subjects With Potentially Clinically Significant Laboratory Abnormalities: Electrolytes Parameters[15][16]

End point description:

Criteria for PCSA: Sodium: <=129 mmol/L, >=160 mmol/L; Potassium: <3 mmol/L, >=5.5 mmol/L and Chloride: <80 mmol/L, >115 mmol/L. Analysis was performed on safety population. This endpoint was planned to be analysed and reported for Part 1 only and not for Part 2, as pre-specified in the protocol.

End point type	Primary

End point timeframe:

From the first IMP administration up to 6 weeks after the last administration of the IMP (i.e., up to 42 weeks for ROW and up to 58 weeks for Japanese subjects)

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: As the endpoint was descriptive in nature, no statistical analysis was provided.

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was reported for all applicable arms in the study.

End point values	Part 1: Placebo (ROW)	Part 1: Venglustat 4 mg (ROW)	Part 1: Venglustat 8 mg (ROW)	Part 1: Venglustat 15 mg (ROW)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	4
Units: subjects				
Sodium <=129 mmol/L	0	0	0	0
Sodium >=160 mmol/L	0	0	0	0
Potassium <3 mmol/L	0	0	0	0
Potassium >=5.5 mmol/L	0	0	0	0
Chloride <80 mmol/L	0	0	0	0
Chloride >115 mmol/L	0	0	0	0

End point values	Part 1: Placebo (Japan only)	Part 1: Venglustat 4 mg (Japan only)	Part 1: Venglustat 8 mg (Japan only)	Part 1: Venglustat 15 mg (Japan only)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: subjects				

Sodium <=129 mmol/L	0	0	0	0
Sodium >=160 mmol/L	0	0	0	0
Potassium <3 mmol/L	0	0	0	0
Potassium >=5.5 mmol/L	0	0	0	0
Chloride <80 mmol/L	0	0	0	0
Chloride >115 mmol/L	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of Subjects With Potentially Clinically Significant Vital Signs Abnormalities

End point title	Part 1: Number of Subjects With Potentially Clinically Significant Vital Signs Abnormalities[17][18]

End point description:

Criteria for PCSA: Systolic blood pressure (SBP) supine: <=95 millimetres of mercury (mmHg) and DFB >=20 mmHg; >=160 mmHg and increase from baseline (IFB) >=20 mmHg; Diastolic blood pressure (DBP) supine: <=45 mmHg and DFB >=10 mmHg; >=110 mmHg and IFB >=10 mmHg; SBP (Orthostatic): <=-20 mmHg; DBP (Orthostatic): <=-10 mmHg; Heart rate (HR) supine: <=50 beats per minute (bpm) and DFB >=20 bpm; >=120 bpm and IFB >=20 bpm; Weight: >=5% DFB; >=5% IFB. Analysis was performed on safety population. This endpoint was planned to be analysed and reported for Part 1 only and not for Part 2, as pre-specified in the protocol.

End point type	Primary

End point timeframe:

From the first IMP administration up to 6 weeks after the last administration of the IMP (i.e., up to 42 weeks for ROW and up to 58 weeks for Japanese subjects)

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: As the endpoint was descriptive in nature, no statistical analysis was provided.

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was reported for all applicable arms in the study.

End point values	Part 1: Placebo (ROW)	Part 1: Venglustat 4 mg (ROW)	Part 1: Venglustat 8 mg (ROW)	Part 1: Venglustat 15 mg (ROW)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	4
Units: subjects				
SBP (supine) <=95 mmHg and DFB >=20 mmHg	0	0	1	0
SBP (supine) >=160 mmHg and IFB >=20 mmHg	0	0	0	2
DBP (supine) <=45 mmHg and DFB >=10 mmHg	0	0	0	0
DBP (supine) >=110 mmHg and IFB >=10 mmHg	0	0	0	0
SBP (Orthostatic): <=-20 mmHg	0	0	0	0
DBP (Orthostatic): <=-10 mmHg	0	0	0	0
HR (supine) <=50 bpm and DFB >= 20 bpm	0	0	0	0

HR (supine) >=120 bpm and IFB >=20 bpm	0	0	0	0
Weight >=5% DFB	0	0	1	0
Weight >=5% IFB	1	0	1	0

End point values	Part 1: Placebo (Japan only)	Part 1: Venglustat 4 mg (Japan only)	Part 1: Venglustat 8 mg (Japan only)	Part 1: Venglustat 15 mg (Japan only)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: subjects				
SBP (supine) <=95 mmHg and DFB >=20 mmHg	0	0	2	0
SBP (supine) >=160 mmHg and IFB >=20 mmHg	0	0	0	0
DBP (supine) <=45 mmHg and DFB >=10 mmHg	0	0	0	0
DBP (supine) >=110 mmHg and IFB >=10 mmHg	0	0	0	0
SBP (Orthostatic): <=-20 mmHg	0	0	0	0
DBP (Orthostatic): <=-10 mmHg	0	0	0	0
HR (supine) <=50 bpm and DFB >= 20 bpm	0	0	0	0
HR (supine) >=120 bpm and IFB >=20 bpm	0	0	0	0
Weight >=5% DFB	0	0	0	0
Weight >=5% IFB	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of Subjects With Potentially Clinically Significant Ophthalmological Abnormalities

End point title	Part 1: Number of Subjects With Potentially Clinically Significant Ophthalmological Abnormalities[19][20]

End point description:

Clinically significant observations in left eye, right eye and any eye were assessed by the investigator based on methods like visual acuity, slit lamp examination, examination of the cornea, lens, and retina. Any abnormal ophthalmological examination finding (which was present at screening or not) on any eye during the treatment-emergent period corresponded to cornea verticillata, cataract and abnormal overall evaluation. Analysis was performed on safety population. This endpoint was planned to be analysed and reported for Part 1 only and not for Part 2, as pre-specified in the protocol.

End point type	Primary

End point timeframe:

From the first IMP administration up to 6 weeks after the last administration of the IMP (i.e., up to 42 weeks for ROW and up to 58 weeks for Japanese subjects)

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: As the endpoint was descriptive in nature, no statistical analysis was provided.

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was reported for all applicable arms in the study.

End point values	Part 1: Placebo (ROW)	Part 1: Venglustat 4 mg (ROW)	Part 1: Venglustat 8 mg (ROW)	Part 1: Venglustat 15 mg (ROW)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	4
Units: subjects				
Any eye	3	3	4	2
Right eye	3	3	4	2
Left eye	3	3	4	2

End point values	Part 1: Placebo (Japan only)	Part 1: Venglustat 4 mg (Japan only)	Part 1: Venglustat 8 mg (Japan only)	Part 1: Venglustat 15 mg (Japan only)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: subjects				
Any eye	2	3	3	0
Right eye	2	2	3	0
Left eye	2	3	3	0

Statistical analyses

No statistical analyses for this end point

Primary: Part 1: Number of Subjects With Potentially Clinically Significant Electrocardiogram Abnormalities

End point title	Part 1: Number of Subjects With Potentially Clinically Significant Electrocardiogram Abnormalities[21][22]

End point description:

Criteria for PCSA: HR: <50 bpm; <50 bpm and DFB >=20 bpm, <40 bpm; >90 bpm, >90 bpm and IFB >=20 bpm, >100 bpm; PR Interval (Int): >200 milliseconds (msec), >200 msec and IFB >=25%, >220 msec; QRS Interval: >110 msec, >110 msec and IFB >=25%, >120 msec; QT Interval: >500 msec; QTc Bazett (QTcB) interval: >450 msec, >480 msec, IFB >30 and <=60 msec, IFB >60 msec; QTc Fridericia (QTc F): >450 msec, >480 msec, IFB >30 and <=60 msec, IFB >60 msec. Analysis was performed on safety population. This endpoint was planned to be analysed and reported for Part 1 only and not for Part 2, as pre-specified in the protocol.

End point type	Primary

End point timeframe:

From the first IMP administration up to 6 weeks after the last administration of the IMP (i.e., up to 42 weeks for ROW and up to 58 weeks for Japanese subjects)

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: As the endpoint was descriptive in nature, no statistical analysis was provided.

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all

the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was reported for all applicable arms in the study.

End point values	Part 1: Placebo (ROW)	Part 1: Venglustat 4 mg (ROW)	Part 1: Venglustat 8 mg (ROW)	Part 1: Venglustat 15 mg (ROW)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	4	4	5	4
Units: subjects				
HR: <50 bpm	0	1	1	0
HR: <50 bpm and DFB >=20 bpm	0	0	0	0
HR: <40 bpm	0	0	0	0
HR: >90 bpm	0	0	0	0
HR: >90 bpm and IFB >=20 bpm	0	0	0	0
HR: >100 bpm	0	0	0	0
PR Int: >200 msec	0	0	0	0
PR Int:>200 msec and IFB >=25%	0	0	0	0
PR Int: >220 msec	0	0	0	0
QRS Int: >110 msec	0	1	1	1
QRS Int:>110 msec and IFB >=25%	0	0	0	0
QRS Int: >120 msec	0	0	1	0
QT Int: >500 msec	0	0	0	0
QTcB Int: >450 msec	0	0	1	0
QTcB Int: >480 msec	0	0	0	0
QTcB Int:IFB >30 and <=60 msec	0	0	1	0
QTcB Int: IFB >60 msec	0	0	0	0
QTc F: >450 msec	0	0	1	0
QTc F: >480 msec	0	0	0	0
QTc F: IFB >30 and <=60 msec	0	0	1	0
QTc F: IFB >60 msec	0	0	0	0

End point values	Part 1: Placebo (Japan only)	Part 1: Venglustat 4 mg (Japan only)	Part 1: Venglustat 8 mg (Japan only)	Part 1: Venglustat 15 mg (Japan only)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	3	3	3	3
Units: subjects				
HR: <50 bpm	1	0	0	0
HR: <50 bpm and DFB >=20 bpm	0	0	0	0
HR: <40 bpm	0	0	0	0
HR: >90 bpm	0	0	1	1
HR: >90 bpm and IFB >=20 bpm	0	0	0	0
HR: >100 bpm	0	0	0	0
PR Int: >200 msec	0	2	0	0
PR Int:>200 msec and IFB >=25%	0	0	0	0
PR Int: >220 msec	0	0	0	0
QRS Int: >110 msec	0	0	0	0
QRS Int:>110 msec and IFB >=25%	0	0	0	0
QRS Int: >120 msec	0	0	0	0

QT Int: >500 msec	0	0	0	0
QTcB Int: >450 msec	0	0	0	0
QTcB Int: >480 msec	0	0	0	0
QTcB Int:IFB >30 and <=60 msec	0	0	0	1
QTcB Int: IFB >60 msec	0	0	0	0
QTc F: >450 msec	0	0	0	0
QTc F: >480 msec	0	0	0	0
QTc F: IFB >30 and <=60 msec	0	0	0	1
QTc F: IFB >60 msec	0	0	0	0

Statistical analyses

No statistical analyses for this end point

Primary: Part 2: Change From Baseline to Week 52 in Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part II+III Total Score

End point title	Part 2: Change From Baseline to Week 52 in Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) Part II+III Total Score[23]

End point description:

MDS-UPDRS:multimodal scale consisting of 4 parts. Part II assessed motor experiences of daily living (total score range:0 to 52). It contained 13 questions completed by subject. Part III assessed motor signs of PD and was administered by rater (total score range:0 to 132). Part III had 33 scores based on 18 items. In both parts, higher score=more severe symptoms. For each question in both parts, numeric score was assigned between 0 to 4, where 0=Normal, 1=Slight, 2=Mild, 3=Moderate, 4=Severe. MDS-UPDRS Total Part II and III score=sum of Part II and III scores with score ranged from 0 (no symptom) to 184 (severe symptoms), where higher scores=more severe symptoms of PD. This endpoint was not planned to be collected and analysed for Part 1, Part 2 DB period re-randomised subjects and Part 2 LTFU period, as pre-specified in the protocol. Intent-to-treat population:all randomised subjects of Part 2 and analysed in randomised treatment group. number of subjects analysed=subjects evaluable.

End point type	Primary

End point timeframe:

Baseline to Week 52

Notes:

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was reported for all applicable arms in the study.

End point values	Part 2, DB period: Placebo	Part 2, DB period: Venglustat 15 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	95	81		
Units: units on a scale				
least squares mean (standard error)	4.71 (± 1.27)	7.29 (± 1.36)		

Statistical analyses

Statistical analysis title	Part 2 DB period: Venglustat 15mg versus Placebo

Statistical analysis description:

Least-squares (LS) mean, standard errors (SE) and p-value were estimated from mixed-effect model with repeated measures (MMRM) analysis which included fixed categorical effects of treatment group, randomisation strata, time point, treatment-by-time point and strata-by-time point interaction and continuous fixed covariates Baseline value and Baseline value-by-time point interaction.

Comparison groups	Part 2, DB period: Venglustat 15 mg v Part 2, DB period: Placebo
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.1679 [24]
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	2.58
Confidence interval	
level	95 %
sides	2-sided
lower limit	-1.1
upper limit	6.27
Variability estimate	Standard error of the mean
Dispersion value	1.87

Notes:

[24] - The threshold for statistical significance was 0.05.

Secondary: Part 2: Change From Baseline to Week 52 in Parkinson's Disease Cognitive Rating Scale (PD-CRS) Total score

End point title	Part 2: Change From Baseline to Week 52 in Parkinson's Disease Cognitive Rating Scale (PD-CRS) Total score[25]

End point description:

PD-CRS detects early cognitive impairment in Parkinson's disease. It is composed of 2 scales, fronto-subcortical scale (items: sustained attention, working memory, alternating and action verbal fluency, clock drawing, immediate and delayed free recall verbal memory) and posterior-cortical scale (items: confrontation naming and clock copying). Total score of fronto-subcortical scale (sum of all items) ranged from 0 (worst) to 104 (maximum score indicates better) and total score of posterior-cortical scale (sum of all items) ranged from 0 (worst) to 30 (maximum score indicates better). PD-CRS Total score=sum of PD-CRS fronto-subcortical score and PDCRS posterior-cortical score, which ranged from 0 to 134, where higher score=less impairment. ITT population. Here, number of subjects analysed=subjects evaluable for this endpoint. This OM was not planned to be collected and analysed for Part 1, Part 2 DB period re-randomised subjects and Part 2 LTFU period, as pre-specified in the protocol.

End point type	Secondary

End point timeframe:

Baseline to Week 52

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was reported for all applicable arms in the study.

End point values	Part 2, DB period: Placebo	Part 2, DB period: Venglustat 15 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	94	82		
Units: units on a scale				

least squares mean (standard error)	0.32 (± 1.27)	-0.65 (± 1.35)		

Statistical analyses

Statistical analysis title	Part 2 DB period: Venglustat 15mg versus Placebo

Statistical analysis description:

LS mean, SE and P-value were estimated from MMRM analysis which included fixed categorical effects of treatment group, randomisation strata, time point, treatment-by-time point and strata-by-time point interaction and continuous fixed covariates Baseline value and Baseline value-by-time point interaction.

Comparison groups	Part 2, DB period: Venglustat 15 mg v Part 2, DB period: Placebo
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5996 [26]
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	-0.97
Confidence interval	
level	95 %
sides	2-sided
lower limit	-4.63
upper limit	2.68
Variability estimate	Standard error of the mean
Dispersion value	1.85

Notes:

[26] - The threshold for statistical significance was 0.05.

Secondary: Part 2: Change From Baseline to Week 52 in Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) PART I+ II+III Score

End point title	Part 2: Change From Baseline to Week 52 in Movement Disorder Society-Unified Parkinson's Disease Rating Scale (MDS-UPDRS) PART I+ II+III Score[27]

End point description:

MDS-UPDRS:multimodal scale consists of 4 parts. Part I assessed non-motor experiences of daily living and has 2 components (total score:0to52): Part IA had 6 questions and was assessed by examiner (total score:0to24). Part IB had 7 questions on non-motor experiences of daily living which was completed by subject (total score:0to28). Part II (13 questions completed by subject) assessed motor experiences of daily living (total score:0to52). Part III assessed motor signs of PD and was administered by rater (total score:0to132). Part III had 33 scores based on 18 items. In all parts, higher score=more symptoms. For each question, numeric score range was 0 to 4, where 0=Normal, 1=Slight, 2=Mild, 3=Moderate, 4=Severe. MDS-UPDRS total score=sum of Parts I, II and III (Range:0 to 236). Higher score=more severe symptoms. ITT population. Number of subjects analysed=subjects evaluable. This endpoint was not planned to be collected and analysed for Part 1, Part 2 DB period re-randomised and LTFU.

End point type	Secondary

End point timeframe:

Baseline to Week 52

Notes:

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

Justification: The endpoint was reported for all applicable arms in the study.

End point values	Part 2, DB period: Placebo	Part 2, DB period: Venglustat 15 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	95	81		
Units: units on a scale				
least squares mean (standard error)	5.87 (± 1.45)	9.99 (± 1.55)		

Statistical analyses

Statistical analysis title	Part 2 DB period: Venglustat 15mg versus Placebo

Statistical analysis description:

LS mean, SE and P-value were estimated from MMRM analysis which included fixed categorical effects of treatment group, randomisation strata, time point, treatment-by-time point and strata-by-time point interaction and continuous fixed covariates Baseline value and Baseline value-by-time-interaction.

Comparison groups	Part 2, DB period: Venglustat 15 mg v Part 2, DB period: Placebo
Number of subjects included in analysis	176
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0535 [28]
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	4.13
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.06
upper limit	8.32
Variability estimate	Standard error of the mean
Dispersion value	2.13

Notes:

[28] - The threshold for statistical significance was 0.05.

Secondary: Part 2: Change From Baseline to Week 52 in Hoehn and Yahr (H and Y) Score

End point title	Part 2: Change From Baseline to Week 52 in Hoehn and Yahr (H and Y) Score[29]

End point description:

H and Y scale measured how Parkinson's symptoms progress and the level of disability. Scale allocated stage scores were from 0 to 5 to indicate relative level of disability as: Stage 0: no symptoms; Stage 1: symptoms on one side of the body only; Stage 2: symptoms on both sides of the body, without impairment of balance; Stage 3: Mild to moderate bilateral disease; some postural instability; physically independent; Stage 4: Severe disability; still able to walk or stand unassisted and Stage 5: Wheelchair bound or bedridden unless aided, where higher stage score described an increased severity of disease. Analysis was performed on ITT population. Here, number of subjects analysed = subjects evaluable for this endpoint. Data for this endpoint was not planned to be collected and analysed for Part 1, Part 2 DB period re-randomised subjects and Part 2 LTFU period, as pre-specified in the protocol.

End point type	Secondary

End point timeframe:

Baseline to Week 52

Notes:

[29] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: The endpoint was reported for all applicable arms in the study.

End point values	Part 2, DB period: Placebo	Part 2, DB period: Venglustat 15 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	95	80		
Units: units on a scale				
least squares mean (standard error)	0.18 (± 0.05)	0.20 (± 0.06)		

Statistical analyses

Statistical analysis title	Part 2 DB period: Venglustat 15mg versus Placebo

Statistical analysis description:

LS mean, SE and P-value: estimated from MMRM analysis which included fixed categorical effects of treatment group, randomisation strata, time point, treatment-by-time point and strata-by-time point interaction and continuous fixed covariates Baseline value and Baseline value-by-time-interaction.

Comparison groups	Part 2, DB period: Venglustat 15 mg v Part 2, DB period: Placebo
Number of subjects included in analysis	175
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.74 [30]
Method	MMRM
Parameter estimate	LS mean difference
Point estimate	0.03
Confidence interval	
level	95 %
sides	2-sided
lower limit	-0.12
upper limit	0.17
Variability estimate	Standard error of the mean
Dispersion value	0.08

Notes:

[30] - The threshold for statistical significance was 0.05.

Adverse events information

Timeframe for reporting adverse events:

From the first IMP administration up to 6 weeks after the last administration of the IMP (i.e., in Part 1: up to 42 weeks for ROW, up to 58 weeks for Japanese subjects; in Part 2 DB period: up to 60 weeks; in Part 2 LTFU period: up to 164 weeks)

Adverse event reporting additional description:

Reported AEs and deaths were TEAEs that developed/worsened in grade or became serious during TEAE period (defined as the time from the first dose of the IMP to the last dose of IMP + 6 weeks). Analysis was performed on safety population.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	24.0

Reporting groups

Reporting group title	Part 1: Placebo (ROW)

Reporting group description:

Subjects from rest of world (ROW, except Japan), received placebo (matched to venglustat) capsule orally once daily (QD) for up to 36 weeks in Part 1.

Reporting group title	Part 1: Venglustat 4 mg (ROW)

Reporting group description:

Subjects from ROW (except Japan), received venglustat 4 milligrams (mg) capsule orally QD for up to 36 weeks in Part 1.

Reporting group title	Part 1: Venglustat 8 mg (ROW)

Reporting group description:

Subjects from ROW (except Japan), received venglustat 8 mg capsule orally QD for up to 36 weeks in Part 1.

Reporting group title	Part 1: Venglustat 15 mg (ROW)

Reporting group description:

Subjects from ROW (except Japan), received venglustat 15 mg capsule orally QD for up to 36 weeks in Part 1.

Reporting group title	Part 1: Placebo (Japan only)

Reporting group description:

Japanese subjects received placebo (matched to venglustat) capsule orally QD for up to 52 weeks in Part 1.

Reporting group title	Part 1: Venglustat 4 mg (Japan only)

Reporting group description:

Japanese subjects received venglustat 4 mg capsule orally QD for up to 52 weeks in Part 1.

Reporting group title	Part 1: Venglustat 8 mg (Japan only)

Reporting group description:

Japanese subjects received venglustat 8 mg capsule orally QD for up to 52 weeks in Part 1.

Reporting group title	Part 1: Venglustat 15 mg (Japan only)

Reporting group description:

Japanese subjects received venglustat 15 mg capsule orally QD for up to 52 weeks in Part 1.

Reporting group title	Part 2, DB period: Placebo

Reporting group description:

Subjects received placebo (matched to venglustat) capsule orally QD for 52 weeks in Part 2 DB period.

Reporting group title	Part 2, DB period: Venglustat 15 mg

Reporting group description:

Subjects received venglustat 15 mg capsule orally QD for 52 weeks in Part 2 DB period.

Reporting group title	Part 2, DB period: Placebo (Re-randomised from Part 1)

Reporting group description:

Subjects who completed Part 1 with placebo (matched to venglustat) or venglustat 4/8/15 mg, met eligibility criteria for Part 2 and agreed to continue in the study, were re-randomised to receive placebo (matched to venglustat) capsule orally QD for 52 weeks in Part 2 DB period.

Reporting group title	Part 2,DB period:Venglustat 15 mg (Re-randomised from Part 1)

Reporting group description:

Subjects who completed Part 1 with placebo (matched to venglustat) or venglustat 4/8/15 mg, met eligibility criteria for Part 2 and agreed to continue in the study, were re-randomised to receive venglustat 15 mg capsule orally QD for 52 weeks in Part 2 DB period.

Reporting group title	Part 2, LTFU period: Placebo then Venglustat 15 mg

Reporting group description:

Subjects who were enrolled in the study in Part 2, received placebo (matched to venglustat), completed Part 2 DB period, entered long-term follow-up (LTFU) period to receive venglustat 15 mg capsule orally QD for 156 weeks.

Reporting group title	Part 2, LTFU period: Venglustat 15 mg

Reporting group description:

Subjects who were enrolled in the study in Part 2, received venglustat 15 mg, completed Part 2 DB period, entered LTFU period to receive venglustat 15 mg capsule orally QD for 156 weeks.

Reporting group title	Part 2,LTFU:Placebo then Veng 15mg (Re-randomised from Part 1)

Reporting group description:

Subjects from Part 1 who were re-randomised in the study in Part 2, received placebo (matched to venglustat) and completed Part 2 DB period, entered LTFU period to receive venglustat (Veng) 15 mg capsule orally QD for 156 weeks.

Reporting group title	Part 2, LTFU: Venglustat 15 mg (Re-randomised from Part 1)

Reporting group description:

Subjects from Part 1 who were re-randomised in the study in Part 2, received venglustat 15 mg and completed Part 2 DB period, entered LTFU period to receive venglustat 15 mg capsule orally QD for 156 weeks.

Serious adverse events	Part 1: Placebo (ROW)	Part 1: Venglustat 4 mg (ROW)	Part 1: Venglustat 8 mg (ROW)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Breast Cancer Female			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Malignant Melanoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Malignant Melanoma In Situ			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Non-Small Cell Lung Cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Ovarian Epithelial Cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Prostate Cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Injury, poisoning and procedural complications			
Anastomotic Leak			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Fall			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Femoral Neck Fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Intentional Overdose			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Post Lumbar Puncture Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Postoperative Delirium			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Radius Fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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

Rib Fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Skin Laceration			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Subdural Haematoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Vascular disorders			
Deep Vein Thrombosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Hypertension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Hypertensive Urgency			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Hypotension			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Orthostatic Hypotension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Cardiac disorders			
Atrial Fibrillation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Cardiac Arrest			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Cardio-Respiratory Arrest			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Nervous system disorders			
Cerebellar Haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Cognitive Disorder			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Freezing Phenomenon			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Lumbar Radiculopathy			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
On And Off Phenomenon			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Parkinson's Disease			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Posterior Reversible Encephalopathy Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Syncope			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Transient Ischaemic Attack			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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			
Anaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Gastrointestinal disorders			
Abdominal Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Impaired Gastric Emptying			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Inguinal Hernia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Intestinal Obstruction			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Volvulus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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			
Hypoxia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Pulmonary Embolism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Psychiatric disorders			
Confusional State			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Hallucination			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Psychotic Disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Suicide Attempt			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Renal and urinary disorders			
Acute Kidney Injury			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Micturition Urgency			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Ureterolithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Musculoskeletal and connective tissue disorders			
Back Pain			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Muscle Rigidity			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Spinal Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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			
Abdominal Abscess			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Covid-19			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Colonic Abscess			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Diverticulitis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Osteomyelitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Sepsis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Subacute Endocarditis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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
Urinary Tract Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (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	Part 1: Venglustat 15 mg (ROW)	Part 1: Placebo (Japan only)	Part 1: Venglustat 4 mg (Japan only)
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
number of deaths (all causes)	0	0	0
number of deaths resulting from	0	0	0

adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Breast Cancer Female			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Malignant Melanoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Malignant Melanoma In Situ			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Non-Small Cell Lung Cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Ovarian Epithelial Cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Prostate Cancer			

alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Injury, poisoning and procedural complications			
Anastomotic Leak			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Fall			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Femoral Neck Fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Intentional Overdose			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Post Lumbar Puncture Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Postoperative Delirium			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Radius Fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Rib Fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Skin Laceration			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Subdural Haematoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Vascular disorders			
Deep Vein Thrombosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Hypertension			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Hypertensive Urgency			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Hypotension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Orthostatic Hypotension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Cardiac disorders			
Atrial Fibrillation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Cardiac Arrest			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Cardio-Respiratory Arrest			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Nervous system disorders			
Cerebellar Haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Cognitive Disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Freezing Phenomenon			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Lumbar Radiculopathy			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
On And Off Phenomenon			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Parkinson's Disease			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Posterior Reversible Encephalopathy Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Syncope			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Transient Ischaemic Attack			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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			
Anaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Gastrointestinal disorders			
Abdominal Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Impaired Gastric Emptying			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Inguinal Hernia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Intestinal Obstruction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Volvulus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Pulmonary Embolism			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Psychiatric disorders			
Confusional State			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Hallucination			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Psychotic Disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Suicide Attempt			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Renal and urinary disorders			
Acute Kidney Injury			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Micturition Urgency			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Ureterolithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Musculoskeletal and connective tissue disorders			
Back Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Muscle Rigidity			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Spinal Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Infections and infestations			
Abdominal Abscess			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Covid-19			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Colonic Abscess			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Diverticulitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Osteomyelitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Pneumonia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Sepsis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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
Subacute Endocarditis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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

Urinary Tract Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (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	Part 1: Venglustat 8 mg (Japan only)	Part 1: Venglustat 15 mg (Japan only)	Part 2, DB period: Placebo
Total subjects affected by serious adverse events			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	12 / 111 (10.81%)
number of deaths (all causes)	0	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer Female			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Malignant Melanoma In Situ			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Small Cell Lung Cancer			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Epithelial Cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Prostate Cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Anastomotic Leak			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Fall			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Femoral Neck Fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional Overdose			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Post Lumbar Puncture Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 111 (1.80%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative Delirium			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius Fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Rib Fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Laceration			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Subdural Haematoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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

Vascular disorders			
Deep Vein Thrombosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Hypertensive Urgency			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Hypotension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Orthostatic Hypotension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Cardiac disorders			
Atrial Fibrillation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Cardiac Arrest			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Cardio-Respiratory Arrest			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Nervous system disorders			
Cerebellar Haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Cognitive Disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Freezing Phenomenon			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Radiculopathy			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
On And Off Phenomenon			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Parkinson's Disease			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Posterior Reversible Encephalopathy Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Syncope			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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			
Anaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Gastrointestinal disorders			
Abdominal Pain			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired Gastric Emptying			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Inguinal Hernia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Intestinal Obstruction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Volvulus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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			
Hypoxia			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Pulmonary Embolism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Psychiatric disorders			
Confusional State			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Hallucination			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Psychotic Disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Suicide Attempt			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Renal and urinary disorders			
Acute Kidney Injury			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Micturition Urgency			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Musculoskeletal and connective tissue disorders			
Back Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Muscle Rigidity			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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			
Abdominal Abscess			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Covid-19			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Colonic Abscess			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Diverticulitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Osteomyelitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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
Sepsis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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

Subacute Endocarditis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (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	Part 2, DB period: Venglustat 15 mg	Part 2, DB period: Placebo (Re-randomised from Part 1)	Part 2,DB period:Venglustat 15 mg (Re-randomised from
Total subjects affected by serious adverse events			
subjects affected / exposed	12 / 110 (10.91%)	0 / 10 (0.00%)	3 / 13 (23.08%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer Female			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Malignant Melanoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Malignant Melanoma In Situ			

alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Non-Small Cell Lung Cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Ovarian Epithelial Cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Prostate Cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Injury, poisoning and procedural complications			
Anastomotic Leak			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Fall			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral Neck Fracture			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Intentional Overdose			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Post Lumbar Puncture Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Postoperative Delirium			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Radius Fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Rib Fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Skin Laceration			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Subdural Haematoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Vascular disorders			
Deep Vein Thrombosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Hypertension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Hypertensive Urgency			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic Hypotension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial Fibrillation			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Arrest			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Cardio-Respiratory Arrest			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Nervous system disorders			
Cerebellar Haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (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
Cognitive Disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (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
Freezing Phenomenon			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (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
Lumbar Radiculopathy			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
On And Off Phenomenon			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Parkinson's Disease			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Posterior Reversible Encephalopathy Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (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
Syncope			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 110 (2.73%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	2 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Gastrointestinal disorders			
Abdominal Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Impaired Gastric Emptying			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Obstruction			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Volvulus			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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			
Hypoxia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional State			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Hallucination			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Psychotic Disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Suicide Attempt			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Renal and urinary disorders			
Acute Kidney Injury			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Micturition Urgency			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Ureterolithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Muscle Rigidity			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Spinal Pain			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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			
Abdominal Abscess			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Covid-19			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Colonic Abscess			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subacute Endocarditis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (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
Urinary Tract Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 2, LTFU period: Placebo then Venglustat 15 mg	Part 2, LTFU period: Venglustat 15 mg	Part 2,LTFU:Placebo then Veng 15mg (Re-randomised from Part 1)
Total subjects affected by serious adverse events			
subjects affected / exposed	15 / 87 (17.24%)	9 / 75 (12.00%)	3 / 10 (30.00%)
number of deaths (all causes)	1	0	0
number of deaths resulting from adverse events	0	0	0
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Breast Cancer Female			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Malignant Melanoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (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
Malignant Melanoma In Situ			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-Small Cell Lung Cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ovarian Epithelial Cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate Cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Injury, poisoning and procedural complications			
Anastomotic Leak			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fall			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femoral Neck Fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intentional Overdose			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Post Lumbar Puncture Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative Delirium			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Radius Fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	1 / 75 (1.33%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Rib Fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin Laceration			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural Haematoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep Vein Thrombosis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	1 / 75 (1.33%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive Urgency			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypotension			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic Hypotension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial Fibrillation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	1 / 75 (1.33%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac Arrest			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Cardio-Respiratory Arrest			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nervous system disorders			
Cerebellar Haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive Disorder			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Freezing Phenomenon			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbar Radiculopathy			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	1 / 75 (1.33%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
On And Off Phenomenon			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parkinson's Disease			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 87 (3.45%)	1 / 75 (1.33%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	2 / 4	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Posterior Reversible Encephalopathy Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	2 / 87 (2.30%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transient Ischaemic Attack			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Abdominal Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Impaired Gastric Emptying			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Inguinal Hernia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal Obstruction			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (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
Volvulus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Hypoxia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary Embolism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional State			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	1 / 75 (1.33%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hallucination			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychotic Disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	1 / 75 (1.33%)	0 / 10 (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
Suicide Attempt			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Acute Kidney Injury			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Micturition Urgency			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ureterolithiasis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back Pain			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 87 (0.00%)	1 / 75 (1.33%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscle Rigidity			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	1 / 75 (1.33%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Abdominal Abscess			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Covid-19			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	1 / 10 (10.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colonic Abscess			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Osteomyelitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sepsis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subacute Endocarditis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary Tract Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 2, LTFU: Venglustat 15 mg (Re-randomised from Part 1)		
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 11 (9.09%)		

number of deaths (all causes)	0		
number of deaths resulting from adverse events	0		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Basal Cell Carcinoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Breast Cancer Female			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malignant Melanoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Malignant Melanoma In Situ			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-Small Cell Lung Cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Ovarian Epithelial Cancer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Prostate Cancer				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Anastomotic Leak				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Fall				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Femoral Neck Fracture				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intentional Overdose				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Post Lumbar Puncture Syndrome				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Postoperative Delirium				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Radius Fracture				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Rib Fracture				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Skin Laceration				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subdural Haematoma				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vascular disorders				
Deep Vein Thrombosis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertension				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypertensive Urgency				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hypotension				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Orthostatic Hypotension				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Atrial Fibrillation				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardiac Arrest				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cardio-Respiratory Arrest				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Cerebellar Haemorrhage				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cognitive Disorder				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Freezing Phenomenon				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lumbar Radiculopathy				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
On And Off Phenomenon				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Parkinson's Disease				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Posterior Reversible Encephalopathy Syndrome				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Syncope				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Transient Ischaemic Attack				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Anaemia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Gastrointestinal disorders				
Abdominal Pain				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Impaired Gastric Emptying				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Inguinal Hernia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal Obstruction				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Volvulus				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory, thoracic and mediastinal disorders				
Hypoxia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary Embolism				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychiatric disorders				
Confusional State				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hallucination				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Psychotic Disorder				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Suicide Attempt				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Renal and urinary disorders				
Acute Kidney Injury				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Micturition Urgency				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ureterolithiasis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Musculoskeletal and connective tissue disorders				
Back Pain				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscle Rigidity				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Spinal Pain				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Abdominal Abscess				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Covid-19				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Colonic Abscess				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Diverticulitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Osteomyelitis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Subacute Endocarditis				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			

Urinary Tract Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Part 1: Placebo (ROW)	Part 1: Venglustat 4 mg (ROW)	Part 1: Venglustat 8 mg (ROW)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	4 / 4 (100.00%)	4 / 5 (80.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin Papilloma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Orthostatic Hypotension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Oedema Peripheral			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain			

alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Ovarian Failure			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Uterine Haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sleep Apnoea Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tonsillar Cyst			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			

Anxiety			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Confusional State			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Delirium			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Depressed Mood			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	1 / 5 (20.00%)
occurrences (all)	0	1	1
Depression			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Drug Abuse			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hallucination			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hallucination, Visual			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	3
Impulsive Behaviour			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Insomnia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Panic Attack			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Poor Quality Sleep			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Rapid Eye Movement Sleep Behaviour Disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine Aminotransferase Increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Blood Creatine Phosphokinase Increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cardiac Murmur			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Hepatic Enzyme Increased			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Weight Decreased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod Bite			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Eyelid Injury			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fall			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ligament Rupture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Limb Injury			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Post Lumbar Puncture Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Procedural Nausea			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Procedural Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Procedural Vomiting			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rib Fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Thermal Burn			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chorea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Cognitive Disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dizziness			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Headache			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 4 (50.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	2	0	1
Hyperreflexia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Loss Of Consciousness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Memory Impairment			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Paraesthesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Parkinson's Disease			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Peripheral Sensory Neuropathy			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Radial Nerve Palsy			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Resting Tremor			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Restless Legs Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sciatica			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Sleep Deficit			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Somnolence			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Tremor			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tympanic Membrane Perforation			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vertigo			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye disorders			
Blepharitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Borderline Glaucoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Cataract Cortical			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Cataract Nuclear			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Corneal Infiltrates			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dry Eye			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	1	0
Eczema Eyelids			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eye Irritation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Glaucoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypermetropia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Vision Blurred			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Discomfort			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Abdominal Distension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Anal Haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Chronic Gastritis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Constipation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Cyclic Vomiting Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dental Caries			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	2 / 5 (40.00%)
occurrences (all)	0	0	2
Dry Mouth			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Eructation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 4 (25.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	1	0	0
Gastritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 4 (25.00%)	1 / 4 (25.00%)	0 / 5 (0.00%)
occurrences (all)	1	1	0
Periodontal Disease			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Vomiting			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin and subcutaneous tissue disorders			
Eczema			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Rash Papular			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Skin Ulcer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urticaria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			

Dysuria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Hypertonic Bladder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Micturition Urgency			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nocturia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary Incontinence			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	2 / 4 (50.00%)	0 / 5 (0.00%)
occurrences (all)	0	2	0
Back Pain			

alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	1 / 5 (20.00%)
occurrences (all)	0	0	1
Extremity Contracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pain In Extremity			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Covid-19			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Empyema			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Fungal Skin Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Pulpitis Dental			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Retinitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Tinea Pedis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Urinary Tract Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased Appetite			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0
Type 2 Diabetes Mellitus			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 4 (0.00%)	0 / 5 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 1: Venglustat 15 mg (ROW)	Part 1: Placebo (Japan only)	Part 1: Venglustat 4 mg (Japan only)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	4 / 4 (100.00%)	2 / 3 (66.67%)	3 / 3 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin Papilloma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Orthostatic Hypotension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
General disorders and administration site conditions			
Fatigue			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Oedema Peripheral			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			

Ovarian Failure			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Uterine Haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dyspnoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sleep Apnoea Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tonsillar Cyst			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 4 (50.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	2	0	0
Confusional State			

alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Delirium			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depressed Mood			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Depression			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Drug Abuse			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucination			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hallucination, Visual			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Impulsive Behaviour			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Insomnia			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	2
Panic Attack			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Poor Quality Sleep			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rapid Eye Movement Sleep Behaviour Disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine Aminotransferase Increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Blood Creatine Phosphokinase Increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cardiac Murmur			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hepatic Enzyme Increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Weight Decreased			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Injury, poisoning and procedural complications			
Arthropod Bite			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eyelid Injury			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fall			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Ligament Rupture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Limb Injury			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Post Lumbar Puncture Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural Nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural Pain			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Procedural Vomiting			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rib Fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Thermal Burn			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chorea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cognitive Disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dizziness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Headache			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Hyperreflexia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Loss Of Consciousness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Memory Impairment			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Parkinson's Disease			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Peripheral Sensory Neuropathy			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Radial Nerve Palsy			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Resting Tremor			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Restless Legs Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sciatica			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Sleep Deficit			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Somnolence			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tremor			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Ear and labyrinth disorders			
Tinnitus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Tympanic Membrane Perforation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vertigo			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	1	0	1
Eye disorders			
Blepharitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Borderline Glaucoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cataract Cortical			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cataract Nuclear			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Corneal Infiltrates			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry Eye			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eczema Eyelids			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eye Irritation			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Glaucoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypermetropia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vision Blurred			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Abdominal Discomfort			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Abdominal Distension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Anal Haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Chronic Gastritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Constipation			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Cyclic Vomiting Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Dental Caries			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Diarrhoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dry Mouth			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Dysphagia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Eructation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	2 / 3 (66.67%)
occurrences (all)	0	0	3

Periodontal Disease			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Vomiting			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	2 / 3 (66.67%)
occurrences (all)	0	0	2
Skin and subcutaneous tissue disorders			
Eczema			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Rash Papular			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Skin Ulcer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urticaria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Hypertonic Bladder			

alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Micturition Urgency			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Nocturia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Urinary Incontinence			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Back Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Extremity Contracture			
alternative dictionary used:			

MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Pain In Extremity			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Infections and infestations			
Covid-19			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Empyema			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Fungal Skin Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 4 (0.00%)	1 / 3 (33.33%)	0 / 3 (0.00%)
occurrences (all)	0	1	0
Pulpitis Dental			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Retinitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 4 (25.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	1	0	0
Tinea Pedis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Urinary Tract Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	1 / 3 (33.33%)
occurrences (all)	0	0	1
Metabolism and nutrition disorders			
Decreased Appetite			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0
Type 2 Diabetes Mellitus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 4 (0.00%)	0 / 3 (0.00%)	0 / 3 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 1: Venglustat 8 mg (Japan only)	Part 1: Venglustat 15 mg (Japan only)	Part 2, DB period: Placebo
Total subjects affected by non-serious adverse events			
subjects affected / exposed	3 / 3 (100.00%)	2 / 3 (66.67%)	87 / 111 (78.38%)

Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin Papilloma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			
Hypertension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	4 / 111 (3.60%)
occurrences (all)	0	0	5
Orthostatic Hypotension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	3 / 111 (2.70%)
occurrences (all)	0	0	3
General disorders and administration site conditions			
Fatigue			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	4 / 111 (3.60%)
occurrences (all)	0	0	4
Oedema Peripheral			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	7 / 111 (6.31%)
occurrences (all)	0	0	8
Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	3 / 111 (2.70%)
occurrences (all)	0	0	4
Reproductive system and breast disorders			
Ovarian Failure			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Uterine Haemorrhage			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Dyspnoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Oropharyngeal Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Sleep Apnoea Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 111 (1.80%)
occurrences (all)	0	0	2
Tonsillar Cyst			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	6 / 111 (5.41%)
occurrences (all)	0	0	6
Confusional State			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 111 (1.80%)
occurrences (all)	0	0	2
Delirium			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	1	0	0
Depressed Mood			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 111 (1.80%)
occurrences (all)	0	0	2
Depression			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	6 / 111 (5.41%)
occurrences (all)	0	0	9
Drug Abuse			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Hallucination			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	3 / 111 (2.70%)
occurrences (all)	1	0	3
Hallucination, Visual			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Impulsive Behaviour			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 111 (1.80%)
occurrences (all)	0	0	2
Insomnia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	6 / 111 (5.41%)
occurrences (all)	0	0	6
Panic Attack			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0

Poor Quality Sleep			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	2
Rapid Eye Movement Sleep Behaviour Disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine Aminotransferase Increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Blood Creatine Phosphokinase Increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Cardiac Murmur			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Hepatic Enzyme Increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Weight Decreased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	3 / 111 (2.70%)
occurrences (all)	0	0	3
Injury, poisoning and procedural complications			
Arthropod Bite			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0

Eyelid Injury			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	0 / 111 (0.00%)
occurrences (all)	0	1	0
Fall			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	18 / 111 (16.22%)
occurrences (all)	0	0	24
Ligament Rupture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Limb Injury			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Post Lumbar Puncture Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	3 / 111 (2.70%)
occurrences (all)	1	1	4
Procedural Nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	1	0	0
Procedural Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Procedural Vomiting			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 3 (33.33%)	1 / 3 (33.33%)	0 / 111 (0.00%)
occurrences (all)	1	1	0
Rib Fracture			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Thermal Burn			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Chorea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Cognitive Disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	4 / 111 (3.60%)
occurrences (all)	0	0	4
Dizziness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	10 / 111 (9.01%)
occurrences (all)	0	0	10
Headache			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	15 / 111 (13.51%)
occurrences (all)	0	0	20
Hyperreflexia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Loss Of Consciousness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Memory Impairment			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 111 (1.80%)
occurrences (all)	0	0	2
Paraesthesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 111 (1.80%)
occurrences (all)	0	0	2
Parkinson's Disease			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	6 / 111 (5.41%)
occurrences (all)	0	0	7
Peripheral Sensory Neuropathy			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Radial Nerve Palsy			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Resting Tremor			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Restless Legs Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0

Sciatica			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Sleep Deficit			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Somnolence			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	3 / 111 (2.70%)
occurrences (all)	0	0	3
Tremor			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	5 / 111 (4.50%)
occurrences (all)	0	0	6
Ear and labyrinth disorders			
Tinnitus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Tympanic Membrane Perforation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Vertigo			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 111 (1.80%)
occurrences (all)	0	0	2
Eye disorders			
Blepharitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	4 / 111 (3.60%)
occurrences (all)	0	0	4
Borderline Glaucoma			

alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Cataract Cortical			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	7 / 111 (6.31%)
occurrences (all)	0	0	7
Cataract Nuclear			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	6 / 111 (5.41%)
occurrences (all)	0	0	7
Corneal Infiltrates			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Dry Eye			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Eczema Eyelids			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Eye Irritation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Glaucoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	1	0	0
Hypermetropia			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Vision Blurred			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Gastrointestinal disorders			
Abdominal Discomfort			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Abdominal Distension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Anal Haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Chronic Gastritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Constipation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	8 / 111 (7.21%)
occurrences (all)	0	1	8
Cyclic Vomiting Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Dental Caries			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Diarrhoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	4 / 111 (3.60%)
occurrences (all)	0	0	4
Dry Mouth			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Dysphagia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Eructation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Gastritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 111 (1.80%)
occurrences (all)	0	0	2
Nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	8 / 111 (7.21%)
occurrences (all)	0	0	9
Periodontal Disease			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Vomiting			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	3 / 111 (2.70%)
occurrences (all)	0	0	3

Skin and subcutaneous tissue disorders			
Eczema			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Rash			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 111 (1.80%)
occurrences (all)	0	0	2
Rash Papular			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Skin Ulcer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Urticaria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 3 (33.33%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	1	0	0
Renal and urinary disorders			
Dysuria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Hypertonic Bladder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Micturition Urgency			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 111 (1.80%)
occurrences (all)	0	0	2
Nocturia			

alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Pollakiuria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	1 / 111 (0.90%)
occurrences (all)	0	1	1
Urinary Incontinence			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Endocrine disorders			
Hypothyroidism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	7 / 111 (6.31%)
occurrences (all)	0	0	7
Back Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	8 / 111 (7.21%)
occurrences (all)	0	0	12
Extremity Contracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	2 / 111 (1.80%)
occurrences (all)	0	0	3
Pain In Extremity			
alternative dictionary used:			

MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	8 / 111 (7.21%)
occurrences (all)	0	0	8
Infections and infestations			
Covid-19			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Conjunctivitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Empyema			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Fungal Skin Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	2
Nasopharyngitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	1 / 3 (33.33%)	11 / 111 (9.91%)
occurrences (all)	0	1	11
Pulpitis Dental			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	1 / 111 (0.90%)
occurrences (all)	0	0	1
Retinitis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Tinea Pedis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Urinary Tract Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	6 / 111 (5.41%)
occurrences (all)	0	0	6
Metabolism and nutrition disorders			
Decreased Appetite			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0
Type 2 Diabetes Mellitus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 3 (0.00%)	0 / 3 (0.00%)	0 / 111 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 2, DB period: Venglustat 15 mg	Part 2, DB period: Placebo (Re-randomised from Part 1)	Part 2,DB period:Venglustat 15 mg (Re-randomised from
Total subjects affected by non-serious adverse events			
subjects affected / exposed	95 / 110 (86.36%)	8 / 10 (80.00%)	11 / 13 (84.62%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin Papilloma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Vascular disorders			

Hypertension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 110 (2.73%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	3	0	1
Orthostatic Hypotension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 110 (2.73%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	3	0	1
General disorders and administration site conditions			
Fatigue			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	12 / 110 (10.91%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	13	0	1
Oedema Peripheral			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Reproductive system and breast disorders			
Ovarian Failure			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Uterine Haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	10 / 110 (9.09%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	11	0	1
Dyspnoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Oropharyngeal Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Sleep Apnoea Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	1 / 10 (10.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Tonsillar Cyst			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Psychiatric disorders			
Anxiety			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	5 / 110 (4.55%)	0 / 10 (0.00%)	2 / 13 (15.38%)
occurrences (all)	5	0	2
Confusional State			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Delirium			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Depressed Mood			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	6 / 110 (5.45%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	8	0	0
Depression			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	9 / 110 (8.18%)	1 / 10 (10.00%)	0 / 13 (0.00%)
occurrences (all)	10	1	0
Drug Abuse			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Hallucination			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 110 (2.73%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	3	0	0
Hallucination, Visual			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Impulsive Behaviour			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Insomnia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	9 / 110 (8.18%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	10	0	0
Panic Attack			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 110 (2.73%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	3	0	0
Poor Quality Sleep			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1

Rapid Eye Movement Sleep Behaviour Disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Investigations			
Alanine Aminotransferase Increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	1 / 10 (10.00%)	0 / 13 (0.00%)
occurrences (all)	1	1	0
Blood Creatine Phosphokinase Increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Cardiac Murmur			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Hepatic Enzyme Increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Weight Decreased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 110 (1.82%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	1
Injury, poisoning and procedural complications			
Arthropod Bite			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Eyelid Injury			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0

Fall			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	10 / 110 (9.09%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	12	0	4
Ligament Rupture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Limb Injury			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Post Lumbar Puncture Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	4 / 110 (3.64%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	4	0	0
Procedural Nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Procedural Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Procedural Vomiting			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Rib Fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Thermal Burn			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Amnesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Chorea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cognitive Disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 110 (2.73%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	3	0	0
Dizziness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	12 / 110 (10.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	14	0	0
Headache			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	22 / 110 (20.00%)	0 / 10 (0.00%)	3 / 13 (23.08%)
occurrences (all)	31	0	3
Hyperreflexia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Hypoaesthesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 110 (1.82%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	1
Loss Of Consciousness			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Memory Impairment			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	2
Parkinson's Disease			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	8 / 110 (7.27%)	0 / 10 (0.00%)	2 / 13 (15.38%)
occurrences (all)	8	0	2
Peripheral Sensory Neuropathy			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Radial Nerve Palsy			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Resting Tremor			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Restless Legs Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	4 / 110 (3.64%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	4	0	0
Sciatica			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	1 / 10 (10.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0

Sleep Deficit			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Somnolence			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	6 / 110 (5.45%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	6	0	0
Tremor			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	8 / 110 (7.27%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	9	0	0
Ear and labyrinth disorders			
Tinnitus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tympanic Membrane Perforation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	1 / 10 (10.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Vertigo			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	1 / 10 (10.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Eye disorders			
Blepharitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 110 (1.82%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	2	0	1
Borderline Glaucoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Cataract Cortical			

alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	4 / 110 (3.64%)	1 / 10 (10.00%)	1 / 13 (7.69%)
occurrences (all)	5	1	2
Cataract Nuclear			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	9 / 110 (8.18%)	1 / 10 (10.00%)	1 / 13 (7.69%)
occurrences (all)	9	1	1
Corneal Infiltrates			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Dry Eye			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Eczema Eyelids			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	1 / 10 (10.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Eye Irritation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	2
Glaucoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Hypermetropia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Vision Blurred			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	3 / 110 (2.73%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	3	0	1
Gastrointestinal disorders			
Abdominal Discomfort			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Abdominal Distension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Anal Haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Chronic Gastritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Constipation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	23 / 110 (20.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	25	0	0
Cyclic Vomiting Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Dental Caries			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	1 / 10 (10.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Diarrhoea			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	5 / 110 (4.55%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	5	0	0
Dry Mouth			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	7 / 110 (6.36%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	7	0	0
Dysphagia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Eructation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Gastritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	23 / 110 (20.91%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	27	0	1
Periodontal Disease			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	1 / 10 (10.00%)	0 / 13 (0.00%)
occurrences (all)	0	1	0
Vomiting			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	9 / 110 (8.18%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	12	0	0
Skin and subcutaneous tissue disorders			
Eczema			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Rash			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 110 (1.82%)	1 / 10 (10.00%)	0 / 13 (0.00%)
occurrences (all)	3	1	0
Rash Papular			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Skin Ulcer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Urticaria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 110 (1.82%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Hypertonic Bladder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Micturition Urgency			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 110 (2.73%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	3	0	0
Nocturia			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	1	0	0
Pollakiuria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1
Urinary Incontinence			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Endocrine disorders			
Hypothyroidism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	5 / 110 (4.55%)	1 / 10 (10.00%)	1 / 13 (7.69%)
occurrences (all)	5	1	1
Back Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	9 / 110 (8.18%)	0 / 10 (0.00%)	2 / 13 (15.38%)
occurrences (all)	14	0	2
Extremity Contracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 110 (1.82%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	2	0	0
Pain In Extremity			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	5 / 110 (4.55%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	5	0	0
Infections and infestations			
Covid-19			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 110 (1.82%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	5	0	0
Empyema			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Fungal Skin Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Gastroenteritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	10 / 110 (9.09%)	3 / 10 (30.00%)	0 / 13 (0.00%)
occurrences (all)	13	4	0
Pulpitis Dental			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Retinitis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	0	0	0
Tinea Pedis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 110 (0.00%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	0	0	1
Upper Respiratory Tract Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 110 (1.82%)	2 / 10 (20.00%)	0 / 13 (0.00%)
occurrences (all)	4	2	0
Urinary Tract Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	11 / 110 (10.00%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	17	0	0
Metabolism and nutrition disorders			
Decreased Appetite			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	6 / 110 (5.45%)	0 / 10 (0.00%)	0 / 13 (0.00%)
occurrences (all)	7	0	0
Type 2 Diabetes Mellitus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 110 (0.91%)	0 / 10 (0.00%)	1 / 13 (7.69%)
occurrences (all)	1	0	1

Non-serious adverse events	Part 2, LTFU period: Placebo then Venglustat 15 mg	Part 2, LTFU period: Venglustat 15 mg	Part 2,LTFU:Placebo then Veng 15mg (Re-randomised from Part 1)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	53 / 87 (60.92%)	39 / 75 (52.00%)	7 / 10 (70.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin Papilloma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vascular disorders			

Hypertension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 87 (3.45%)	0 / 75 (0.00%)	1 / 10 (10.00%)
occurrences (all)	3	0	1
Orthostatic Hypotension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 87 (2.30%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
General disorders and administration site conditions			
Fatigue			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 87 (3.45%)	1 / 75 (1.33%)	0 / 10 (0.00%)
occurrences (all)	3	1	0
Oedema Peripheral			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	2 / 75 (2.67%)	0 / 10 (0.00%)
occurrences (all)	1	2	0
Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Reproductive system and breast disorders			
Ovarian Failure			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Uterine Haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	2 / 87 (2.30%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Dyspnoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	1 / 75 (1.33%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Oropharyngeal Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Sleep Apnoea Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Tonsillar Cyst			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	7 / 87 (8.05%)	2 / 75 (2.67%)	1 / 10 (10.00%)
occurrences (all)	7	3	1
Confusional State			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Delirium			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Depressed Mood			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Depression			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	6 / 87 (6.90%)	3 / 75 (4.00%)	0 / 10 (0.00%)
occurrences (all)	6	3	0
Drug Abuse			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Hallucination			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 87 (2.30%)	2 / 75 (2.67%)	0 / 10 (0.00%)
occurrences (all)	2	2	0
Hallucination, Visual			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	1 / 75 (1.33%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
Impulsive Behaviour			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Insomnia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	5 / 87 (5.75%)	3 / 75 (4.00%)	1 / 10 (10.00%)
occurrences (all)	6	3	1
Panic Attack			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	1 / 75 (1.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Poor Quality Sleep			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	1 / 75 (1.33%)	0 / 10 (0.00%)
occurrences (all)	1	1	0

Rapid Eye Movement Sleep Behaviour Disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Investigations			
Alanine Aminotransferase Increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	1 / 75 (1.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Blood Creatine Phosphokinase Increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	1 / 75 (1.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Cardiac Murmur			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hepatic Enzyme Increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Weight Decreased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 87 (2.30%)	2 / 75 (2.67%)	0 / 10 (0.00%)
occurrences (all)	2	2	0
Injury, poisoning and procedural complications			
Arthropod Bite			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eyelid Injury			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Fall			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	9 / 87 (10.34%)	2 / 75 (2.67%)	0 / 10 (0.00%)
occurrences (all)	12	3	0
Ligament Rupture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Limb Injury			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Post Lumbar Puncture Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 87 (2.30%)	3 / 75 (4.00%)	0 / 10 (0.00%)
occurrences (all)	2	3	0
Procedural Nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Procedural Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	1 / 75 (1.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Procedural Vomiting			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rib Fracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Thermal Burn			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Nervous system disorders			
Amnesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Chorea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cognitive Disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 87 (3.45%)	1 / 75 (1.33%)	1 / 10 (10.00%)
occurrences (all)	3	1	1
Dizziness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	6 / 87 (6.90%)	1 / 75 (1.33%)	0 / 10 (0.00%)
occurrences (all)	6	1	0
Headache			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 87 (2.30%)	3 / 75 (4.00%)	0 / 10 (0.00%)
occurrences (all)	2	3	0
Hyperreflexia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 87 (3.45%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Loss Of Consciousness			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Memory Impairment			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Paraesthesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	1 / 75 (1.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Parkinson's Disease			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	11 / 87 (12.64%)	4 / 75 (5.33%)	0 / 10 (0.00%)
occurrences (all)	11	4	0
Peripheral Sensory Neuropathy			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Radial Nerve Palsy			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Resting Tremor			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Restless Legs Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	1 / 75 (1.33%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Sciatica			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0

Sleep Deficit			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Somnolence			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	3 / 75 (4.00%)	0 / 10 (0.00%)
occurrences (all)	0	3	0
Tremor			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 87 (3.45%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	3	0	0
Ear and labyrinth disorders			
Tinnitus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Tympanic Membrane Perforation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vertigo			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Eye disorders			
Blepharitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Borderline Glaucoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Cataract Cortical			

alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	5 / 87 (5.75%)	3 / 75 (4.00%)	0 / 10 (0.00%)
occurrences (all)	6	4	0
Cataract Nuclear			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	11 / 87 (12.64%)	4 / 75 (5.33%)	0 / 10 (0.00%)
occurrences (all)	11	4	0
Corneal Infiltrates			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dry Eye			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eczema Eyelids			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Eye Irritation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Glaucoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	1 / 75 (1.33%)	0 / 10 (0.00%)
occurrences (all)	0	1	0
Hypermetropia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vision Blurred			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	2 / 87 (2.30%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	2	0	0
Gastrointestinal disorders			
Abdominal Discomfort			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Abdominal Distension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Anal Haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Chronic Gastritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Constipation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	3 / 87 (3.45%)	3 / 75 (4.00%)	1 / 10 (10.00%)
occurrences (all)	3	4	1
Cyclic Vomiting Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Dental Caries			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Diarrhoea			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 87 (1.15%)	1 / 75 (1.33%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Dry Mouth			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Dysphagia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Eructation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	5 / 87 (5.75%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	5	0	0
Periodontal Disease			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Vomiting			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	4 / 87 (4.60%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	4	0	0
Skin and subcutaneous tissue disorders			
Eczema			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Rash			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	2 / 75 (2.67%)	0 / 10 (0.00%)
occurrences (all)	0	2	0
Rash Papular			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Skin Ulcer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Urticaria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Dysuria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Hypertonic Bladder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Micturition Urgency			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	1 / 75 (1.33%)	0 / 10 (0.00%)
occurrences (all)	1	1	0
Nocturia			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Pollakiuria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Urinary Incontinence			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	1 / 75 (1.33%)	1 / 10 (10.00%)
occurrences (all)	1	1	1
Endocrine disorders			
Hypothyroidism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Musculoskeletal and connective tissue disorders			
Arthralgia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	4 / 75 (5.33%)	0 / 10 (0.00%)
occurrences (all)	0	4	0
Back Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	2 / 75 (2.67%)	0 / 10 (0.00%)
occurrences (all)	1	2	0
Extremity Contracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Muscle Spasms			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	1	0	0
Pain In Extremity			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	2 / 87 (2.30%)	1 / 75 (1.33%)	0 / 10 (0.00%)
occurrences (all)	2	1	0
Infections and infestations			
Covid-19			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	4 / 75 (5.33%)	0 / 10 (0.00%)
occurrences (all)	1	4	0
Conjunctivitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	2 / 75 (2.67%)	0 / 10 (0.00%)
occurrences (all)	1	2	0
Empyema			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	1 / 10 (10.00%)
occurrences (all)	0	0	1
Fungal Skin Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Gastroenteritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Nasopharyngitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Pulpitis Dental			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Retinitis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Tinea Pedis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Upper Respiratory Tract Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 87 (1.15%)	0 / 75 (0.00%)	1 / 10 (10.00%)
occurrences (all)	1	0	1
Urinary Tract Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	2 / 87 (2.30%)	3 / 75 (4.00%)	0 / 10 (0.00%)
occurrences (all)	2	3	0
Metabolism and nutrition disorders			
Decreased Appetite			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0
Type 2 Diabetes Mellitus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 87 (0.00%)	0 / 75 (0.00%)	0 / 10 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part 2, LTFU: Venglustat 15 mg (Re-randomised from Part 1)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	8 / 11 (72.73%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Skin Papilloma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Vascular disorders			

Hypertension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Orthostatic Hypotension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Fatigue			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Oedema Peripheral			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Ovarian Failure			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Uterine Haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Dyspnoea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Oropharyngeal Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Sleep Apnoea Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Tonsillar Cyst			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Anxiety			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Confusional State			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Delirium			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Depressed Mood			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Depression				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Drug Abuse				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Hallucination				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Hallucination, Visual				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Impulsive Behaviour				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Insomnia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Panic Attack				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Poor Quality Sleep				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			

Rapid Eye Movement Sleep Behaviour Disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Investigations			
Alanine Aminotransferase Increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Blood Creatine Phosphokinase Increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Cardiac Murmur			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Hepatic Enzyme Increased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Weight Decreased			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Injury, poisoning and procedural complications			
Arthropod Bite			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Eyelid Injury			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		

Fall				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	3 / 11 (27.27%)			
occurrences (all)	3			
Ligament Rupture				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Limb Injury				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
Post Lumbar Puncture Syndrome				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Procedural Nausea				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Procedural Pain				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Procedural Vomiting				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Rib Fracture				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Thermal Burn				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Amnesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Chorea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Cognitive Disorder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Dizziness			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Headache			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Hyperreflexia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Hypoaesthesia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Loss Of Consciousness			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
Memory Impairment				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Paraesthesia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Parkinson's Disease				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
Peripheral Sensory Neuropathy				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Radial Nerve Palsy				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Resting Tremor				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Restless Legs Syndrome				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
Sciatica				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			

Sleep Deficit			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Somnolence			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Tremor			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Tinnitus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Tympanic Membrane Perforation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Vertigo			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Eye disorders			
Blepharitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Borderline Glaucoma			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Cataract Cortical			

alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Cataract Nuclear				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	2 / 11 (18.18%)			
occurrences (all)	2			
Corneal Infiltrates				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
Dry Eye				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	1 / 11 (9.09%)			
occurrences (all)	1			
Eczema Eyelids				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Eye Irritation				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Glaucoma				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Hypermetropia				
alternative dictionary used: MedDRA 24.0				
subjects affected / exposed	0 / 11 (0.00%)			
occurrences (all)	0			
Vision Blurred				
alternative dictionary used: MedDRA 24.0				

subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Abdominal Discomfort			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Abdominal Distension			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Anal Haemorrhage			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Chronic Gastritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Constipation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Cyclic Vomiting Syndrome			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Dental Caries			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Diarrhoea			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Dry Mouth			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Dysphagia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Eructation			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Gastritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Nausea			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Periodontal Disease			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Vomiting			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Eczema			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Rash			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Rash Papular			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Skin Ulcer			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Urticaria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Dysuria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Hypertonic Bladder			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Micturition Urgency			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Nocturia			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Pollakiuria			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Urinary Incontinence			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Endocrine disorders			
Hypothyroidism			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Back Pain			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Extremity Contracture			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Muscle Spasms			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Pain In Extremity			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Infections and infestations			
Covid-19			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Conjunctivitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Empyema			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Fungal Skin Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Gastroenteritis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	1 / 11 (9.09%)		
occurrences (all)	1		
Nasopharyngitis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Pulpitis Dental			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Retinitis			
alternative dictionary used: MedDRA 24.0			

subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Tinea Pedis			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Upper Respiratory Tract Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Urinary Tract Infection			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Metabolism and nutrition disorders			
Decreased Appetite			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		
Type 2 Diabetes Mellitus			
alternative dictionary used: MedDRA 24.0			
subjects affected / exposed	0 / 11 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
08 December 2016	The following changes were made: - Updated inclusion and exclusion criteria. - In Part 2 Treatment Phase, site Visit 4 at Week 0, Day 3 had been removed from Part 2: Study schedule of assessments (Periods 1 and 2) flowchart for consistency (it was added to original protocol in error). Therefore, visit numbers throughout the protocol had been renumbered.
06 June 2017	The following changes were made: - Updated inclusion and exclusion criteria: 'Increase the subject upper age limit from 70 to 80 years old'. - Revised exclusion criteria to specify the prohibited duration of medication use and deleted the words 'of screening'. - Clarified that the internal review committee can comprise individuals involved in the conduct of the study. - Updated table of contents, flow charts, sections, table footnotes and citations and renumbered references. - Tables were reformatted. - Abbreviations were updated in text and table footnotes. - References were updated.
03 September 2020	The following changes were made: - Added the supplementary visits and corresponding assessments related to the 1-year prolongation of the long-term follow-up period (Period 3). - Clarified the objectives of the long-term follow-up period (period 3). - Specified that Visit 15 (Week 208) would be the last study visit for subjects who would be transitioned to a long-term study with GZ/SAR402671. - Clarified the PD medications allowed during the study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

Limitations of the trial such as small numbers of subjects analysed or technical problems leading to unreliable data.

This study did not achieve its primary or secondary endpoints at the time of the analysis of the double-blind 52-week treatment period of Part 2 and was terminated early.

Notes: