



Clinical trial results:

Single Arm, Open Label Phase 1b/2 Study of SGN-LIV1A in Combination with Pembrolizumab for First-Line Treatment of Patients with Unresectable Locally Advanced or Metastatic Triple-Negative Breast Cancer

Summary

EudraCT number	2017-002289-35
Trial protocol	ES
Global end of trial date	30 September 2024

Results information

Result version number	v1 (current)
This version publication date	23 October 2025
First version publication date	23 October 2025

Trial information

Trial identification

Sponsor protocol code	C5741001
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03310957
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Seagen Inc.
Sponsor organisation address	21823 30th Drive S.E., Bothell, United States, 98021
Public contact	Seagen Inc., Chief Medical Officer, 1 8554732436, medinfo@seagen.com
Scientific contact	Seagen Inc., Chief Medical Officer, 1 8554732436, medinfo@seagen.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	25 March 2025
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	30 September 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

(i) To evaluate the safety and tolerability of the combination of ladiratuzumab vedotin (LV; SGN-LIV1A) and pembrolizumab in participants with locally-advanced or metastatic triple-negative breast cancer (LA/M TNBC) (ii) To identify the recommended dose and schedule of LV in combination with pembrolizumab in participants with LA/M TNBC (iii) To evaluate the confirmed objective response rate (ORR) as measured by Response Evaluation Criteria in Solid Tumors (RECIST) version (v)1.1 of the combination of LV and pembrolizumab in participants with LA/M TNBC.

Protection of trial subjects:

The study was in compliance with the ethical principles derived from the Declaration of Helsinki and in compliance with all International Council for Harmonization (ICH) Good Clinical Practice (GCP) Guidelines. All the local regulatory requirements pertinent to safety of trials participants were followed.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	15 March 2018
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy, Safety
Long term follow-up duration	61 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Germany: 12
Country: Number of subjects enrolled	Korea, Republic of: 8
Country: Number of subjects enrolled	Spain: 45
Country: Number of subjects enrolled	United States: 120
Worldwide total number of subjects	185
EEA total number of subjects	57

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	0

months)	
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	141
From 65 to 84 years	44
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

A total of 185 participants were enrolled at multiple sites.

Pre-assignment

Screening details:

Participants were enrolled into Part A, Part B, Part C, and Part D sequentially.

Period 1

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

Blinding implementation details:

Open-label study, no blinding was done.

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A, B: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab

Arm description:

Participants received SGN-LIV 2.0 milligram per kilogram (mg/kg) by intravenous (IV) infusion on Day 1 of each 21-day cycle every 3 weeks (Q3WK) given over approximately 30 minutes followed by pembrolizumab 200 mg IV as a 30-minute infusion on Day 1 of each 21-day cycle.

Arm type	Experimental
Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

200 mg was administered on Day 1 of each 21-day cycle as a 30-minute infusion.

Investigational medicinal product name	SGN-LIV
Investigational medicinal product code	
Other name	Ladiratuzumab Vedotin, LV
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Infusion

Dosage and administration details:

2.0 mg/kg was administered on Day 1 of every 21-day cycle by IV infusion given over approximately 30 minutes.

Arm title	Part A, B: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab
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Arm description:

Participants received SGN-LIV 2.5 mg/kg by IV infusion on Day 1 of each 21-day cycle (Q3WK) given over approximately 30 minutes followed by Pembrolizumab 200 mg IV as a 30-minute infusion on Day 1 of each 21-day cycle.

Arm type	Experimental
Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:	
200 mg was administered on Day 1 of each 21-day cycle as a 30-minute infusion.	
Investigational medicinal product name	SGN-LIV
Investigational medicinal product code	
Other name	Ladiratuzumab Vedotin, LV
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Infusion
Dosage and administration details:	
2.5 mg/kg was administered on Day 1 of every 21-day cycle by IV infusion given over approximately 30 minutes.	
Arm title	Part C: SGN-LIV 1.0 mg/kg (Q1WK) + Pembrolizumab
Arm description:	
Participants received SGN-LIV 1.0 mg/kg on Day 1, Day 8, and Day 15 in every 3-week cycle every week (Q1WK) by IV infusion given over approximately 30 minutes followed by pembrolizumab 200 mg as a 30-minute infusion on Day 1 of each 21-day cycle in Part C.	
Arm type	Experimental
Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion
Dosage and administration details:	
200 mg was administered on Day 1, 8 and 15 of each 21-day cycle as a 30-minute infusion.	
Investigational medicinal product name	SGN-LIV
Investigational medicinal product code	
Other name	Ladiratuzumab Vedotin, LV
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Infusion
Dosage and administration details:	
1.0 mg/kg was administered on Day 1, 8 and 15 of every 21-day cycle by IV infusion given over approximately 30 minutes.	
Arm title	Part C: SGN-LIV 1.25 mg/kg (Q1WK) + Pembrolizumab
Arm description:	
Participants received 1.25 mg/kg on Day 1, 8 and 15 of every 21-day cycle by IV infusion given over approximately 30 minutes followed by 200 mg Pembrolizumab as a 30-minute infusion on Day 1 of each 21-day cycle in Part C.	
Arm type	Experimental
Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion
Dosage and administration details:	
200 mg was administered on Day 1, 8 and 15 of each 21-day cycle as a 30-minute infusion.	
Investigational medicinal product name	SGN-LIV
Investigational medicinal product code	
Other name	Ladiratuzumab Vedotin, LV
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Infusion
Dosage and administration details:	
1.0 mg/kg was administered on Day 1, 8 and 15 of every 21-day cycle by IV infusion given over approximately 30 minutes.	
Arm title	Part D: SGN-LIV 1.5 mg/kg (2Q3WK) + Pembrolizumab

Arm description:

Participants received SGN-LIV 1.5 mg/kg on Day 1 and Day 8 of every 21-day cycle twice every 3 weeks (2Q3WK) by IV infusion given over approximately 30 minutes followed by Pembrolizumab 200 mg as a 30-minute infusion on Day 1 of each 21-day cycle in Part D.

Arm type	Experimental
Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Infusion

Dosage and administration details:

200 mg was administered on Day 1, 8 of each 21-day cycle as a 30-minute infusion.

Investigational medicinal product name	SGN-LIV
Investigational medicinal product code	
Other name	Ladiratuzumab Vedotin, LV
Pharmaceutical forms	Powder for solution for injection
Routes of administration	Infusion

Dosage and administration details:

1.5 mg/kg was administered on Day 1, 8 of every 21-day cycle by IV infusion given over approximately 30 minutes.

Number of subjects in period 1	Part A, B: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab	Part A, B: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab	Part C: SGN-LIV 1.0 mg/kg (Q1WK) + Pembrolizumab
Started	33	59	3
Completed	0	0	0
Not completed	33	59	3
Adverse event, serious fatal	23	39	1
Consent withdrawn by subject	2	6	-
Site terminated	1	2	-
Unspecified	5	7	2
Lost to follow-up	2	5	-

Number of subjects in period 1	Part C: SGN-LIV 1.25 mg/kg (Q1WK) + Pembrolizumab	Part D: SGN-LIV 1.5 mg/kg (2Q3WK) + Pembrolizumab
Started	53	37
Completed	0	0
Not completed	53	37
Adverse event, serious fatal	29	7
Consent withdrawn by subject	4	3
Site terminated	2	8
Unspecified	14	17
Lost to follow-up	4	2

Baseline characteristics

Reporting groups

Reporting group title	Part A, B: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab
Reporting group description:	
Participants received SGN-LIV 2.0 milligram per kilogram (mg/kg) by intravenous (IV) infusion on Day 1 of each 21-day cycle every 3 weeks (Q3WK) given over approximately 30 minutes followed by pembrolizumab 200 mg IV as a 30-minute infusion on Day 1 of each 21-day cycle.	
Reporting group title	Part A, B: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab
Reporting group description:	
Participants received SGN-LIV 2.5 mg/kg by IV infusion on Day 1 of each 21-day cycle (Q3WK) given over approximately 30 minutes followed by Pembrolizumab 200 mg IV as a 30-minute infusion on Day 1 of each 21-day cycle.	
Reporting group title	Part C: SGN-LIV 1.0 mg/kg (Q1WK) + Pembrolizumab
Reporting group description:	
Participants received SGN-LIV 1.0 mg/kg on Day 1, Day 8, and Day 15 in every 3-week cycle every week (Q1WK) by IV infusion given over approximately 30 minutes followed by pembrolizumab 200 mg as a 30-minute infusion on Day 1 of each 21-day cycle in Part C.	
Reporting group title	Part C: SGN-LIV 1.25 mg/kg (Q1WK) + Pembrolizumab
Reporting group description:	
Participants received 1.25 mg/kg on Day 1, 8 and 15 of every 21-day cycle by IV infusion given over approximately 30 minutes followed by 200 mg Pembrolizumab as a 30-minute infusion on Day 1 of each 21-day cycle in Part C.	
Reporting group title	Part D: SGN-LIV 1.5 mg/kg (2Q3WK) + Pembrolizumab
Reporting group description:	
Participants received SGN-LIV 1.5 mg/kg on Day 1 and Day 8 of every 21-day cycle twice every 3 weeks (2Q3WK) by IV infusion given over approximately 30 minutes followed by Pembrolizumab 200 mg as a 30-minute infusion on Day 1 of each 21-day cycle in Part D.	

Reporting group values	Part A, B: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab	Part A, B: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab	Part C: SGN-LIV 1.0 mg/kg (Q1WK) + Pembrolizumab
Number of subjects	33	59	3
Age Categorical			
Units: Subjects			

Age continuous			
Data reported is per treatment received.			
Units: years			
arithmetic mean	53.4	55.2	45.0
standard deviation	± 12.1	± 12.7	± 14.1
Gender categorical			
Data reported is per treatment received.			
Units: Subjects			
Male	0	0	0
Female	33	59	3
Race			
Data reported is per treatment received.			
Units: Subjects			
White	19	44	0
Black or African American	9	8	1
Asian	4	1	1
Unknown	0	5	1

American Indian or Alaska Native	0	1	0
Other	1	0	0
Ethnicity			
Data reported is per treatment received.			
Units: Subjects			
Hispanic or Latino	4	7	0
Not Hispanic or Latino	29	45	2
Unknown	0	7	1

Reporting group values	Part C: SGN-LIV 1.25 mg/kg (Q1WK) + Pembrolizumab	Part D: SGN-LIV 1.5 mg/kg (2Q3WK) + Pembrolizumab	Total
Number of subjects	53	37	185
Age Categorical			
Units: Subjects			

Age continuous			
Data reported is per treatment received.			
Units: years			
arithmetic mean	57.6	54.6	
standard deviation	± 12.7	± 11.0	-
Gender categorical			
Data reported is per treatment received.			
Units: Subjects			
Male	0	0	0
Female	53	37	185
Race			
Data reported is per treatment received.			
Units: Subjects			
White	31	33	127
Black or African American	10	3	31
Asian	6	1	13
Unknown	4	0	10
American Indian or Alaska Native	2	0	3
Other	0	0	1
Ethnicity			
Data reported is per treatment received.			
Units: Subjects			
Hispanic or Latino	5	4	20
Not Hispanic or Latino	43	29	148
Unknown	5	4	17

End points

End points reporting groups

Reporting group title	Part A, B: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab
Reporting group description: Participants received SGN-LIV 2.0 milligram per kilogram (mg/kg) by intravenous (IV) infusion on Day 1 of each 21-day cycle every 3 weeks (Q3WK) given over approximately 30 minutes followed by pembrolizumab 200 mg IV as a 30-minute infusion on Day 1 of each 21-day cycle.	
Reporting group title	Part A, B: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab
Reporting group description: Participants received SGN-LIV 2.5 mg/kg by IV infusion on Day 1 of each 21-day cycle (Q3WK) given over approximately 30 minutes followed by Pembrolizumab 200 mg IV as a 30-minute infusion on Day 1 of each 21-day cycle.	
Reporting group title	Part C: SGN-LIV 1.0 mg/kg (Q1WK) + Pembrolizumab
Reporting group description: Participants received SGN-LIV 1.0 mg/kg on Day 1, Day 8, and Day 15 in every 3-week cycle every week (Q1WK) by IV infusion given over approximately 30 minutes followed by pembrolizumab 200 mg as a 30-minute infusion on Day 1 of each 21-day cycle in Part C.	
Reporting group title	Part C: SGN-LIV 1.25 mg/kg (Q1WK) + Pembrolizumab
Reporting group description: Participants received 1.25 mg/kg on Day 1, 8 and 15 of every 21-day cycle by IV infusion given over approximately 30 minutes followed by 200 mg Pembrolizumab as a 30-minute infusion on Day 1 of each 21-day cycle in Part C.	
Reporting group title	Part D: SGN-LIV 1.5 mg/kg (2Q3WK) + Pembrolizumab
Reporting group description: Participants received SGN-LIV 1.5 mg/kg on Day 1 and Day 8 of every 21-day cycle twice every 3 weeks (2Q3WK) by IV infusion given over approximately 30 minutes followed by Pembrolizumab 200 mg as a 30-minute infusion on Day 1 of each 21-day cycle in Part D.	

Primary: Number of Participants With Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs)

End point title	Number of Participants With Treatment Emergent Adverse Events (TEAEs) and Serious Adverse Events (SAEs) ^[1]
End point description: An adverse event (AE) was any untoward medical occurrence in a study participant administered a medicinal product and which did not necessarily have a causal relationship with the study treatment. SAE was defined as any untoward medical occurrence that, at any dose, meets one or more of the criteria: death, life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, congenital anomaly or birth defect and other medically significant events. TEAEs were defined as newly occurring (not present at baseline) or worsened after first dose of investigational product within 30 days after last dose date or within 90 days for SAE. AEs included SAEs and all non-SAEs. Safety analysis set included all participants who received any amount of SGN-LIV1A or pembrolizumab.	
End point type	Primary
End point timeframe: From start of study treatment up to 30 days after last dose for AEs and up to 90 days post last dose for SAEs (maximum exposure to any study intervention was 27 months; follow-up for AEs=maximum up to 28 months; follow-up for SAEs=maximum up to 30 months)	

Notes:

[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive analysis was planned for this endpoint.

End point values	Part A, B: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab	Part A, B: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab	Part C: SGN- LIV 1.0 mg/kg (Q1WK) + Pembrolizumab	Part C: SGN- LIV 1.25 mg/kg (Q1WK) + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	32	59	2	53
Units: Participants				
Participants With AEs	32	59	2	53
Participants With SAEs	17	35	1	28

End point values	Part D: SGN- LIV 1.5 mg/kg (2Q3WK) + Pembrolizumab			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: Participants				
Participants With AEs	36			
Participants With SAEs	14			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Treatment Related TEAEs and SAEs

End point title	Number of Participants With Treatment Related TEAEs and SAEs ^[2]
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End point description:

An AE was any untoward medical occurrence in a study participant administered a medicinal product and which did not necessarily have a causal relationship with the study treatment. SAE was defined as any untoward medical occurrence that, at any dose, meets one or more of the criteria: death, life-threatening, required inpatient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, congenital anomaly or birth defect and other medically significant events. AEs included SAEs and all non-SAEs. A treatment-related AE was any untoward medical occurrence attributed to the study drug in a participant who received study drug. Relatedness to study drug was assessed by the investigator. Safety analysis set included all participants who received any amount of SGN-LIV1A or pembrolizumab.

End point type	Primary
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End point timeframe:

From start of study treatment up to 30 days after last dose for AEs and up to 90 days post last dose for SAEs (maximum exposure to any study intervention was 27 months; follow-up for AEs=maximum up to 28 months; follow-up for SAEs=maximum up to 30 months)

Notes:

[2] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive analysis was planned for this endpoint.

End point values	Part A, B: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab	Part A, B: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab	Part C: SGN- LIV 1.0 mg/kg (Q1WK) + Pembrolizumab	Part C: SGN- LIV 1.25 mg/kg (Q1WK) + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	32	59	2	53
Units: Participants				
Participants With Treatment Related AEs	29	58	2	52
Participants With Treatment Related SAEs	6	20	0	20

End point values	Part D: SGN- LIV 1.5 mg/kg (2Q3WK) + Pembrolizumab			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: Participants				
Participants With Treatment Related AEs	35			
Participants With Treatment Related SAEs	8			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Maximum Post-Baseline Laboratory Toxicity Grade (0 to 4) in any Hematology Parameter

End point title	Number of Participants With Maximum Post-Baseline Laboratory Toxicity Grade (0 to 4) in any Hematology Parameter ^[3]
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End point description:

In this outcome measure, number of participants with maximum post-baseline laboratory toxicity grade in any hematology parameter are reported. As per NCI-CTCAE v4.03: Grade 1= mild, Grade 2= moderate, Grade 3= severe, and Grade 4= life-threatening consequences; urgent intervention indicated; Grade 0 = within normal limits. Hematology parameters evaluated: hemoglobin, leukocytes, lymphocytes, neutrophils and platelets. Safety analysis set included all participants who received any amount of SGN-LIV1A or pembrolizumab.

End point type	Primary
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End point timeframe:

From start of study treatment up to 30 days after last dose (maximum exposure to any study intervention was 27 months; follow-up = maximum up to 28 months)

Notes:

[3] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive analysis was planned for this endpoint.

End point values	Part A, B: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab	Part A, B: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab	Part C: SGN- LIV 1.0 mg/kg (Q1WK) + Pembrolizumab	Part C: SGN- LIV 1.25 mg/kg (Q1WK) + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	32	59	2	53
Units: Participants				
Grade 0	2	3	0	4
Grade 1	6	8	1	6
Grade 2	12	27	1	25
Grade 3	8	15	0	14
Grade 4	1	5	0	4

End point values	Part D: SGN- LIV 1.5 mg/kg (2Q3WK) + Pembrolizumab			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: Participants				
Grade 0	2			
Grade 1	6			
Grade 2	12			
Grade 3	13			
Grade 4	3			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With AEs of Grade <3 and Grade ≥3 per National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v 4.03

End point title	Number of Participants With AEs of Grade <3 and Grade ≥3 per National Cancer Institute (NCI) Common Terminology Criteria for Adverse Events (CTCAE) v 4.03 ^[4]
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End point description:

An AE was any untoward medical occurrence in a study participant administered a medicinal product and which did not necessarily have a causal relationship with the study treatment. AEs severity were graded using the NCI CTCAE v4.03; where Grade 1= mild AE, Grade 2= moderate AE, Grade 3= severe AE, and Grade 4= life-threatening consequences; urgent intervention indicated, Grade 5= indicated death related to AE. Safety analysis set included all participants who received any amount of SGN-LIV1A or pembrolizumab.

End point type	Primary
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End point timeframe:

From start of study treatment up to 30 days after last dose for AEs (maximum exposure to any study intervention was 27 months)

Notes:

[4] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive analysis was planned for this endpoint.

End point values	Part A, B: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab	Part A, B: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab	Part C: SGN- LIV 1.0 mg/kg (Q1WK) + Pembrolizumab	Part C: SGN- LIV 1.25 mg/kg (Q1WK) + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	32	59	2	53
Units: Participants				
< Grade 3	10	10	0	6
>= Grade 3	22	49	2	47

End point values	Part D: SGN- LIV 1.5 mg/kg (2Q3WK) + Pembrolizumab			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: Participants				
< Grade 3	5			
>= Grade 3	31			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Maximum Post-Baseline Laboratory Toxicity Grade (0 to 4) in any Serum Chemistry Parameter

End point title	Number of Participants With Maximum Post-Baseline Laboratory Toxicity Grade (0 to 4) in any Serum Chemistry Parameter ^[5]
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End point description:

In this outcome measure, number of participants with maximum post-baseline laboratory toxicity grade in any serum chemistry parameters are reported. As per NCI-CTCAE v4.03: Grade 1= mild, Grade 2= moderate, Grade 3= severe, and Grade 4= life-threatening consequences; urgent intervention indicated; Grade 0 = within normal limits. Serum chemistry parameters evaluated: alanine aminotransferase, albumin, alkaline phosphatase, amylase, aspartate aminotransferase, bilirubin, calcium corrected for albumin, calcium- ionized, creatinine, gamma glutamyl transferase, glucose, lipase, phosphate, potassium, sodium and urate. Safety analysis set included all participants who received any amount of SGN-LIV1A or pembrolizumab.

End point type	Primary
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End point timeframe:

From start of study treatment up to 30 days after last dose (maximum exposure to any study intervention was 27 months; follow-up = maximum up to 28 months)

Notes:

[5] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive analysis was planned for this endpoint.

End point values	Part A, B: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab	Part A, B: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab	Part C: SGN- LIV 1.0 mg/kg (Q1WK) + Pembrolizumab	Part C: SGN- LIV 1.25 mg/kg (Q1WK) + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	32	59	2	53
Units: Participants				
Grade 1	10	9	1	4
Grade 2	6	4	1	10
Grade 3	12	37	0	36
Grade 4	1	9	0	3

End point values	Part D: SGN- LIV 1.5 mg/kg (2Q3WK) + Pembrolizumab			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: Participants				
Grade 1	12			
Grade 2	4			
Grade 3	17			
Grade 4	3			

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With Dose Limiting Toxicities (DLT): Part A and Part C

End point title	Number of Participants With Dose Limiting Toxicities (DLT): Part A and Part C ^[6] ^[7]
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End point description:

DLT : hematologic and/or non-hematologic AE specified in protocol that is considered related to SGN-LIV or the combination and cannot be attributed to pembrolizumab alone including: any clinically significant, non-hematologic AE ≥ Grade 3 according to NCI CTCAE v4.03, Grade 3 febrile neutropenia, Grade 4 thrombocytopenia or Grade 3 thrombocytopenia associated with clinically significant bleeding that required medical intervention, Grade 4 anemia unrelated to underlying disease, discontinuation during Cycle 1 due to treatment-related toxicity/ inability to receive all 3 doses of SGN-LIV (Days 1, 8, and 15) as participant not met dosing criteria (Part C only)prolonged delay (>2 weeks) in initiating Cycle 2 due to treatment-related toxicity and Grade 5 event (death). DLT-evaluable (DE) analysis = all treated participants in Part A who either(1) experienced a DLT or(2) received at least 75% of intended SGN-LIV1A and pembrolizumab doses and were followed for the full DLT evaluation period.

End point type	Primary
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End point timeframe:

Cycle 1 (up to 21 days)

Notes:

[6] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive analysis was planned for this endpoint.

[7] - 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: This endpoint was planned only for Part A and Part C.

End point values	Part A, B: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab	Part A, B: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab	Part C: SGN- LIV 1.0 mg/kg (Q1WK) + Pembrolizumab	Part C: SGN- LIV 1.25 mg/kg (Q1WK) + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	7	12	2	2
Units: Participants	0	2	0	0

Statistical analyses

No statistical analyses for this end point

Primary: ORR as Determined by the Investigator According to RECIST v1.1

End point title	ORR as Determined by the Investigator According to RECIST v1.1 ^[8]
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End point description:

ORR was defined as the percentage of participants with confirmed complete response (CR) or partial response (PR) according to RECIST v1.1. CR: disappearance of all target lesions. Any pathological lymph nodes must have reduction in short axis to <10 mm. PR: ≥30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. All treated analysis set included all participants who received any amount of SGN-LIV1A or pembrolizumab. Kaplan Meier method was used for 95% confidence interval.

End point type	Primary
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End point timeframe:

From start of study treatment up to date of confirmed CR or PR (maximum up to 30 months)

Notes:

[8] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.

Justification: Only descriptive analysis was planned for this endpoint.

End point values	Part A, B: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab	Part A, B: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab	Part C: SGN- LIV 1.0 mg/kg (Q1WK) + Pembrolizumab	Part C: SGN- LIV 1.25 mg/kg (Q1WK) + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	32	59	2	53
Units: Percentage of participants				
number (confidence interval 95%)	34 (18.6 to 53.2)	41 (28.1 to 54.3)	50 (1.3 to 98.7)	47 (33.3 to 61.4)

End point values	Part D: SGN- LIV 1.5 mg/kg (2Q3WK) + Pembrolizumab			
Subject group type	Reporting group			
Number of subjects analysed	36			

Units: Percentage of participants				
number (confidence interval 95%)	39 (23.1 to 56.5)			

Statistical analyses

No statistical analyses for this end point

Secondary: Disease Control Rate (DCR)

End point title	Disease Control Rate (DCR)
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End point description:

DCR was defined as percentage of participants with CR, PR, or stable disease (SD) per RECIST v1.1. CR: disappearance of all target lesions. Any pathological lymph nodes must have reduction in short axis to <10 mm. PR: $\geq 30\%$ decrease in the sum of diameters of target lesions, taking as reference the baseline sum diameters. SD: neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for progression, taking as reference the smallest sum diameters while on study. Progression: at least a 20% increase in the sum of diameters of target lesions, taking as reference smallest sum on study (this includes baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 0.5 cm. Appearance of one or more new lesions. All treated analysis set included all participants who received any amount of SGN-LIV1A or pembrolizumab. Clopper-Pearson method was used for 95% confidence interval.

End point type	Secondary
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End point timeframe:

From start of study treatment up to date of CR or PR or SD (maximum up to 30 months)

End point values	Part A, B: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab	Part A, B: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab	Part C: SGN- LIV 1.0 mg/kg (Q1WK) + Pembrolizumab	Part C: SGN- LIV 1.25 mg/kg (Q1WK) + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	32	59	2	53
Units: Months				
number (confidence interval 95%)	59 (40.6 to 76.3)	81 (69.1 to 90.3)	50 (1.3 to 98.7)	77 (63.8 to 87.7)

End point values	Part D: SGN- LIV 1.5 mg/kg (2Q3WK) + Pembrolizumab			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: Months				
number (confidence interval 95%)	69 (51.9 to 83.7)			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) per RECIST v1.1

End point title	Duration of Response (DOR) per RECIST v1.1
End point description: DOR = time from first documentation of objective response (subsequently confirmed) per investigator to first documentation of disease progression, or death due to any cause, whichever came first. CR: disappearance of all target lesions. Any pathological lymph nodes (reduction in short axis to <10 mm). PR: $\geq 30\%$ decrease in sum of diameters of target lesions, taking reference baseline sum diameters. Progression: at least a 20% increase in sum of diameters of target lesions, reference smallest sum on study (includes baseline sum if that is smallest on study). In addition to relative increase of 20%, sum must also demonstrate an absolute increase of at least 0.5 cm. Appearance of one or more new lesions. Kaplan-Meier method used for DOR evaluation. All treated analysis set evaluated. DOR was calculated for participants who achieved confirmed CR or PR. Here, "99999" and "-99999" suggests lower and upper limit of 95%CI could not be estimated due to insufficient participants with events.	
End point type	Secondary
End point timeframe: From the date of first CR or PR until the date of the first documentation of progression or death, or censoring date, whichever came first (maximum up to 30 months)	

End point values	Part A, B: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab	Part A, B: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab	Part C: SGN- LIV 1.0 mg/kg (Q1WK) + Pembrolizumab	Part C: SGN- LIV 1.25 mg/kg (Q1WK) + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	11	24	1	25
Units: Months				
median (confidence interval 95%)	4.5 (2.9 to 6.9)	5.8 (3.1 to 9.9)	4.2 (-99999 to 99999)	4.4 (3.6 to 6.6)

End point values	Part D: SGN- LIV 1.5 mg/kg (2Q3WK) + Pembrolizumab			
Subject group type	Reporting group			
Number of subjects analysed	14			
Units: Months				
median (confidence interval 95%)	8.3 (5.7 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)
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End point description:

OS was defined as the time from start of study treatment to date of death due to any cause. In the absence of confirmation of death, OS was censored at the last date the participant was known to be alive. Kaplan-Meier method was used for OS evaluation. All treated analysis set included all participants who received any amount of SGN-LIV1A or pembrolizumab. Here, "99999" and "-99999" suggests that median and upper and/or lower limit of 95%CI could not be estimated due to insufficient participants with events.

End point type	Secondary
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End point timeframe:

From start of study treatment until the date of death, or censoring date, whichever came first (maximum up to 30 months)

End point values	Part A, B: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab	Part A, B: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab	Part C: SGN- LIV 1.0 mg/kg (Q1WK) + Pembrolizumab	Part C: SGN- LIV 1.25 mg/kg (Q1WK) + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	32	59	2	53
Units: Months				
median (confidence interval 95%)	14.6 (8.1 to 26.6)	14.8 (11.9 to 25.9)	99999 (-99999 to 99999)	19.4 (11.1 to 99999)

End point values	Part D: SGN- LIV 1.5 mg/kg (2Q3WK) + Pembrolizumab			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: Months				
median (confidence interval 95%)	99999 (-99999 to 99999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS)

End point title	Progression-Free Survival (PFS)
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End point description:

PFS was defined as the time from start of study treatment to first documentation of disease progression based upon the disease assessment per RECISTv1.1 or clinical progression, or to death due to any cause, whichever came first. Progression: at least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum on study (this includes the baseline sum if that is the smallest on study). In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 0.5 cm. The appearance of one or more new lesions. Kaplan-Meier method was used for PFS evaluation. All treated analysis set included all participants who received any amount of SGN-LIV1A or pembrolizumab. Here, "99999" suggests that upper limit of 95%CI could not be estimated due to insufficient participants with events.

End point type	Secondary
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End point timeframe:

From start of study treatment until the date of the first documentation of progression or death, or censoring date, whichever came first (maximum up to 30 months)

End point values	Part A, B: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab	Part A, B: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab	Part C: SGN- LIV 1.0 mg/kg (Q1WK) + Pembrolizumab	Part C: SGN- LIV 1.25 mg/kg (Q1WK) + Pembrolizumab
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	32	59	2	53
Units: Months				
median (confidence interval 95%)	3.5 (1.7 to 4.1)	4.2 (3.9 to 5.6)	3.3 (1.0 to 99999)	4.8 (4.1 to 5.6)

End point values	Part D: SGN- LIV 1.5 mg/kg (2Q3WK) + Pembrolizumab			
Subject group type	Reporting group			
Number of subjects analysed	36			
Units: Months				
median (confidence interval 95%)	4.2 (2.7 to 8.3)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From start of study treatment up to 30 days and up to 90 days post last dose for AEs and SAEs respectively (maximum exposure to any study treatment = 27 months; follow-up: AEs = maximum up to 28 months; All-cause mortality, SAEs = maximum up to 30 months)

Adverse event reporting additional description:

Same event may appear as both SAE and non-SAE but are distinct events. An event may be categorized as serious in 1 participant and non-serious in another, or a participant may have experienced both SAE and non-SAE.

Assessment type	Non-systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	v27.1
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Reporting groups

Reporting group title	Part C: SGN-LIV 1.0 mg/kg (Q1WK) + Pembrolizumab
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Reporting group description:

Participants received SGN-LIV 1.0 mg/kg on Day 1, Day 8, and Day 15 in every 3-week cycle every week (Q1WK) by IV infusion given over approximately 30 minutes followed by pembrolizumab 200 mg as a 30-minute infusion on Day 1 of each 21-day cycle in Part C.

Reporting group title	Part C: SGN-LIV 1.25 mg/kg (Q1WK) + Pembrolizumab
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Reporting group description:

Participants received 1.25 mg/kg on Day 1, 8 and 15 of every 21-day cycle by IV infusion given over approximately 30 minutes followed by 200 mg Pembrolizumab as a 30-minute infusion on Day 1 of each 21-day cycle in Part C.

Reporting group title	Part D: SGN-LIV 1.5 mg/kg (2Q3WK) + Pembrolizumab
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Reporting group description:

Participants received SGN-LIV 1.5 mg/kg on Day 1 and Day 8 of every 21-day cycle twice every 3 weeks (2Q3WK) by IV infusion given over approximately 30 minutes followed by Pembrolizumab 200 mg as a 30-minute infusion on Day 1 of each 21-day cycle in Part D.

Reporting group title	Part B: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab
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Reporting group description:

Participants received SGN-LIV 2.5 mg/kg by IV infusion on Day 1 of each 21-day cycle (Q3WK) given over approximately 30 minutes followed by Pembrolizumab 200 mg IV as a 30-minute infusion on Day 1 of each 21-day cycle in Part B.

Reporting group title	Part A: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab
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Reporting group description:

Participants received SGN-LIV 2.5 mg/kg by IV infusion on Day 1 of each 21-day cycle (Q3WK) given over approximately 30 minutes followed by Pembrolizumab 200 mg IV as a 30-minute infusion on Day 1 of each 21-day cycle in Part B.

Reporting group title	Part B: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab
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Reporting group description:

Participants received SGN-LIV 2.0 mg/kg by IV infusion on Day 1 of each 21-day cycle Q3WK given over approximately 30 minutes followed by pembrolizumab 200 mg IV as a 30-minute infusion on Day 1 of each 21-day cycle in Part B.

Reporting group title	Part A: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab
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Reporting group description:

Participants received SGN-LIV 2.0 milligram per kilogram (mg/kg) by intravenous (IV) infusion on Day 1 of each 21-day cycle every 3 weeks (Q3WK) given over approximately 30 minutes followed by pembrolizumab 200 mg IV as a 30-minute infusion on Day 1 of each 21-day cycle in Part A.

Serious adverse events	Part C: SGN-LIV 1.0 mg/kg (Q1WK) + Pembrolizumab	Part C: SGN-LIV 1.25 mg/kg (Q1WK) + Pembrolizumab	Part D: SGN-LIV 1.5 mg/kg (2Q3WK) + Pembrolizumab
Total subjects affected by serious adverse events			
subjects affected / exposed	1 / 2 (50.00%)	28 / 53 (52.83%)	14 / 36 (38.89%)
number of deaths (all causes)	1	29	7
number of deaths resulting from adverse events	0	6	3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour associated fever			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
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			
Aortic thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematoma			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
General disorders and administration site conditions			
Device related thrombosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			

subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	3 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Gait disturbance			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Immune system disorders			
Haemophagocytic lymphohistiocytosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Immune-mediated adverse reaction			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	1 / 1	0 / 0
Asthma			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Dyspnoea			
subjects affected / exposed	1 / 2 (50.00%)	2 / 53 (3.77%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 2	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	2 / 36 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated lung disease			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Pneumothorax			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Pulmonary embolism			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 2	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Respiratory distress			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Respiratory failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
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			

Mental status changes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Product issues			
Thrombosis in device			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anticoagulation drug level above therapeutic			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutrophil count decreased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Injury, poisoning and procedural complications			
Fall			

subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Femur fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
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			
Sinus tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Atrial fibrillation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
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			
Acute motor-sensory axonal neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Aphasia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Brachial plexopathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic inflammatory demyelinating polyradiculoneuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dizziness			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Headache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparaesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraesthesia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neuropathy peripheral			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Lumbosacral plexopathy			

subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Peripheral motor neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
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			
Febrile neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	2 / 36 (5.56%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anaemia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			

Keratitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	2 / 36 (5.56%)
occurrences causally related to treatment / all	0 / 0	1 / 2	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal distension			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	3 / 53 (5.66%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated enterocolitis			

subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal pseudo-obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
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			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated cholangitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
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 and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Rash maculo-papular			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin ulcer			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
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			
subjects affected / exposed	0 / 2 (0.00%)	3 / 53 (5.66%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	2 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
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 failure			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nephrolithiasis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Hydronephrosis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Endocrine disorders			
Hypophysitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
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			
Fistula			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Flank pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
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			
Bacteraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anorectal infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
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 cellulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
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			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Cellulitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cystitis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Lymph gland infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Escherichia bacteraemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cytomegalovirus gastritis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Mastitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Parotitis			

subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Pneumonia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
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 cytomegaloviral			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Pyelonephritis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	1 / 36 (2.78%)
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			
subjects affected / exposed	0 / 2 (0.00%)	4 / 53 (7.55%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 4	0 / 0
deaths causally related to treatment / all	0 / 0	2 / 2	0 / 0
Septic shock			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
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			

subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	1 / 36 (2.78%)
occurrences causally related to treatment / all	0 / 0	1 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (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
Failure to thrive			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			

subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic acidosis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	1 / 36 (2.78%)
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 B: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab	Part A: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab	Part B: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab
Total subjects affected by serious adverse events			
subjects affected / exposed	27 / 47 (57.45%)	8 / 12 (66.67%)	13 / 25 (52.00%)
number of deaths (all causes)	31	8	18
number of deaths resulting from adverse events	0	0	3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour associated fever			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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			
Aortic thrombosis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Deep vein thrombosis			

subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Haematoma			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Device related thrombosis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthenia			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Fatigue			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (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
Pyrexia			
subjects affected / exposed	2 / 47 (4.26%)	0 / 12 (0.00%)	2 / 25 (8.00%)
occurrences causally related to treatment / all	1 / 2	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Non-cardiac chest pain			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (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
Gait disturbance			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune system disorders			

Haemophagocytic lymphohistiocytosis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated adverse reaction			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
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			
Acute respiratory failure			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dyspnoea			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (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
Pneumonitis			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Pleural effusion			
subjects affected / exposed	2 / 47 (4.26%)	0 / 12 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 2	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated lung disease			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumothorax			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
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			
subjects affected / exposed	2 / 47 (4.26%)	0 / 12 (0.00%)	0 / 25 (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
Respiratory distress			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
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 failure			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Confusional state			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Product issues			
Thrombosis in device			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Investigations			
Alanine aminotransferase increased			

subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (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
Anticoagulation drug level above therapeutic			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (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
Neutrophil count decreased			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
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			
Fall			
subjects affected / exposed	2 / 47 (4.26%)	0 / 12 (0.00%)	0 / 25 (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
Hip fracture			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Femur fracture			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (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 disorders			
Sinus tachycardia			

subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Atrial fibrillation			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Palpitations			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (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
Nervous system disorders			
Acute motor-sensory axonal neuropathy			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Aphasia			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Brachial plexopathy			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Cerebrovascular accident			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Chronic inflammatory demyelinating polyradiculoneuropathy			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Dizziness			

subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (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
Headache			
subjects affected / exposed	1 / 47 (2.13%)	2 / 12 (16.67%)	2 / 25 (8.00%)
occurrences causally related to treatment / all	0 / 1	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hemiparaesthesia			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (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
Paraesthesia			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Neuropathy peripheral			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lumbosacral plexopathy			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral motor neuropathy			
subjects affected / exposed	2 / 47 (4.26%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Seizure			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Peripheral sensory neuropathy			

subjects affected / exposed	2 / 47 (4.26%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	2 / 2	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	1 / 47 (2.13%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	2 / 47 (4.26%)	0 / 12 (0.00%)	0 / 25 (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
Anaemia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neutropenia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Keratitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
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			
Colitis			
subjects affected / exposed	1 / 47 (2.13%)	1 / 12 (8.33%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	0 / 47 (0.00%)	2 / 12 (16.67%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Abdominal distension			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (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
Constipation			
subjects affected / exposed	1 / 47 (2.13%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastritis			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Diarrhoea			
subjects affected / exposed	1 / 47 (2.13%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 47 (0.00%)	2 / 12 (16.67%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	2 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated enterocolitis			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Intestinal pseudo-obstruction			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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			
subjects affected / exposed	1 / 47 (2.13%)	1 / 12 (8.33%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 1	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			

subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Small intestinal obstruction			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Stomatitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vomiting			
subjects affected / exposed	2 / 47 (4.26%)	1 / 12 (8.33%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	1 / 2	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Immune-mediated cholangitis			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Rash maculo-papular			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Skin ulcer			

subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
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			
subjects affected / exposed	3 / 47 (6.38%)	0 / 12 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Renal failure			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Nephrolithiasis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hydronephrosis			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Haematuria			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Hypophysitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypothyroidism			

subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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			
Fistula			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Back pain			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Arthralgia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Flank pain			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Muscular weakness			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Pain in extremity			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pathological fracture			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			

Bacteraemia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anorectal infection			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abscess limb			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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 cellulitis			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Cellulitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Clostridium difficile colitis			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Cystitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lymph gland infection			

subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Escherichia bacteraemia			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Device related infection			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Cytomegalovirus gastritis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mastitis			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Parotitis			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	1 / 47 (2.13%)	1 / 12 (8.33%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia cytomegaloviral			

subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
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 tract infection			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
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			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	2 / 25 (8.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Septic shock			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Urinary tract infection			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diabetic ketoacidosis			

subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Hypokalaemia			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Failure to thrive			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertriglyceridaemia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	1 / 25 (4.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophosphataemia			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Metabolic acidosis			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (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
Hypovolaemia			

subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
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 A: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab		
Total subjects affected by serious adverse events			
subjects affected / exposed	4 / 7 (57.14%)		
number of deaths (all causes)	5		
number of deaths resulting from adverse events	1		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour associated fever			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Vascular disorders			
Aortic thrombosis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Deep vein thrombosis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Haematoma			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Device related thrombosis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Asthenia			

subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Fatigue			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Non-cardiac chest pain			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gait disturbance			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune system disorders			
Haemophagocytic lymphohistiocytosis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune-mediated adverse reaction			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute respiratory failure			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		

Asthma				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dyspnoea				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pleural effusion				
subjects affected / exposed	1 / 7 (14.29%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Immune-mediated lung disease				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pulmonary embolism				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory distress				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory failure				

subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Psychiatric disorders			
Mental status changes			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Confusional state			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Product issues			
Thrombosis in device			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anticoagulation drug level above therapeutic			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neutrophil count decreased			

subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hip fracture			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Femur fracture			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders			
Sinus tachycardia			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Atrial fibrillation			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Palpitations			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nervous system disorders			
Acute motor-sensory axonal neuropathy			

subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Aphasia				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Brachial plexopathy				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular accident				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Chronic inflammatory demyelinating polyradiculoneuropathy				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Dizziness				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Headache				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Hemiparaesthesia				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Paraesthesia				

subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Neuropathy peripheral			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Lumbosacral plexopathy			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral motor neuropathy			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Seizure			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Syncope			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Blood and lymphatic system disorders			
Febrile neutropenia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Anaemia			

subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Neutropenia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Keratitis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Abdominal pain			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal distension			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Gastritis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			

subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Ileus				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Immune-mediated enterocolitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Intestinal pseudo-obstruction				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Nausea				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pancreatitis acute				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Small intestinal obstruction				
subjects affected / exposed	1 / 7 (14.29%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Stomatitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Vomiting				

subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Immune-mediated cholangitis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Rash maculo-papular			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Skin ulcer			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract obstruction			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Renal failure			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Nephrolithiasis			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hydronephrosis			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haematuria			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Hypophysitis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypothyroidism			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Musculoskeletal and connective tissue disorders			
Fistula			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Back pain			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		

Arthralgia				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Flank pain				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Muscular weakness				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pain in extremity				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pathological fracture				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Infections and infestations				
Bacteraemia				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Anorectal infection				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Abscess limb				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Breast cellulitis				

subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
COVID-19				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cellulitis				
subjects affected / exposed	1 / 7 (14.29%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Clostridium difficile colitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cystitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Lymph gland infection				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Escherichia bacteraemia				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Device related infection				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Cytomegalovirus gastritis				

subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Mastitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Parotitis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumocystis jirovecii pneumonia				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pneumonia cytomegaloviral				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Pyelonephritis				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Respiratory tract infection				
subjects affected / exposed	0 / 7 (0.00%)			
occurrences causally related to treatment / all	0 / 0			
deaths causally related to treatment / all	0 / 0			
Sepsis				

subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Septic shock			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diabetic ketoacidosis			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hyponatraemia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypokalaemia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Failure to thrive			

subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypertriglyceridaemia			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoglycaemia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypophosphataemia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Metabolic acidosis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences causally related to treatment / all	0 / 0		
deaths causally related to treatment / all	0 / 0		
Hypovolaemia			
subjects affected / exposed	0 / 7 (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 C: SGN-LIV 1.0 mg/kg (Q1WK) + Pembrolizumab	Part C: SGN-LIV 1.25 mg/kg (Q1WK) + Pembrolizumab	Part D: SGN-LIV 1.5 mg/kg (2Q3WK) + Pembrolizumab
Total subjects affected by non-serious adverse events			
subjects affected / exposed	2 / 2 (100.00%)	53 / 53 (100.00%)	36 / 36 (100.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lipoma of breast			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0

Cancer pain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 53 (0.00%) 0	0 / 36 (0.00%) 0
Vascular disorders			
Haematoma subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 53 (0.00%) 0	0 / 36 (0.00%) 0
Hot flush subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	2 / 53 (3.77%) 2	2 / 36 (5.56%) 2
Hypertension subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	2 / 53 (3.77%) 5	3 / 36 (8.33%) 4
Hypotension subjects affected / exposed occurrences (all)	1 / 2 (50.00%) 1	2 / 53 (3.77%) 2	2 / 36 (5.56%) 3
General disorders and administration site conditions			
Chills subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 53 (0.00%) 0	0 / 36 (0.00%) 0
Catheter site erosion subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 53 (0.00%) 0	0 / 36 (0.00%) 0
Catheter site oedema subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 53 (0.00%) 0	0 / 36 (0.00%) 0
Chest discomfort subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 53 (0.00%) 0	0 / 36 (0.00%) 0
Chest pain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 53 (0.00%) 0	0 / 36 (0.00%) 0
Asthenia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	5 / 53 (9.43%) 7	9 / 36 (25.00%) 21
Fatigue			

subjects affected / exposed	1 / 2 (50.00%)	32 / 53 (60.38%)	16 / 36 (44.44%)
occurrences (all)	1	41	17
Gait disturbance			
subjects affected / exposed	0 / 2 (0.00%)	3 / 53 (5.66%)	0 / 36 (0.00%)
occurrences (all)	0	3	0
Malaise			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Non-cardiac chest pain			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	0 / 36 (0.00%)
occurrences (all)	0	4	0
Oedema peripheral			
subjects affected / exposed	0 / 2 (0.00%)	6 / 53 (11.32%)	4 / 36 (11.11%)
occurrences (all)	0	9	4
Performance status decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Peripheral swelling			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Puncture site pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	0 / 2 (0.00%)	10 / 53 (18.87%)	5 / 36 (13.89%)
occurrences (all)	0	11	7
Pain			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	1 / 36 (2.78%)
occurrences (all)	0	2	1
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Dysmenorrhoea			

subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Intermenstrual bleeding			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	0 / 2 (0.00%)	7 / 53 (13.21%)	3 / 36 (8.33%)
occurrences (all)	0	7	3
Dysphonia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	3 / 36 (8.33%)
occurrences (all)	0	2	3
Dyspnoea			
subjects affected / exposed	0 / 2 (0.00%)	6 / 53 (11.32%)	3 / 36 (8.33%)
occurrences (all)	0	7	3
Dyspnoea exertional			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	2 / 36 (5.56%)
occurrences (all)	0	0	2
Epistaxis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Haemoptysis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Hypoxia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Nasal congestion			
subjects affected / exposed	0 / 2 (0.00%)	3 / 53 (5.66%)	0 / 36 (0.00%)
occurrences (all)	0	3	0
Oropharyngeal pain			

subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	1 / 36 (2.78%)
occurrences (all)	0	2	1
Pleural effusion			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	1 / 36 (2.78%)
occurrences (all)	0	2	1
Pneumonitis			
subjects affected / exposed	0 / 2 (0.00%)	5 / 53 (9.43%)	3 / 36 (8.33%)
occurrences (all)	0	6	3
Rhinorrhoea			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Pulmonary embolism			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	4 / 36 (11.11%)
occurrences (all)	0	0	4
Sinus congestion			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	0 / 36 (0.00%)
occurrences (all)	0	2	0
Wheezing			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Upper-airway cough syndrome			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Irritability			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Insomnia			
subjects affected / exposed	0 / 2 (0.00%)	17 / 53 (32.08%)	6 / 36 (16.67%)
occurrences (all)	0	18	6
Depression			

subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	0 / 36 (0.00%)
occurrences (all)	0	2	0
Confusional state			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	0 / 36 (0.00%)
occurrences (all)	0	3	0
Anxiety			
subjects affected / exposed	0 / 2 (0.00%)	7 / 53 (13.21%)	3 / 36 (8.33%)
occurrences (all)	0	8	3
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	19 / 53 (35.85%)	10 / 36 (27.78%)
occurrences (all)	0	24	16
Amylase increased			
subjects affected / exposed	0 / 2 (0.00%)	4 / 53 (7.55%)	4 / 36 (11.11%)
occurrences (all)	0	4	4
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	23 / 53 (43.40%)	11 / 36 (30.56%)
occurrences (all)	0	30	16
Blood glucose increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	2 / 36 (5.56%)
occurrences (all)	0	0	2
Blood bilirubin increased			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	2 / 36 (5.56%)
occurrences (all)	0	2	3
Blood creatinine increased			
subjects affected / exposed	0 / 2 (0.00%)	4 / 53 (7.55%)	1 / 36 (2.78%)
occurrences (all)	0	6	1
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	6 / 36 (16.67%)
occurrences (all)	0	3	7
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			

subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	2 / 36 (5.56%)
occurrences (all)	0	3	2
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 2 (0.00%)	3 / 53 (5.66%)	2 / 36 (5.56%)
occurrences (all)	0	3	2
Neutrophil count decreased			
subjects affected / exposed	0 / 2 (0.00%)	4 / 53 (7.55%)	2 / 36 (5.56%)
occurrences (all)	0	4	3
Lipase increased			
subjects affected / exposed	0 / 2 (0.00%)	9 / 53 (16.98%)	3 / 36 (8.33%)
occurrences (all)	0	10	3
Lymphocyte count decreased			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
High density lipoprotein decreased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Weight decreased			
subjects affected / exposed	1 / 2 (50.00%)	19 / 53 (35.85%)	11 / 36 (30.56%)
occurrences (all)	1	24	11
White blood cell count decreased			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	0 / 36 (0.00%)
occurrences (all)	0	3	0
Injury, poisoning and procedural complications			
Eye contusion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Skin abrasion			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Incision site erythema			

subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Infusion related reaction			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Fall			
subjects affected / exposed	0 / 2 (0.00%)	6 / 53 (11.32%)	2 / 36 (5.56%)
occurrences (all)	0	7	2
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 2 (0.00%)	3 / 53 (5.66%)	4 / 36 (11.11%)
occurrences (all)	0	3	4
Sinus tachycardia			
subjects affected / exposed	2 / 2 (100.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	2	0	0
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	1 / 2 (50.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	1	0	0
Headache			
subjects affected / exposed	0 / 2 (0.00%)	10 / 53 (18.87%)	6 / 36 (16.67%)
occurrences (all)	0	14	8
Ataxia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	0 / 36 (0.00%)
occurrences (all)	0	2	0
Balance disorder			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Cognitive disorder			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Dizziness			
subjects affected / exposed	1 / 2 (50.00%)	14 / 53 (26.42%)	3 / 36 (8.33%)
occurrences (all)	1	18	3
Dysgeusia			

subjects affected / exposed	0 / 2 (0.00%)	7 / 53 (13.21%)	6 / 36 (16.67%)
occurrences (all)	0	7	6
Peripheral sensorimotor neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	1 / 36 (2.78%)
occurrences (all)	0	3	1
Peripheral motor neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	8 / 53 (15.09%)	4 / 36 (11.11%)
occurrences (all)	0	11	4
Paraesthesia			
subjects affected / exposed	0 / 2 (0.00%)	5 / 53 (9.43%)	0 / 36 (0.00%)
occurrences (all)	0	5	0
Neuropathy peripheral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	2 / 36 (5.56%)
occurrences (all)	0	0	2
Loss of consciousness			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Hypoaesthesia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	1 / 36 (2.78%)
occurrences (all)	0	2	1
Peripheral sensory neuropathy			
subjects affected / exposed	0 / 2 (0.00%)	19 / 53 (35.85%)	13 / 36 (36.11%)
occurrences (all)	0	25	16
Vocal cord paresis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Tremor			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Taste disorder			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Restless legs syndrome			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	0 / 36 (0.00%)
occurrences (all)	0	2	0
Peroneal nerve palsy			

subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 53 (0.00%) 0	0 / 36 (0.00%) 0
Blood and lymphatic system disorders			
Increased tendency to bruise subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 53 (0.00%) 0	0 / 36 (0.00%) 0
Anaemia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	8 / 53 (15.09%) 11	3 / 36 (8.33%) 4
Leukocytosis subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 53 (0.00%) 0	2 / 36 (5.56%) 2
Leukopenia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	5 / 53 (9.43%) 9	2 / 36 (5.56%) 2
Neutropenia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	11 / 53 (20.75%) 19	11 / 36 (30.56%) 26
Thrombocytopenia subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 53 (0.00%) 0	2 / 36 (5.56%) 5
Ear and labyrinth disorders			
Ear pain subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 53 (0.00%) 0	0 / 36 (0.00%) 0
Vertigo subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	0 / 53 (0.00%) 0	1 / 36 (2.78%) 1
Eye disorders			
Dry eye subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	4 / 53 (7.55%) 4	3 / 36 (8.33%) 3
Keratitis subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	1 / 53 (1.89%) 1	4 / 36 (11.11%) 4
Photophobia			

subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Vision blurred			
subjects affected / exposed	0 / 2 (0.00%)	9 / 53 (16.98%)	1 / 36 (2.78%)
occurrences (all)	0	11	1
Visual acuity reduced			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	2 / 36 (5.56%)
occurrences (all)	0	0	2
Visual impairment			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	1 / 36 (2.78%)
occurrences (all)	0	2	1
Abdominal distension			
subjects affected / exposed	0 / 2 (0.00%)	3 / 53 (5.66%)	2 / 36 (5.56%)
occurrences (all)	0	3	2
Abdominal pain			
subjects affected / exposed	0 / 2 (0.00%)	16 / 53 (30.19%)	7 / 36 (19.44%)
occurrences (all)	0	17	7
Abdominal pain upper			
subjects affected / exposed	0 / 2 (0.00%)	4 / 53 (7.55%)	4 / 36 (11.11%)
occurrences (all)	0	4	5
Constipation			
subjects affected / exposed	0 / 2 (0.00%)	25 / 53 (47.17%)	12 / 36 (33.33%)
occurrences (all)	0	27	14
Diarrhoea			
subjects affected / exposed	0 / 2 (0.00%)	30 / 53 (56.60%)	16 / 36 (44.44%)
occurrences (all)	0	44	27
Dry mouth			
subjects affected / exposed	0 / 2 (0.00%)	6 / 53 (11.32%)	3 / 36 (8.33%)
occurrences (all)	0	7	4
Dyspepsia			
subjects affected / exposed	0 / 2 (0.00%)	6 / 53 (11.32%)	3 / 36 (8.33%)
occurrences (all)	0	7	3

Dysphagia			
subjects affected / exposed	0 / 2 (0.00%)	3 / 53 (5.66%)	0 / 36 (0.00%)
occurrences (all)	0	3	0
Nausea			
subjects affected / exposed	0 / 2 (0.00%)	35 / 53 (66.04%)	20 / 36 (55.56%)
occurrences (all)	0	57	22
Gastritis			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 2 (50.00%)	6 / 53 (11.32%)	1 / 36 (2.78%)
occurrences (all)	1	7	1
Haematochezia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	2 / 36 (5.56%)
occurrences (all)	0	0	2
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	2 / 36 (5.56%)
occurrences (all)	0	0	2
Flatulence			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	2 / 36 (5.56%)
occurrences (all)	0	1	3
Retching			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Stomatitis			
subjects affected / exposed	0 / 2 (0.00%)	6 / 53 (11.32%)	4 / 36 (11.11%)
occurrences (all)	0	6	4
Tongue haemorrhage			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Toothache			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Vomiting			
subjects affected / exposed	0 / 2 (0.00%)	17 / 53 (32.08%)	13 / 36 (36.11%)
occurrences (all)	0	33	17

Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 2 (0.00%)	3 / 53 (5.66%)	10 / 36 (27.78%)
occurrences (all)	0	3	17
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 2 (0.00%)	3 / 53 (5.66%)	2 / 36 (5.56%)
occurrences (all)	0	3	2
Blister			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	1 / 2 (50.00%)	17 / 53 (32.08%)	12 / 36 (33.33%)
occurrences (all)	1	17	12
Erythema			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	1 / 36 (2.78%)
occurrences (all)	0	3	1
Hyperhidrosis			
subjects affected / exposed	1 / 2 (50.00%)	1 / 53 (1.89%)	0 / 36 (0.00%)
occurrences (all)	1	1	0
Night sweats			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Pain of skin			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Skin hyperpigmentation			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Rash maculo-papular			
subjects affected / exposed	0 / 2 (0.00%)	7 / 53 (13.21%)	5 / 36 (13.89%)
occurrences (all)	0	7	5
Rash macular			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	1 / 36 (2.78%)
occurrences (all)	0	2	1
Rash			

subjects affected / exposed	0 / 2 (0.00%)	5 / 53 (9.43%)	7 / 36 (19.44%)
occurrences (all)	0	7	8
Pruritus			
subjects affected / exposed	0 / 2 (0.00%)	13 / 53 (24.53%)	5 / 36 (13.89%)
occurrences (all)	0	13	6
Scab			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Urticaria			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	1 / 36 (2.78%)
occurrences (all)	0	1	2
Skin induration			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	2 / 36 (5.56%)
occurrences (all)	0	1	2
Haematuria			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	1 / 36 (2.78%)
occurrences (all)	0	1	1
Urinary tract pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	1 / 36 (2.78%)
occurrences (all)	0	2	1
Renal colic			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0

Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 2 (0.00%)	3 / 53 (5.66%)	4 / 36 (11.11%)
occurrences (all)	0	3	4
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 2 (0.00%)	14 / 53 (26.42%)	12 / 36 (33.33%)
occurrences (all)	0	20	14
Bone pain			
subjects affected / exposed	0 / 2 (0.00%)	3 / 53 (5.66%)	4 / 36 (11.11%)
occurrences (all)	0	3	4
Back pain			
subjects affected / exposed	0 / 2 (0.00%)	7 / 53 (13.21%)	2 / 36 (5.56%)
occurrences (all)	0	10	2
Coccydynia			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Muscular weakness			
subjects affected / exposed	0 / 2 (0.00%)	7 / 53 (13.21%)	3 / 36 (8.33%)
occurrences (all)	0	7	3
Muscle spasms			
subjects affected / exposed	0 / 2 (0.00%)	3 / 53 (5.66%)	1 / 36 (2.78%)
occurrences (all)	0	4	1
Joint swelling			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Musculoskeletal chest pain			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	2 / 36 (5.56%)
occurrences (all)	0	1	2
Myalgia			
subjects affected / exposed	0 / 2 (0.00%)	8 / 53 (15.09%)	6 / 36 (16.67%)
occurrences (all)	0	10	9
Neck pain			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Pain in extremity			

subjects affected / exposed occurrences (all)	0 / 2 (0.00%) 0	11 / 53 (20.75%) 17	0 / 36 (0.00%) 0
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 2 (0.00%)	3 / 53 (5.66%)	1 / 36 (2.78%)
occurrences (all)	0	3	1
Catheter site infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Chronic sinusitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Herpes zoster			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Diverticulitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Folliculitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Conjunctivitis viral			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 2 (0.00%)	3 / 53 (5.66%)	0 / 36 (0.00%)
occurrences (all)	0	3	0
Oral herpes			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	2 / 36 (5.56%)
occurrences (all)	0	0	2
Urinary tract infection			
subjects affected / exposed	0 / 2 (0.00%)	6 / 53 (11.32%)	6 / 36 (16.67%)
occurrences (all)	0	13	7

Skin infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	2 / 36 (5.56%)
occurrences (all)	0	0	2
Upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	1 / 36 (2.78%)
occurrences (all)	0	0	1
Sinusitis			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	3 / 36 (8.33%)
occurrences (all)	0	0	3
Vaginal infection			
subjects affected / exposed	0 / 2 (0.00%)	1 / 53 (1.89%)	0 / 36 (0.00%)
occurrences (all)	0	1	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	0 / 2 (0.00%)	19 / 53 (35.85%)	10 / 36 (27.78%)
occurrences (all)	0	20	14
Dehydration			
subjects affected / exposed	0 / 2 (0.00%)	5 / 53 (9.43%)	3 / 36 (8.33%)
occurrences (all)	0	8	3
Hyperglycaemia			
subjects affected / exposed	0 / 2 (0.00%)	14 / 53 (26.42%)	10 / 36 (27.78%)
occurrences (all)	0	21	11
Hypoalbuminaemia			
subjects affected / exposed	0 / 2 (0.00%)	2 / 53 (3.77%)	2 / 36 (5.56%)
occurrences (all)	0	4	2
Hypokalaemia			
subjects affected / exposed	0 / 2 (0.00%)	15 / 53 (28.30%)	9 / 36 (25.00%)
occurrences (all)	0	24	11
Hypocalcaemia			
subjects affected / exposed	0 / 2 (0.00%)	3 / 53 (5.66%)	1 / 36 (2.78%)
occurrences (all)	0	3	1
Hypomagnesaemia			

subjects affected / exposed	0 / 2 (0.00%)	9 / 53 (16.98%)	4 / 36 (11.11%)
occurrences (all)	0	11	4
Hyponatraemia			
subjects affected / exposed	0 / 2 (0.00%)	3 / 53 (5.66%)	2 / 36 (5.56%)
occurrences (all)	0	3	2
Hypophosphataemia			
subjects affected / exposed	0 / 2 (0.00%)	4 / 53 (7.55%)	2 / 36 (5.56%)
occurrences (all)	0	4	2
Vitamin B12 deficiency			
subjects affected / exposed	0 / 2 (0.00%)	0 / 53 (0.00%)	0 / 36 (0.00%)
occurrences (all)	0	0	0

Non-serious adverse events	Part B: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab	Part A: SGN-LIV 2.5 mg/kg (Q3WK) + Pembrolizumab	Part B: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab
Total subjects affected by non-serious adverse events			
subjects affected / exposed	47 / 47 (100.00%)	12 / 12 (100.00%)	23 / 25 (92.00%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lipoma of breast			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Cancer pain			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
Vascular disorders			
Haematoma			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Hot flush			
subjects affected / exposed	1 / 47 (2.13%)	2 / 12 (16.67%)	2 / 25 (8.00%)
occurrences (all)	1	2	2
Hypertension			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Hypotension			
subjects affected / exposed	4 / 47 (8.51%)	1 / 12 (8.33%)	2 / 25 (8.00%)
occurrences (all)	4	1	2
General disorders and administration			

site conditions			
Chills			
subjects affected / exposed	4 / 47 (8.51%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	5	1	0
Catheter site erosion			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Catheter site oedema			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Chest discomfort			
subjects affected / exposed	2 / 47 (4.26%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	3	1	0
Chest pain			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Asthenia			
subjects affected / exposed	5 / 47 (10.64%)	3 / 12 (25.00%)	4 / 25 (16.00%)
occurrences (all)	6	5	4
Fatigue			
subjects affected / exposed	31 / 47 (65.96%)	10 / 12 (83.33%)	11 / 25 (44.00%)
occurrences (all)	35	12	11
Gait disturbance			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Malaise			
subjects affected / exposed	1 / 47 (2.13%)	1 / 12 (8.33%)	1 / 25 (4.00%)
occurrences (all)	1	1	1
Non-cardiac chest pain			
subjects affected / exposed	6 / 47 (12.77%)	2 / 12 (16.67%)	2 / 25 (8.00%)
occurrences (all)	7	2	2
Oedema peripheral			
subjects affected / exposed	2 / 47 (4.26%)	1 / 12 (8.33%)	2 / 25 (8.00%)
occurrences (all)	2	2	2
Performance status decreased			

subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Peripheral swelling			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
Puncture site pain			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	11 / 47 (23.40%)	3 / 12 (25.00%)	6 / 25 (24.00%)
occurrences (all)	14	3	7
Pain			
subjects affected / exposed	4 / 47 (8.51%)	2 / 12 (16.67%)	1 / 25 (4.00%)
occurrences (all)	4	2	1
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	1 / 47 (2.13%)	3 / 12 (25.00%)	0 / 25 (0.00%)
occurrences (all)	2	3	0
Dysmenorrhoea			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Vaginal haemorrhage			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Intermenstrual bleeding			
subjects affected / exposed	1 / 47 (2.13%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	1	1	0
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	15 / 47 (31.91%)	3 / 12 (25.00%)	6 / 25 (24.00%)
occurrences (all)	19	3	6
Dysphonia			
subjects affected / exposed	4 / 47 (8.51%)	0 / 12 (0.00%)	1 / 25 (4.00%)
occurrences (all)	5	0	1
Dyspnoea			

subjects affected / exposed	8 / 47 (17.02%)	3 / 12 (25.00%)	5 / 25 (20.00%)
occurrences (all)	9	3	5
Dyspnoea exertional			
subjects affected / exposed	1 / 47 (2.13%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	1	1	0
Epistaxis			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Haemoptysis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
Hypoxia			
subjects affected / exposed	1 / 47 (2.13%)	1 / 12 (8.33%)	1 / 25 (4.00%)
occurrences (all)	1	1	2
Nasal congestion			
subjects affected / exposed	4 / 47 (8.51%)	0 / 12 (0.00%)	1 / 25 (4.00%)
occurrences (all)	4	0	1
Oropharyngeal pain			
subjects affected / exposed	4 / 47 (8.51%)	0 / 12 (0.00%)	2 / 25 (8.00%)
occurrences (all)	5	0	2
Pleural effusion			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	2 / 25 (8.00%)
occurrences (all)	0	0	2
Pneumonitis			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Rhinorrhoea			
subjects affected / exposed	5 / 47 (10.64%)	1 / 12 (8.33%)	1 / 25 (4.00%)
occurrences (all)	5	1	1
Pulmonary embolism			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Sinus congestion			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Wheezing			

subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	1 / 12 (8.33%) 2	0 / 25 (0.00%) 0
Upper-airway cough syndrome subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	1 / 12 (8.33%) 1	0 / 25 (0.00%) 0
Psychiatric disorders			
Adjustment disorder with depressed mood subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	1 / 12 (8.33%) 1	0 / 25 (0.00%) 0
Irritability subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 12 (0.00%) 0	0 / 25 (0.00%) 0
Insomnia subjects affected / exposed occurrences (all)	5 / 47 (10.64%) 6	3 / 12 (25.00%) 3	4 / 25 (16.00%) 4
Depression subjects affected / exposed occurrences (all)	2 / 47 (4.26%) 3	4 / 12 (33.33%) 4	0 / 25 (0.00%) 0
Confusional state subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	1 / 12 (8.33%) 1	0 / 25 (0.00%) 0
Anxiety subjects affected / exposed occurrences (all)	2 / 47 (4.26%) 2	2 / 12 (16.67%) 2	3 / 25 (12.00%) 3
Investigations			
Alanine aminotransferase increased subjects affected / exposed occurrences (all)	11 / 47 (23.40%) 17	2 / 12 (16.67%) 3	4 / 25 (16.00%) 4
Amylase increased subjects affected / exposed occurrences (all)	1 / 47 (2.13%) 1	0 / 12 (0.00%) 0	0 / 25 (0.00%) 0
Aspartate aminotransferase increased subjects affected / exposed occurrences (all)	10 / 47 (21.28%) 19	2 / 12 (16.67%) 3	3 / 25 (12.00%) 4
Blood glucose increased			

subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Blood bilirubin increased			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Blood alkaline phosphatase increased			
subjects affected / exposed	3 / 47 (6.38%)	0 / 12 (0.00%)	1 / 25 (4.00%)
occurrences (all)	6	0	2
Blood lactate dehydrogenase increased			
subjects affected / exposed	3 / 47 (6.38%)	1 / 12 (8.33%)	1 / 25 (4.00%)
occurrences (all)	5	1	2
Blood thyroid stimulating hormone increased			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	3 / 47 (6.38%)	0 / 12 (0.00%)	2 / 25 (8.00%)
occurrences (all)	3	0	2
Neutrophil count decreased			
subjects affected / exposed	2 / 47 (4.26%)	2 / 12 (16.67%)	2 / 25 (8.00%)
occurrences (all)	4	4	2
Lipase increased			
subjects affected / exposed	3 / 47 (6.38%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	3	0	0
Lymphocyte count decreased			
subjects affected / exposed	2 / 47 (4.26%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	2	1	0
High density lipoprotein decreased			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Neutrophil count increased			

subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	1 / 12 (8.33%) 4	0 / 25 (0.00%) 0
Weight decreased subjects affected / exposed occurrences (all)	13 / 47 (27.66%) 15	6 / 12 (50.00%) 7	5 / 25 (20.00%) 5
White blood cell count decreased subjects affected / exposed occurrences (all)	3 / 47 (6.38%) 4	0 / 12 (0.00%) 0	0 / 25 (0.00%) 0
Injury, poisoning and procedural complications			
Eye contusion subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 12 (0.00%) 0	0 / 25 (0.00%) 0
Skin abrasion subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 12 (0.00%) 0	0 / 25 (0.00%) 0
Incision site erythema subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 12 (0.00%) 0	0 / 25 (0.00%) 0
Infusion related reaction subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	1 / 12 (8.33%) 1	1 / 25 (4.00%) 1
Fall subjects affected / exposed occurrences (all)	3 / 47 (6.38%) 3	1 / 12 (8.33%) 1	1 / 25 (4.00%) 1
Cardiac disorders			
Tachycardia subjects affected / exposed occurrences (all)	1 / 47 (2.13%) 1	1 / 12 (8.33%) 1	1 / 25 (4.00%) 1
Sinus tachycardia subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 12 (0.00%) 0	0 / 25 (0.00%) 0
Nervous system disorders			
Altered state of consciousness subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 12 (0.00%) 0	0 / 25 (0.00%) 0
Headache			

subjects affected / exposed	9 / 47 (19.15%)	5 / 12 (41.67%)	6 / 25 (24.00%)
occurrences (all)	17	5	7
Ataxia			
subjects affected / exposed	1 / 47 (2.13%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	1	1	0
Balance disorder			
subjects affected / exposed	2 / 47 (4.26%)	0 / 12 (0.00%)	2 / 25 (8.00%)
occurrences (all)	2	0	2
Cognitive disorder			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Dizziness			
subjects affected / exposed	5 / 47 (10.64%)	1 / 12 (8.33%)	3 / 25 (12.00%)
occurrences (all)	7	2	5
Dysgeusia			
subjects affected / exposed	1 / 47 (2.13%)	1 / 12 (8.33%)	1 / 25 (4.00%)
occurrences (all)	1	2	1
Peripheral sensorimotor neuropathy			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Peripheral motor neuropathy			
subjects affected / exposed	4 / 47 (8.51%)	2 / 12 (16.67%)	0 / 25 (0.00%)
occurrences (all)	4	2	0
Paraesthesia			
subjects affected / exposed	4 / 47 (8.51%)	2 / 12 (16.67%)	2 / 25 (8.00%)
occurrences (all)	4	2	2
Neuropathy peripheral			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Loss of consciousness			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Hypoaesthesia			
subjects affected / exposed	3 / 47 (6.38%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	3	2	0
Peripheral sensory neuropathy			

subjects affected / exposed	23 / 47 (48.94%)	5 / 12 (41.67%)	8 / 25 (32.00%)
occurrences (all)	30	7	8
Vocal cord paresis			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Tremor			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Taste disorder			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Restless legs syndrome			
subjects affected / exposed	3 / 47 (6.38%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	3	0	0
Peroneal nerve palsy			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Blood and lymphatic system disorders			
Increased tendency to bruise			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Anaemia			
subjects affected / exposed	11 / 47 (23.40%)	0 / 12 (0.00%)	2 / 25 (8.00%)
occurrences (all)	14	0	2
Leukocytosis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Leukopenia			
subjects affected / exposed	3 / 47 (6.38%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	3	0	0
Neutropenia			
subjects affected / exposed	13 / 47 (27.66%)	2 / 12 (16.67%)	0 / 25 (0.00%)
occurrences (all)	21	4	0
Thrombocytopenia			
subjects affected / exposed	2 / 47 (4.26%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0

Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	2 / 47 (4.26%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	3	1	0
Vertigo			
subjects affected / exposed	2 / 47 (4.26%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	2	1	0
Eye disorders			
Dry eye			
subjects affected / exposed	3 / 47 (6.38%)	3 / 12 (25.00%)	1 / 25 (4.00%)
occurrences (all)	3	3	1
Keratitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Photophobia			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Vision blurred			
subjects affected / exposed	4 / 47 (8.51%)	3 / 12 (25.00%)	4 / 25 (16.00%)
occurrences (all)	4	3	4
Visual acuity reduced			
subjects affected / exposed	2 / 47 (4.26%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Visual impairment			
subjects affected / exposed	0 / 47 (0.00%)	2 / 12 (16.67%)	0 / 25 (0.00%)
occurrences (all)	0	2	0
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Abdominal distension			
subjects affected / exposed	3 / 47 (6.38%)	2 / 12 (16.67%)	1 / 25 (4.00%)
occurrences (all)	4	2	1
Abdominal pain			
subjects affected / exposed	11 / 47 (23.40%)	5 / 12 (41.67%)	4 / 25 (16.00%)
occurrences (all)	12	5	6
Abdominal pain upper			

subjects affected / exposed	7 / 47 (14.89%)	2 / 12 (16.67%)	0 / 25 (0.00%)
occurrences (all)	9	2	0
Constipation			
subjects affected / exposed	21 / 47 (44.68%)	5 / 12 (41.67%)	10 / 25 (40.00%)
occurrences (all)	25	9	11
Diarrhoea			
subjects affected / exposed	26 / 47 (55.32%)	9 / 12 (75.00%)	5 / 25 (20.00%)
occurrences (all)	39	15	7
Dry mouth			
subjects affected / exposed	4 / 47 (8.51%)	3 / 12 (25.00%)	2 / 25 (8.00%)
occurrences (all)	4	3	2
Dyspepsia			
subjects affected / exposed	3 / 47 (6.38%)	2 / 12 (16.67%)	1 / 25 (4.00%)
occurrences (all)	3	3	1
Dysphagia			
subjects affected / exposed	0 / 47 (0.00%)	2 / 12 (16.67%)	1 / 25 (4.00%)
occurrences (all)	0	2	1
Nausea			
subjects affected / exposed	32 / 47 (68.09%)	9 / 12 (75.00%)	12 / 25 (48.00%)
occurrences (all)	38	13	17
Gastritis			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 47 (6.38%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	3	1	0
Haematochezia			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Flatulence			
subjects affected / exposed	2 / 47 (4.26%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Retching			

subjects affected / exposed	2 / 47 (4.26%)	2 / 12 (16.67%)	1 / 25 (4.00%)
occurrences (all)	2	2	1
Stomatitis			
subjects affected / exposed	1 / 47 (2.13%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	1	2	0
Tongue haemorrhage			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Toothache			
subjects affected / exposed	2 / 47 (4.26%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	2	1	0
Vomiting			
subjects affected / exposed	14 / 47 (29.79%)	7 / 12 (58.33%)	4 / 25 (16.00%)
occurrences (all)	26	11	6
Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	3 / 47 (6.38%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	6	0	0
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Blister			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Alopecia			
subjects affected / exposed	25 / 47 (53.19%)	7 / 12 (58.33%)	7 / 25 (28.00%)
occurrences (all)	25	7	7
Erythema			
subjects affected / exposed	2 / 47 (4.26%)	2 / 12 (16.67%)	0 / 25 (0.00%)
occurrences (all)	2	4	0
Hyperhidrosis			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Night sweats			

subjects affected / exposed	2 / 47 (4.26%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	2	1	0
Pain of skin			
subjects affected / exposed	1 / 47 (2.13%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	1	1	0
Skin hyperpigmentation			
subjects affected / exposed	1 / 47 (2.13%)	1 / 12 (8.33%)	1 / 25 (4.00%)
occurrences (all)	1	1	1
Rash maculo-papular			
subjects affected / exposed	9 / 47 (19.15%)	5 / 12 (41.67%)	5 / 25 (20.00%)
occurrences (all)	12	8	5
Rash macular			
subjects affected / exposed	4 / 47 (8.51%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	5	0	0
Rash			
subjects affected / exposed	4 / 47 (8.51%)	2 / 12 (16.67%)	1 / 25 (4.00%)
occurrences (all)	8	2	1
Pruritus			
subjects affected / exposed	12 / 47 (25.53%)	3 / 12 (25.00%)	5 / 25 (20.00%)
occurrences (all)	15	4	5
Scab			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Skin ulcer			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	1 / 25 (4.00%)
occurrences (all)	1	0	1
Urticaria			
subjects affected / exposed	1 / 47 (2.13%)	2 / 12 (16.67%)	2 / 25 (8.00%)
occurrences (all)	2	4	2
Skin induration			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0

Haematuria			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Urinary tract pain			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Urinary incontinence			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Renal colic			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Micturition urgency			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	4 / 47 (8.51%)	3 / 12 (25.00%)	2 / 25 (8.00%)
occurrences (all)	5	3	2
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	13 / 47 (27.66%)	6 / 12 (50.00%)	8 / 25 (32.00%)
occurrences (all)	16	7	9
Bone pain			
subjects affected / exposed	6 / 47 (12.77%)	6 / 12 (50.00%)	2 / 25 (8.00%)
occurrences (all)	7	7	2
Back pain			
subjects affected / exposed	4 / 47 (8.51%)	3 / 12 (25.00%)	5 / 25 (20.00%)
occurrences (all)	5	4	7
Coccydynia			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Muscular weakness			
subjects affected / exposed	10 / 47 (21.28%)	2 / 12 (16.67%)	2 / 25 (8.00%)
occurrences (all)	11	2	3
Muscle spasms			

subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	3 / 12 (25.00%) 3	1 / 25 (4.00%) 1
Joint swelling subjects affected / exposed occurrences (all)	1 / 47 (2.13%) 1	1 / 12 (8.33%) 1	0 / 25 (0.00%) 0
Musculoskeletal chest pain subjects affected / exposed occurrences (all)	1 / 47 (2.13%) 1	0 / 12 (0.00%) 0	2 / 25 (8.00%) 2
Myalgia subjects affected / exposed occurrences (all)	4 / 47 (8.51%) 4	3 / 12 (25.00%) 5	6 / 25 (24.00%) 7
Neck pain subjects affected / exposed occurrences (all)	1 / 47 (2.13%) 1	2 / 12 (16.67%) 3	1 / 25 (4.00%) 1
Pain in extremity subjects affected / exposed occurrences (all)	8 / 47 (17.02%) 10	4 / 12 (33.33%) 4	2 / 25 (8.00%) 2
Infections and infestations			
COVID-19 subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 12 (0.00%) 0	0 / 25 (0.00%) 0
Catheter site infection subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 12 (0.00%) 0	0 / 25 (0.00%) 0
Chronic sinusitis subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	1 / 12 (8.33%) 1	0 / 25 (0.00%) 0
Herpes zoster subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	1 / 12 (8.33%) 1	0 / 25 (0.00%) 0
Diverticulitis subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 12 (0.00%) 0	0 / 25 (0.00%) 0
Folliculitis subjects affected / exposed occurrences (all)	0 / 47 (0.00%) 0	0 / 12 (0.00%) 0	0 / 25 (0.00%) 0

Conjunctivitis viral			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Oral candidiasis			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	1 / 25 (4.00%)
occurrences (all)	0	1	1
Oral herpes			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Respiratory tract infection			
subjects affected / exposed	1 / 47 (2.13%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	1	0	0
Urinary tract infection			
subjects affected / exposed	6 / 47 (12.77%)	1 / 12 (8.33%)	1 / 25 (4.00%)
occurrences (all)	9	1	2
Skin infection			
subjects affected / exposed	1 / 47 (2.13%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	1	1	0
Upper respiratory tract infection			
subjects affected / exposed	4 / 47 (8.51%)	0 / 12 (0.00%)	2 / 25 (8.00%)
occurrences (all)	5	0	3
Sinusitis			
subjects affected / exposed	0 / 47 (0.00%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	0	1	0
Vaginal infection			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Viral upper respiratory tract infection			
subjects affected / exposed	0 / 47 (0.00%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	18 / 47 (38.30%)	7 / 12 (58.33%)	9 / 25 (36.00%)
occurrences (all)	19	8	10
Dehydration			

subjects affected / exposed	7 / 47 (14.89%)	2 / 12 (16.67%)	1 / 25 (4.00%)
occurrences (all)	9	2	1
Hyperglycaemia			
subjects affected / exposed	10 / 47 (21.28%)	0 / 12 (0.00%)	1 / 25 (4.00%)
occurrences (all)	11	0	1
Hypoalbuminaemia			
subjects affected / exposed	3 / 47 (6.38%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	3	0	0
Hypokalaemia			
subjects affected / exposed	11 / 47 (23.40%)	7 / 12 (58.33%)	4 / 25 (16.00%)
occurrences (all)	20	10	5
Hypocalcaemia			
subjects affected / exposed	2 / 47 (4.26%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	2	0	0
Hypomagnesaemia			
subjects affected / exposed	5 / 47 (10.64%)	1 / 12 (8.33%)	2 / 25 (8.00%)
occurrences (all)	6	1	2
Hyponatraemia			
subjects affected / exposed	3 / 47 (6.38%)	1 / 12 (8.33%)	1 / 25 (4.00%)
occurrences (all)	6	1	1
Hypophosphataemia			
subjects affected / exposed	2 / 47 (4.26%)	0 / 12 (0.00%)	0 / 25 (0.00%)
occurrences (all)	3	0	0
Vitamin B12 deficiency			
subjects affected / exposed	1 / 47 (2.13%)	1 / 12 (8.33%)	0 / 25 (0.00%)
occurrences (all)	1	1	0

Non-serious adverse events	Part A: SGN-LIV 2.0 mg/kg (Q3WK) + Pembrolizumab		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	7 / 7 (100.00%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Lipoma of breast			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Cancer pain			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0		
Vascular disorders			
Haematoma			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Hot flush			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Hypertension			
subjects affected / exposed	2 / 7 (28.57%)		
occurrences (all)	2		
Hypotension			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Catheter site erosion			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Catheter site oedema			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Chest discomfort			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Chest pain			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Asthenia			
subjects affected / exposed	2 / 7 (28.57%)		
occurrences (all)	2		
Fatigue			

subjects affected / exposed	5 / 7 (71.43%)		
occurrences (all)	6		
Gait disturbance			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Malaise			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Non-cardiac chest pain			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Oedema peripheral			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Performance status decreased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Peripheral swelling			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Puncture site pain			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Pyrexia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Pain			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	2 / 7 (28.57%)		
occurrences (all)	2		
Dysmenorrhoea			

subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Vaginal haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Intermenstrual bleeding			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Dysphonia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Dyspnoea			
subjects affected / exposed	3 / 7 (42.86%)		
occurrences (all)	3		
Dyspnoea exertional			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Epistaxis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Haemoptysis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Hypoxia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Nasal congestion			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Oropharyngeal pain			

subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Pleural effusion			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Pneumonitis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Rhinorrhoea			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Pulmonary embolism			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Sinus congestion			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Wheezing			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Upper-airway cough syndrome			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Psychiatric disorders			
Adjustment disorder with depressed mood			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Irritability			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Insomnia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Depression			

subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Confusional state			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Anxiety			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Amylase increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Blood glucose increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Blood bilirubin increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Blood creatinine increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Blood thyroid stimulating hormone increased			

subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Neutrophil count decreased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Lipase increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Lymphocyte count decreased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
High density lipoprotein decreased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Neutrophil count increased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Weight decreased			
subjects affected / exposed	2 / 7 (28.57%)		
occurrences (all)	2		
White blood cell count decreased			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Injury, poisoning and procedural complications			
Eye contusion			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Skin abrasion			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	3		
Incision site erythema			

subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Infusion related reaction			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Fall			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	2		
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Sinus tachycardia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Nervous system disorders			
Altered state of consciousness			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Headache			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	2		
Ataxia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Balance disorder			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Cognitive disorder			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Dizziness			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Dysgeusia			

subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Peripheral sensorimotor neuropathy			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Peripheral motor neuropathy			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Paraesthesia			
subjects affected / exposed	2 / 7 (28.57%)		
occurrences (all)	2		
Neuropathy peripheral			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Loss of consciousness			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Hypoaesthesia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Vocal cord paresis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Tremor			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Taste disorder			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Restless legs syndrome			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Peroneal nerve palsy			

subjects affected / exposed occurrences (all)	0 / 7 (0.00%) 0		
Blood and lymphatic system disorders			
Increased tendency to bruise			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Anaemia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Leukocytosis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Leukopenia			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Neutropenia			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Thrombocytopenia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Ear and labyrinth disorders			
Ear pain			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Vertigo			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Eye disorders			
Dry eye			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Keratitis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Photophobia			

subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Vision blurred			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Visual acuity reduced			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Visual impairment			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Abdominal distension			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Abdominal pain			
subjects affected / exposed	2 / 7 (28.57%)		
occurrences (all)	2		
Abdominal pain upper			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Constipation			
subjects affected / exposed	2 / 7 (28.57%)		
occurrences (all)	3		
Diarrhoea			
subjects affected / exposed	4 / 7 (57.14%)		
occurrences (all)	7		
Dry mouth			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Dyspepsia			
subjects affected / exposed	2 / 7 (28.57%)		
occurrences (all)	2		

Dysphagia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Nausea			
subjects affected / exposed	7 / 7 (100.00%)		
occurrences (all)	9		
Gastritis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Haematochezia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Immune-mediated enterocolitis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Flatulence			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Retching			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Stomatitis			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Tongue haemorrhage			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Toothache			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Vomiting			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	3		

Hepatobiliary disorders			
Hypertransaminasaemia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Skin and subcutaneous tissue disorders			
Dry skin			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Blister			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Alopecia			
subjects affected / exposed	5 / 7 (71.43%)		
occurrences (all)	5		
Erythema			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Hyperhidrosis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Night sweats			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Pain of skin			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Skin hyperpigmentation			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Rash maculo-papular			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Rash macular			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Rash			

subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Pruritus			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Scab			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Skin ulcer			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Urticaria			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Skin induration			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	2		
Haematuria			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Urinary tract pain			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Urinary incontinence			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Renal colic			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Micturition urgency			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		

Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 7 (28.57%)		
occurrences (all)	3		
Bone pain			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Back pain			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Coccydynia			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Muscular weakness			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Muscle spasms			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Joint swelling			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Musculoskeletal chest pain			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Myalgia			
subjects affected / exposed	2 / 7 (28.57%)		
occurrences (all)	2		
Neck pain			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Pain in extremity			

subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Infections and infestations			
COVID-19			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Catheter site infection			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Chronic sinusitis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Herpes zoster			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Diverticulitis			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Folliculitis			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Conjunctivitis viral			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Oral candidiasis			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Oral herpes			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Urinary tract infection			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		

Skin infection			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Upper respiratory tract infection			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Sinusitis			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Vaginal infection			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Viral upper respiratory tract infection			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	2 / 7 (28.57%)		
occurrences (all)	2		
Dehydration			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Hyperglycaemia			
subjects affected / exposed	2 / 7 (28.57%)		
occurrences (all)	2		
Hypoalbuminaemia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Hypokalaemia			
subjects affected / exposed	3 / 7 (42.86%)		
occurrences (all)	6		
Hypocalcaemia			
subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Hypomagnesaemia			

subjects affected / exposed	1 / 7 (14.29%)		
occurrences (all)	1		
Hyponatraemia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Hypophosphataemia			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		
Vitamin B12 deficiency			
subjects affected / exposed	0 / 7 (0.00%)		
occurrences (all)	0		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
29 May 2018	Amendment 1: SGN-LV dose modification changes to elevated blood glucose and neutropenia, Pembrolizumab dose modification changes to myocarditis, nephritis, other immune-related AEs, Added criteria to permit concomitant radiotherapy, New section added on management of hyperglycemia, Specified criteria for repeat testing of HbA1c or referral for glucose management, Pregnancy test added at 24 weeks after EOT, Added a measurement of vital signs within 2 hours after each infusion
28 February 2020	Amendment 5 - Appendix G Updated guidance on contraception. Added LV dosing criteria.
24 July 2020	Amendment 6 - Added serum chemistry panel collection to Day 8 and Day 15 during Cycles 1 and 2 in the weekly dosing schedule. Updated pembrolizumab maximum dose to include 35 cycles (approximately 2 years). Revised language to state that the maximum dose of LV in Part C is 200 mg per infusion.
05 March 2021	Amendment 8: Updated pembrolizumab dose modifications table.
09 November 2021	Amendment 9: Added eligibility criterion for Part D participants with mTNBC in the LA/MBC setting who also have PD-L1 CPS<10 to the inclusion criteria and that PD-L1 status will be determined locally at the investigative site using the PD-L1 IHC 22C3 pharmDx FDA-approved test. Added that only CBC will be done for Part D.
24 May 2022	Amendment 10: Removed the following text from Appendix G. Hormonal methods of contraception (excluding progestin-only pills; method must be associated with inhibition of ovulation), unless contraindicated

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported