Clinical trial results:
A Multicenter, Open-label Phase 2 Study of Lenvatinib (E7080/MK-7902) Plus Pembrolizumab (MK-3475) in Previously Treated Subjects with Selected Solid Tumors (LEAP-005)

Summary

EudraCT number	2018-003747-37
Trial protocol	FR DE GB IT
Global end of trial date	28 October 2024

Results information

Result version number	v1 (current)
This version publication date	31 October 2025
First version publication date	31 October 2025

Trial information

Trial identification

Sponsor protocol code	7902-005

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03797326
WHO universal trial number (UTN)	-

Notes:

Sponsors

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

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	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	28 October 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	28 October 2024
Global end of trial reached?	Yes
Global end of trial date	28 October 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The purpose of this study is to determine the safety and efficacy of combination therapy with pembrolizumab (MK-3475) and lenvatinib (E7080/MK-7902) in participants with triple negative breast cancer (TNBC), ovarian cancer, gastric cancer, colorectal cancer (CRC), glioblastoma (GBM), biliary tract cancers (BTC), or pancreatic cancer.

Protection of trial subjects:

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

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	12 February 2019
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 8
Country: Number of subjects enrolled	Australia: 34
Country: Number of subjects enrolled	Canada: 35
Country: Number of subjects enrolled	Chile: 47
Country: Number of subjects enrolled	Colombia: 12
Country: Number of subjects enrolled	France: 75
Country: Number of subjects enrolled	Germany: 16
Country: Number of subjects enrolled	Israel: 52
Country: Number of subjects enrolled	Italy: 36
Country: Number of subjects enrolled	Korea, Republic of: 60
Country: Number of subjects enrolled	Russian Federation: 20
Country: Number of subjects enrolled	Spain: 96
Country: Number of subjects enrolled	Switzerland: 32
Country: Number of subjects enrolled	Taiwan: 3
Country: Number of subjects enrolled	Thailand: 3
Country: Number of subjects enrolled	United Kingdom: 36
Country: Number of subjects enrolled	United States: 46
Worldwide total number of subjects	611
EEA total number of subjects	223

Notes:

Subjects enrolled per age group	
In utero	0
Preterm newborn - gestational age < 37 wk	0
Newborns (0-27 days)	0
Infants and toddlers (28 days-23 months)	0
Children (2-11 years)	0
Adolescents (12-17 years)	0
Adults (18-64 years)	398
From 65 to 84 years	212
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

This study was conducted at 85 centers in 17 countries.

Pre-assignment

Screening details:

Participants were enrolled and allocated to 1 of 8 cohorts to receive either Lenvatinib in combination with Pembrolizumab or Lenvatinib monotherapy.

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Cohort A: Triple Negative Breast Cancer (Lenva + Pembro)

Arm description:

Participants received Pembrolizumab (pembro) 200 mg via intravenous (IV) infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years) PLUS Lenvatinib (lenva) 20 mg via oral capsule once a day (QD) up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.

Arm type	Experimental
Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	MK-3475, Keytruda®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg administered via intravenous (IV) infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years).

Investigational medicinal product name	Lenvatinib
Investigational medicinal product code	
Other name	MK-7902, E7080, LENVIMA™
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

20 mg administered via oral capsule once a day (QD) up to at least 2 years.

Arm title	Cohort B: Ovarian Cancer (Lenva + Pembro)

Arm description:

Participants received Pembro 200 mg via IV infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years) PLUS Lenva 20 mg via oral capsule QD up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.

Arm type	Experimental
Investigational medicinal product name	Lenvatinib
Investigational medicinal product code	
Other name	MK-7902, E7080, LENVIMA™
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

20 mg administered via oral capsule QD up to at least 2 years.

Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	MK-3475, Keytruda®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg administered via IV infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years).

Arm title	Cohort C: Gastric Cancer (Lenva + Pembro)

Arm description:

Participants received Pembro 200 mg via IV infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years) PLUS Lenva 20 mg via oral capsule QD up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.

Arm type	Experimental
Investigational medicinal product name	Lenvatinib
Investigational medicinal product code	
Other name	MK-7902, E7080, LENVIMA™
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

20 mg administered via oral capsule QD up to at least 2 years.

Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	MK-3475, Keytruda®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg administered via IV infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years).

Arm title	Cohort D1: Colorectal Cancer (Lenva + Pembro)

Arm description:

Participants received Pembro 200 mg via IV infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years) PLUS Lenva 20 mg via oral capsule QD up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.

Arm type	Experimental
Investigational medicinal product name	Lenvatinib
Investigational medicinal product code	
Other name	MK-7902, E7080, LENVIMA™
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

20 mg administered via oral capsule QD up to at least 2 years.

Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	MK-3475, Keytruda®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg administered via IV infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years).

Arm title	Cohort D2: Colorectal Cancer (Lenva)

Arm description:

Participants received Lenva 24 mg via oral capsule QD up to at least 2 years. Participants continued

study intervention until progressive disease or unacceptable toxicity.

Arm type	Experimental
Investigational medicinal product name	Lenvatinib
Investigational medicinal product code	
Other name	MK-7902, E7080, LENVIMA™
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

24 mg administered via oral capsule QD up to at least 2 years.

Arm title	Cohort E: Glioblastoma Multiforma (Lenva + Pembro)

Arm description:

Participants received Pembro 200 mg via intravenous (IV) infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years) PLUS Lenva 20 mg via oral capsule QD up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.

Arm type	Experimental
Investigational medicinal product name	Lenvatinib
Investigational medicinal product code	
Other name	MK-7902, E7080, LENVIMA™
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

20 mg administered via oral capsule QD up to at least 2 years.

Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	MK-3475, Keytruda®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg administered via IV infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years).

Arm title	Cohort F: Biliary Tract Cancer (Lenva + Pembro)

Arm description:

Participants received Pembro 200 mg via IV infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years) PLUS Lenva 20 mg via oral capsule QD up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.

Arm type	Experimental
Investigational medicinal product name	Lenvatinib
Investigational medicinal product code	
Other name	MK-7902, E7080, LENVIMA™
Pharmaceutical forms	Capsule
Routes of administration	Oral use

Dosage and administration details:

20 mg administered via oral capsule QD up to at least 2 years.

Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	MK-3475, Keytruda®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

200 mg administered via IV infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years).

Arm title	Cohort G: Pancreatic Cancer (Lenva + Pembro)

Arm description:	
Participants received Pembro 200 mg via IV infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years) PLUS Lenva 20 mg via oral capsule QD up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.	
Arm type	Experimental
Investigational medicinal product name	Lenvatinib
Investigational medicinal product code	
Other name	MK-7902, E7080, LENVIMA™
Pharmaceutical forms	Capsule
Routes of administration	Oral use
Dosage and administration details:	
20 mg administered via oral capsule QD up to at least 2 years.	
Investigational medicinal product name	Pembrolizumab
Investigational medicinal product code	
Other name	MK-3475, Keytruda®
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use
Dosage and administration details:	
200 mg administered via IV infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years).	

Number of subjects in period 1	Cohort A: Triple Negative Breast Cancer (Lenva + Pembro)	Cohort B: Ovarian Cancer (Lenva + Pembro)	Cohort C: Gastric Cancer (Lenva + Pembro)
Started	31	31	102
Treated	31	31	99
Completed	0	0	0
Not completed	31	31	102
Death	27	28	95
Enrolled in error	-	-	3
Sponsor Decision	3	3	3
Withdrawal by Subject	-	-	1
Lost to follow-up	1	-	-

Number of subjects in period 1	Cohort D1: Colorectal Cancer (Lenva + Pembro)	Cohort D2: Colorectal Cancer (Lenva)	Cohort E: Glioblastoma Multiforma (Lenva + Pembro)
Started	107	32	102
Treated	105	30	101
Completed	0	0	0
Not completed	107	32	102
Death	95	30	96
Enrolled in error	2	2	1
Sponsor Decision	6	-	3
Withdrawal by Subject	3	-	2

Lost to follow-up	1	-	-

Number of subjects in period 1	Cohort F: Biliary Tract Cancer (Lenva + Pembro)	Cohort G: Pancreatic Cancer (Lenva + Pembro)
Started	103	103
Treated	102	103
Completed	0	0
Not completed	103	103
Death	97	98
Enrolled in error	1	-
Sponsor Decision	3	2
Withdrawal by Subject	2	3
Lost to follow-up	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Cohort A: Triple Negative Breast Cancer (Lenva + Pembro)
Reporting group description:	
Participants received Pembrolizumab (pembro) 200 mg via intravenous (IV) infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years) PLUS Lenvatinib (lenva) 20 mg via oral capsule once a day (QD) up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.	
Reporting group title	Cohort B: Ovarian Cancer (Lenva + Pembro)
Reporting group description:	
Participants received Pembro 200 mg via IV infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years) PLUS Lenva 20 mg via oral capsule QD up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.	
Reporting group title	Cohort C: Gastric Cancer (Lenva + Pembro)
Reporting group description:	
Participants received Pembro 200 mg via IV infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years) PLUS Lenva 20 mg via oral capsule QD up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.	
Reporting group title	Cohort D1: Colorectal Cancer (Lenva + Pembro)
Reporting group description:	
Participants received Pembro 200 mg via IV infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years) PLUS Lenva 20 mg via oral capsule QD up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.	
Reporting group title	Cohort D2: Colorectal Cancer (Lenva)
Reporting group description:	
Participants received Lenva 24 mg via oral capsule QD up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.	
Reporting group title	Cohort E: Glioblastoma Multiforma (Lenva + Pembro)
Reporting group description:	
Participants received Pembro 200 mg via intravenous (IV) infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years) PLUS Lenva 20 mg via oral capsule QD up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.	
Reporting group title	Cohort F: Biliary Tract Cancer (Lenva + Pembro)
Reporting group description:	
Participants received Pembro 200 mg via IV infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years) PLUS Lenva 20 mg via oral capsule QD up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.	
Reporting group title	Cohort G: Pancreatic Cancer (Lenva + Pembro)
Reporting group description:	
Participants received Pembro 200 mg via IV infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years) PLUS Lenva 20 mg via oral capsule QD up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.	

Reporting group values	Cohort A: Triple Negative Breast Cancer (Lenva + Pembro)	Cohort B: Ovarian Cancer (Lenva + Pembro)	Cohort C: Gastric Cancer (Lenva + Pembro)
Number of subjects	31	31	102
Age Categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0

Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	25	18	68
From 65-84 years	5	13	34
85 years and over	1	0	0
Age Continuous			
Units: years			
arithmetic mean	54.8	61.5	59.0
standard deviation	± 11.8	± 9.5	± 12.0
Gender Categorical			
Units: Participants			
Female	31	31	30
Male	0	0	72
Race			
Units: Subjects			
ASIAN	5	4	11
BLACK OR AFRICAN AMERICAN	0	0	2
MULTIPLE	0	0	2
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	0
WHITE	22	23	70
MISSING	4	4	17
Ethnicity			
Units: Subjects			
HISPANIC OR LATINO	6	2	17
NOT HISPANIC OR LATINO	19	23	64
NOT REPORTED	6	6	21
UNKNOWN	0	0	0

Reporting group values	Cohort D1: Colorectal Cancer (Lenva + Pembro)	Cohort D2: Colorectal Cancer (Lenva)	Cohort E: Glioblastoma Multiforma (Lenva + Pembro)
Number of subjects	107	32	102
Age Categorical			
Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	71	25	83
From 65-84 years	36	7	19
85 years and over	0	0	0
Age Continuous			
Units: years			
arithmetic mean	58.8	57.0	55.4
standard deviation	± 11.1	± 10.5	± 10.7

Gender Categorical Units: Participants			
Female	32	14	38
Male	75	18	64
Race Units: Subjects			
ASIAN	17	2	17
BLACK OR AFRICAN AMERICAN	4	2	0
MULTIPLE	4	3	1
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	1
WHITE	71	25	72
MISSING	11	0	11
Ethnicity Units: Subjects			
HISPANIC OR LATINO	19	9	13
NOT HISPANIC OR LATINO	77	23	73
NOT REPORTED	11	0	16
UNKNOWN	0	0	0

Reporting group values	Cohort F: Biliary Tract Cancer (Lenva + Pembro)	Cohort G: Pancreatic Cancer (Lenva + Pembro)	Total
Number of subjects	103	103	611
Age Categorical Units: Participants			
In utero	0	0	0
Preterm newborn infants (gestational age < 37 wks)	0	0	0
Newborns (0-27 days)	0	0	0
Infants and toddlers (28 days-23 months)	0	0	0
Children (2-11 years)	0	0	0
Adolescents (12-17 years)	0	0	0
Adults (18-64 years)	52	56	398
From 65-84 years	51	47	212
85 years and over	0	0	1
Age Continuous Units: years			
arithmetic mean	63.0	62.8	
standard deviation	± 9.1	± 9.8	-
Gender Categorical Units: Participants			
Female	53	42	271
Male	50	61	340
Race Units: Subjects			
ASIAN	18	8	82
BLACK OR AFRICAN AMERICAN	1	2	11
MULTIPLE	0	3	13
NATIVE HAWAIIAN OR OTHER PACIFIC ISLANDER	0	0	1
WHITE	71	90	444
MISSING	13	0	60

Ethnicity Units: Subjects			
HISPANIC OR LATINO	9	16	91
NOT HISPANIC OR LATINO	76	86	441
NOT REPORTED	18	0	78
UNKNOWN	0	1	1

End points

End points reporting groups

Reporting group title	Cohort A: Triple Negative Breast Cancer (Lenva + Pembro)
Reporting group description:	
Participants received Pembrolizumab (pembro) 200 mg via intravenous (IV) infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years) PLUS Lenvatinib (lenva) 20 mg via oral capsule once a day (QD) up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.	
Reporting group title	Cohort B: Ovarian Cancer (Lenva + Pembro)
Reporting group description:	
Participants received Pembro 200 mg via IV infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years) PLUS Lenva 20 mg via oral capsule QD up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.	
Reporting group title	Cohort C: Gastric Cancer (Lenva + Pembro)
Reporting group description:	
Participants received Pembro 200 mg via IV infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years) PLUS Lenva 20 mg via oral capsule QD up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.	
Reporting group title	Cohort D1: Colorectal Cancer (Lenva + Pembro)
Reporting group description:	
Participants received Pembro 200 mg via IV infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years) PLUS Lenva 20 mg via oral capsule QD up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.	
Reporting group title	Cohort D2: Colorectal Cancer (Lenva)
Reporting group description:	
Participants received Lenva 24 mg via oral capsule QD up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.	
Reporting group title	Cohort E: Glioblastoma Multiforma (Lenva + Pembro)
Reporting group description:	
Participants received Pembro 200 mg via intravenous (IV) infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years) PLUS Lenva 20 mg via oral capsule QD up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.	
Reporting group title	Cohort F: Biliary Tract Cancer (Lenva + Pembro)
Reporting group description:	
Participants received Pembro 200 mg via IV infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years) PLUS Lenva 20 mg via oral capsule QD up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.	
Reporting group title	Cohort G: Pancreatic Cancer (Lenva + Pembro)
Reporting group description:	
Participants received Pembro 200 mg via IV infusion on Day 1 of each 21-day cycle (Q3W) for up to 35 cycles (up to 2 years) PLUS Lenva 20 mg via oral capsule QD up to at least 2 years. Participants continued study intervention until progressive disease or unacceptable toxicity.	

Primary: Objective Response Rate (ORR) per Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST 1.1) by Investigator Assessment

End point title	Objective Response Rate (ORR) per Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST 1.1) by Investigator Assessment[1][2]
End point description:	
ORR was defined as the percentage of participants who had a best overall response of either Complete Response (CR): Disappearance of all target lesions or Partial Response (PR): At least a 30% decrease in the sum of diameters of target lesions as assessed by RECIST 1.1. The percentage of participants who experienced a CR or PR as assessed by RECIST 1.1 by investigator assessment was presented. Per protocol, only data for Cohorts A and B were presented for this endpoint. Analysis population consisted	

of all allocated participants who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Up to approximately 66 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: No statistical comparison between treatment arms of the current study were planned for this endpoint.
[2] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, no analysis was planned for Cohorts C, D1, D2, E, F, G.

End point values	Cohort A: Triple Negative Breast Cancer (Lenva + Pembro)	Cohort B: Ovarian Cancer (Lenva + Pembro)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	31		
Units: Percentage of Participants				
number (confidence interval 95%)	22.6 (9.6 to 41.1)	25.8 (11.9 to 44.6)		

Statistical analyses

No statistical analyses for this end point

Primary: Objective Response Rate (ORR) per Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST 1.1) or Response Assessment in Neuro-Oncology (RANO) Criteria (for Glioblastoma Multiforma [GBM] Only), by Blinded Independent Central Review (BICR)

End point title	Objective Response Rate (ORR) per Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST 1.1) or Response Assessment in Neuro-Oncology (RANO) Criteria (for Glioblastoma Multiforma [GBM] Only), by Blinded Independent Central Review (BICR)[3][4]

End point description:

ORR was defined as the percentage of participants who have a best overall response of either Complete Response (CR): Disappearance of all target lesions or Partial Response (PR): At least a 30% decrease in the sum of diameters of target lesions as assessed by RECIST 1.1. For participants with GBM, response was assessed according to RANO criteria whereby ORR was defined as the percentage of participants who have a best overall response of either Complete response (CR): Disappearance of all target lesions or Partial response (PR): sum of products of diameters decreased by ≥50% from baseline value. The percentage of participants who experienced a CR or PR as assessed by RECIST 1.1 or RANO by BICR was presented. Per protocol, only data for Cohorts C, D1, D2, E, F, and G were presented for this endpoint. Analysis population consisted of all allocated participants who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Up to approximately 66 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: No statistical comparison between treatment arms of the current study were planned for this endpoint.

[4] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, no analysis was planned for Cohorts A and B.

End point values	Cohort C: Gastric Cancer (Lenva + Pembro)	Cohort D1: Colorectal Cancer (Lenva + Pembro)	Cohort D2: Colorectal Cancer (Lenva)	Cohort E: Glioblastoma Multiforma (Lenva + Pembro)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	99	105	30	101
Units: Percentage of Participants				
number (confidence interval 95%)	15.2 (8.7 to 23.8)	14.3 (8.2 to 22.5)	6.7 (0.8 to 22.1)	21.8 (14.2 to 31.1)

End point values	Cohort F: Biliary Tract Cancer (Lenva + Pembro)	Cohort G: Pancreatic Cancer (Lenva + Pembro)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102	103		
Units: Percentage of Participants				
number (confidence interval 95%)	17.6 (10.8 to 26.4)	7.8 (3.4 to 14.7)		

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants With One or More Adverse Events (AEs)

End point title	Number of Participants With One or More Adverse Events

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a study intervention. The number of participants with at least one or more AE is presented. Analysis population consisted of all allocated participants who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Up to approximately 66 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: No statistical comparison between treatment arms of the current study were planned for this endpoint.

End point values	Cohort A: Triple Negative Breast Cancer (Lenva + Pembro)	Cohort B: Ovarian Cancer (Lenva + Pembro)	Cohort C: Gastric Cancer (Lenva + Pembro)	Cohort D1: Colorectal Cancer (Lenva + Pembro)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	31	99	105
Units: Participants	31	31	97	104

End point values	Cohort D2: Colorectal Cancer (Lenva)	Cohort E: Glioblastoma Multiforma (Lenva + Pembro)	Cohort F: Biliary Tract Cancer (Lenva + Pembro)	Cohort G: Pancreatic Cancer (Lenva + Pembro)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	101	102	103
Units: Participants	30	101	102	103

Statistical analyses

No statistical analyses for this end point

Primary: Number of Participants who Discontinued From Study Treatment Due to an AE

End point title	Number of Participants who Discontinued From Study Treatment Due to an AE[6]

End point description:

An AE was defined as any untoward medical occurrence in a clinical study participant, temporally associated with the use of study intervention, whether or not considered related to the study intervention. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding), symptom, or disease (new or exacerbated) temporally associated with the use of a study intervention. The number of participants who discontinued from study treatment due to an AE is presented. Analysis population consisted of all allocated participants who received at least 1 dose of study intervention.

End point type	Primary

End point timeframe:

Up to approximately 62 months

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: No statistical comparison between treatment arms of the current study were planned for this endpoint.

End point values	Cohort A: Triple Negative Breast Cancer (Lenva + Pembro)	Cohort B: Ovarian Cancer (Lenva + Pembro)	Cohort C: Gastric Cancer (Lenva + Pembro)	Cohort D1: Colorectal Cancer (Lenva + Pembro)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	31	99	105
Units: Participants	5	11	23	19

End point values	Cohort D2: Colorectal Cancer (Lenva)	Cohort E: Glioblastoma Multiforma (Lenva + Pembro)	Cohort F: Biliary Tract Cancer (Lenva + Pembro)	Cohort G: Pancreatic Cancer (Lenva + Pembro)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	101	102	103
Units: Participants	4	11	20	19

Statistical analyses

No statistical analyses for this end point

Secondary: Disease Control Rate (DCR) per RECIST 1.1 by Investigator Assessment

End point title	Disease Control Rate (DCR) per RECIST 1.1 by Investigator Assessment[7]

End point description:

DCR was defined per RECIST 1.1 as the percentage of participants who have a Complete Response (CR: Disappearance of all target lesions) or Partial Response (PR: At least a 30% decrease in the sum of diameters of target lesions) or Stable Disease (SD: Neither sufficient shrinkage to qualify for PR nor sufficient increase to qualify for progressive disease [PD: At least a 20% increase in the sum of diameters of target lesions and an absolute increase of at least 5 mm]). The appearance of one or more new lesions is also considered PD. Disease Control rate per RECIST 1.1 by investigator assessment is presented. Per protocol, only data for Cohorts A and B were presented for this endpoint. Analysis population consisted of all allocated participants who received at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

Up to approximately 66 months

Notes:

[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: Per protocol, no analysis was planned for Cohorts C, D1, D2, E, F, G.

End point values	Cohort A: Triple Negative Breast Cancer (Lenva + Pembro)	Cohort B: Ovarian Cancer (Lenva + Pembro)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	16	24		
Units: Percentage of Participants				
number (confidence interval 95%)	51.6 (33.1 to 69.8)	77.4 (58.9 to 90.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Disease Control Rate (DCR) per RECIST 1.1 or RANO Criteria (GBM only) by BICR

End point title	Disease Control Rate (DCR) per RECIST 1.1 or RANO Criteria (GBM only) by BICR[8]

End point description:

DCR was defined as the percentage of participants who have Complete Response (CR: Disappearance of all target lesions) or Partial Response (PR: At least 30% decrease in the sum of diameters of target lesions) or Stable Disease (SD: Neither sufficient shrinkage to qualify for PR nor increase to qualify for progressive disease [PD: At least 20% increase in the sum of diameters of target lesions and an absolute increase of at least 5 mm. Appearance of one or more new lesions is also considered PD.]). For GBM, response was assessed by RANO criteria. Overall response was based on radiographic response (CR: disappearance of all target lesions, PR: sum of products of diameters [SPD] decreased by ≥ 50% from baseline and SD: SPD <50% decreased from baseline, but <25% increased from nadir) and clinical performance status with steroid dose. Analysis population consists participants who received at least 1 dose of drug. Per protocol, only data for Cohorts C, D1, D2, E, F, and G were presented.

End point type	Secondary

End point timeframe:

Up to approximately 66 months

Notes:

[8] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, no analysis was planned for Cohorts A and B.

End point values	Cohort C: Gastric Cancer (Lenva + Pembro)	Cohort D1: Colorectal Cancer (Lenva + Pembro)	Cohort D2: Colorectal Cancer (Lenva)	Cohort E: Glioblastoma Multiforma (Lenva + Pembro)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	99	105	30	101
Units: Percentage of Participants				
number (confidence interval 95%)	53.5 (43.2 to 63.6)	52.4 (42.4 to 62.2)	56.7 (37.4 to 74.5)	57.4 (47.2 to 67.2)

End point values	Cohort F: Biliary Tract Cancer (Lenva + Pembro)	Cohort G: Pancreatic Cancer (Lenva + Pembro)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102	103		
Units: Percentage of Participants				
number (confidence interval 95%)	64.7 (54.6 to 73.9)	37.9 (28.5 to 48.0)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) per RECIST 1.1 Criteria by Investigator Assessment

End point title	Duration of Response (DOR) per RECIST 1.1 Criteria by Investigator Assessment[9]

End point description:

DOR was defined as time from first documented evidence of Complete Response (CR: disappearance of all target lesions) or Partial Response (PR: at least a 30% decrease in the sum of diameters of target lesions) until progressive disease (PD) or death. Per RECIST 1.1, PD is defined as at least a 20% increase in the sum of diameters of target lesions. In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. The appearance of one or more new lesions is also considered PD. Duration of response per RECIST 1.1 by investigator assessment is presented. Per protocol, only data for Cohorts A and B were presented for this endpoint. Analysis population consisted of all allocated participants who received at least 1 dose of study intervention and had confirmed complete response or partial response. A value of 9999 indicates upper limit not reached at time of data cut-off due to insufficient number of responding participants with relapse.

End point type	Secondary

End point timeframe:

Up to approximately 66 months

Notes:

[9] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, no analysis was planned for Cohorts C, D1, D2, E, F, G.

End point values	Cohort A: Triple Negative Breast Cancer (Lenva + Pembro)	Cohort B: Ovarian Cancer (Lenva + Pembro)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	7	8		
Units: Months				
median (confidence interval 95%)	22.9 (4.2 to 9999)	15.3 (6.4 to 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) per RECIST 1.1 or RANO Criteria (GBM Only) by BICR

End point title	Duration of Response (DOR) per RECIST 1.1 or RANO Criteria (GBM Only) by BICR[10]

End point description:

DOR was defined as time from first documented evidence of Complete Response (CR: disappearance of all target lesions) or Partial Response (PR: at least a 30% decrease in the sum of diameters of target lesions) until progressive disease (PD) or death. Per RECIST 1.1, PD was defined as ≥ 20% increase in the sum of diameters of target lesions with an absolute increase of ≥ 5mm. Appearance of ≥1 new lesions are also considered PD. For GBM, overall RANO response was based on radiographic response (CR: disappearance of all target lesions, PR: SPD decreased by ≥ 50% from baseline value) and clinical performance status with steroid dose. Analysis population consists allocated participants who received at least 1 dose of drug and had confirmed CR or PR. Per protocol, only data for Cohorts C, D1, D2, E, F, and G were presented. A value of 9999 indicates median, lower limit and/or upper limit not reached at time of data cut-off due to insufficient number of responding participants with relapse.

End point type	Secondary

End point timeframe:

Up to approximately 66 months

Notes:

[10] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, no analysis was planned for Cohorts A and B.

End point values	Cohort C: Gastric Cancer (Lenva + Pembro)	Cohort D1: Colorectal Cancer (Lenva + Pembro)	Cohort D2: Colorectal Cancer (Lenva)	Cohort E: Glioblastoma Multiforma (Lenva + Pembro)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	15	15	2	22
Units: Months				
median (confidence interval 95%)	8.3 (4.2 to 9999)	8.3 (4.2 to 18.5)	9999 (9999 to 9999)	4.6 (3.2 to 15.6)

End point values	Cohort F: Biliary Tract Cancer (Lenva + Pembro)	Cohort G: Pancreatic Cancer (Lenva + Pembro)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	18	8		
Units: Months				
median (confidence interval 95%)	6.2 (4.2 to 7.1)	5.8 (2.7 to 9999)		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS) per RECIST 1.1 or RANO Criteria (GBM Only) by BICR

End point title	Progression-Free Survival (PFS) per RECIST 1.1 or RANO Criteria (GBM Only) by BICR[11]

End point description:

PFS was defined as the time from date of study treatment to the first documented progressive disease (PD) based on RECIST 1.1 (or RANO for GBM participants). Per RECIST 1.1, PD was defined as ≥20% increase in the sum of diameters of target lesions. In addition to the relative increase of 20%, the sum must also have demonstrated an absolute increase of ≥5 mm. The appearance of one or more new lesions was also considered PD. For participants with GBM, either radiological progression or clinical deterioration (not attributable to a nontumor-related cause) qualifies as PD. The percentage of participants who experienced PFS per RECIST 1.1 or RANO by BICR is presented. Per protocol, only data for Cohorts C, D1, D2, E, F, and G were presented for this endpoint. Analysis population consisted of all allocated participants who received at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

Up to approximately 66 months

Notes:

[11] - 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: Per protocol, no analysis was planned for Cohorts A and B.

End point values	Cohort C: Gastric Cancer (Lenva + Pembro)	Cohort D1: Colorectal Cancer (Lenva + Pembro)	Cohort D2: Colorectal Cancer (Lenva)	Cohort E: Glioblastoma Multiforma (Lenva + Pembro)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	99	105	30	101
Units: Months				
median (confidence interval 95%)	3.5 (2.3 to 4.1)	3.4 (2.1 to 4.1)	3.4 (2.1 to 4.8)	3.0 (2.8 to 4.1)

End point values	Cohort F: Biliary Tract Cancer (Lenva + Pembro)	Cohort G: Pancreatic Cancer (Lenva + Pembro)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	102	103		
Units: Months				
median (confidence interval 95%)	4.1 (3.6 to 5.9)	2.1 (2.1 to 3.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS) per RECIST 1.1 by Investigator Assessment

End point title	Progression-Free Survival (PFS) per RECIST 1.1 by Investigator Assessment[12]

End point description:

PFS was defined as the time from date of study treatment to the first documented progressive disease (PD) based on RECIST 1.1, modified to follow a maximum of 10 target lesions and a maximum of 5 target lesions per organ or death due to any cause, whichever occurred first. Per RECIST 1.1, PD was defined as ≥20% increase in the sum of diameters of target lesions. In addition to the relative increase of 20%, the sum must also have demonstrated an absolute increase of ≥5 mm. The appearance of one or more new lesions was also considered PD. The percentage of participants who experienced PFS per RECIST 1.1 by investigator assessment is presented. Per protocol, only data for Cohorts A and B were presented for this endpoint. Analysis population consisted of all allocated participants who received at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

Up to approximately 66 months

Notes:

[12] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: Per protocol, no analysis was planned for Cohorts C, D1, D2, E, F, G.

End point values	Cohort A: Triple Negative Breast Cancer (Lenva + Pembro)	Cohort B: Ovarian Cancer (Lenva + Pembro)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	31	31		
Units: Months				
median (confidence interval 95%)	4.2 (1.7 to 6.3)	6.1 (4.1 to 9.4)		

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

OS was defined as the time from the date of study treatment to the date of death due to any cause. Participants without documented death at the time of the final analysis were censored at the date of the last follow-up. The OS for all participants is presented. Analysis population consisted of all allocated participants who received at least 1 dose of study intervention.

End point type	Secondary

End point timeframe:

Up to approximately 66 months

End point values	Cohort A: Triple Negative Breast Cancer (Lenva + Pembro)	Cohort B: Ovarian Cancer (Lenva + Pembro)	Cohort C: Gastric Cancer (Lenva + Pembro)	Cohort D1: Colorectal Cancer (Lenva + Pembro)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	31	31	99	105
Units: Months				
median (confidence interval 95%)	11.4 (4.1 to 21.7)	21.3 (11.7 to 32.3)	4.7 (3.8 to 6.1)	8.7 (7.0 to 10.0)

End point values	Cohort D2: Colorectal Cancer (Lenva)	Cohort E: Glioblastoma Multiforma (Lenva + Pembro)	Cohort F: Biliary Tract Cancer (Lenva + Pembro)	Cohort G: Pancreatic Cancer (Lenva + Pembro)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	101	102	103
Units: Months				
median (confidence interval 95%)	7.9 (5.6 to 14.9)	8.6 (7.4 to 10.8)	7.9 (5.6 to 9.5)	4.3 (3.8 to 5.4)

Statistical analyses

No statistical analyses for this end point

Secondary: Area under the Concentration Curve at Steady State (AUCss) of Lenvatinib

End point title	Area under the Concentration Curve at Steady State (AUCss) of Lenvatinib[13]

End point description:

Blood samples were collected at pre-specified timepoints to determine the AUCss in participants receiving Lenvatinib (Lenva) co-administered with Pembrolizumab (Pembro). AUCss was defined as a measure of drug exposure that was calculated as the product of plasma drug concentration and time after drug administration at steady state. AUCss determined by blood samples collected pre-dose and at designated timepoints post-dose are presented. Noncompartmental analysis was used to calculate AUC0ss for each participant. Mean and standard deviation of AUCss were calculated for each cohort. As specified in the protocol, pharmacokinetic analysis was not planned or conducted in Cohorts D2 and G. Analysis population consists of all allocated participants who received at least 1 dose of study intervention and had data available for this endpoint.

End point type	Secondary

End point timeframe:

Cycle 1 Day 1: 0.5-4 hours and 6-10 hours post-dose; Cycle 1 Day 15: pre-dose and 2-12 hours post-dose; Cycle 2 Day 1: pre-dose, 0.5-4 hours, and 6-10 hours post-dose (up to approximately 23 days). Each cycle is 21 days.

Notes:

[13] - 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: Per protocol, no analysis was planned for Cohorts D2 and G.

End point values	Cohort A: Triple Negative Breast Cancer (Lenva + Pembro)	Cohort B: Ovarian Cancer (Lenva + Pembro)	Cohort C: Gastric Cancer (Lenva + Pembro)	Cohort D1: Colorectal Cancer (Lenva + Pembro)
Subject group type	Reporting group	Reporting group	Reporting group	Reporting group
Number of subjects analysed	30	31	93	104
Units: ng*hr/mL				
arithmetic mean (standard deviation)	3253 (± 1029)	3145 (± 984)	2392 (± 803)	2994 (± 1143)

End point values	Cohort E: Glioblastoma Multiforma (Lenva + Pembro)	Cohort F: Biliary Tract Cancer (Lenva + Pembro)		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	100	100		
Units: ng*hr/mL				
arithmetic mean (standard deviation)	2617 (± 804)	2886 (± 838)		

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to approximately 66 months

Adverse event reporting additional description:

Serious and Other adverse events (AEs) includes all participants who received ≥1 dose of study drug. All-Cause Mortality includes all enrolled participants. MedDRA preferred terms "Neoplasm progression","Malignant neoplasm progression"&"Disease progression" not related to study treatment are excluded as AEs. Data are reported by treatment received.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.1

Reporting groups

Reporting group title	TNBC (Lenva + Pembro)
Reporting group description: -	
Reporting group title	Ovarian (Lenva + Pembro)
Reporting group description: -	
Reporting group title	Gastric (Lenva + Pembro)
Reporting group description: -	
Reporting group title	Pancreatic (Lenva + Pembro)
Reporting group description: -	
Reporting group title	CRC (Lenva)
Reporting group description: -	
Reporting group title	GBM (Lenva + Pembro)
Reporting group description: -	
Reporting group title	BTC (Lenva + Pembro)
Reporting group description: -	
Reporting group title	CRC (Lenva + Pembro)
Reporting group description: -	

Serious adverse events	TNBC (Lenva + Pembro)	Ovarian (Lenva + Pembro)	Gastric (Lenva + Pembro)
Total subjects affected by serious adverse events			
subjects affected / exposed	16 / 31 (51.61%)	19 / 31 (61.29%)	57 / 99 (57.58%)
number of deaths (all causes)	27	28	97
number of deaths resulting from adverse events	1	1	8
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transitional cell carcinoma			

subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid cancer			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Tumour pain			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	0 / 99 (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
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	0 / 99 (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
Haemorrhage			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Hypertension			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive crisis			

subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive urgency			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	0 / 99 (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
Iliac artery occlusion			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous haemorrhage			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Surgical and medical procedures			
Assisted suicide			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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			
Chest pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
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 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	0 / 31 (0.00%)	2 / 31 (6.45%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	2 / 99 (2.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General physical health deterioration			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Social circumstances			

Loss of personal independence in daily activities			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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			
Epistaxis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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 / 31 (3.23%)	0 / 31 (0.00%)	0 / 99 (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
Acute respiratory failure			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	1 / 31 (3.23%)	0 / 31 (0.00%)	0 / 99 (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
Lung consolidation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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	1 / 31 (3.23%)	1 / 31 (3.23%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	1 / 1	1 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	1 / 31 (3.23%)	0 / 31 (0.00%)	0 / 99 (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

Pneumonitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	2 / 99 (2.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disorientation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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			
Stent malfunction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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 dislocation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Investigations			
Blood creatinine increased			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	0 / 99 (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
Blood bilirubin increased			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	0 / 99 (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	1 / 31 (3.23%)	0 / 31 (0.00%)	0 / 99 (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
Alanine aminotransferase increased			
subjects affected / exposed	1 / 31 (3.23%)	0 / 31 (0.00%)	0 / 99 (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
Haemoglobin decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Injury, poisoning and procedural complications			
Cervical vertebral fracture			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral injury			
subjects affected / exposed	1 / 31 (3.23%)	0 / 31 (0.00%)	0 / 99 (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
Infusion related reaction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal anastomosis complication			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rib fracture			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Stoma site haemorrhage			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Stomal hernia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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 stoma complication			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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			
Cardiac arrest			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	2 / 99 (2.02%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Bradycardia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Angina pectoris			
subjects affected / exposed	1 / 31 (3.23%)	0 / 31 (0.00%)	0 / 99 (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
Acute coronary syndrome			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			

subjects affected / exposed	1 / 31 (3.23%)	0 / 31 (0.00%)	0 / 99 (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
Cardiomyopathy			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity myocarditis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular dysfunction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocarditis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Sinus tachycardia			
subjects affected / exposed	1 / 31 (3.23%)	0 / 31 (0.00%)	0 / 99 (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
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cerebrovascular accident			

subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	1 / 31 (3.23%)	0 / 31 (0.00%)	0 / 99 (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
Embolic stroke			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 31 (0.00%)	2 / 31 (6.45%)	0 / 99 (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
Hepatic encephalopathy			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intracranial pressure increased			

subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Leukoencephalopathy			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	0 / 99 (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
Metabolic encephalopathy			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myasthenic syndrome			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Neurotoxicity			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraneoplastic neurological syndrome			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			

subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord haemorrhage			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Status epilepticus			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	1 / 31 (3.23%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Vasogenic cerebral oedema			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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 encephalopathy			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wernicke's encephalopathy			

subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thrombotic microangiopathy			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic uraemic syndrome			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ascites			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall haematoma			

subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain upper			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	2 / 99 (2.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal pain			
subjects affected / exposed	1 / 31 (3.23%)	0 / 31 (0.00%)	4 / 99 (4.04%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal perforation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal obstruction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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	1 / 31 (3.23%)	2 / 31 (6.45%)	3 / 99 (3.03%)
occurrences causally related to treatment / all	1 / 1	1 / 2	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			

subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	0 / 99 (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
Duodenal stenosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric ulcer haemorrhage			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric perforation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Gastric haemorrhage			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Dysphagia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal haemorrhage			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haematemesis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	2 / 99 (2.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal obstruction			

subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated pancreatitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal dilatation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 31 (0.00%)	3 / 31 (9.68%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	1 / 3	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal pseudo-obstruction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal haemorrhage			

subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	0 / 99 (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
Jejunal perforation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestinal obstruction			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal stenosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal perforation			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	2 / 99 (2.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	2 / 2
Obstruction gastric			

subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	1 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	0 / 99 (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
Stomatitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	2 / 99 (2.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varices oesophageal			

subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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	0 / 31 (0.00%)	2 / 31 (6.45%)	2 / 99 (2.02%)
occurrences causally related to treatment / all	0 / 0	1 / 2	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	0 / 99 (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
Bile duct stone			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	0 / 99 (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
Biliary tract disorder			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis acute			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholecystitis			
subjects affected / exposed	0 / 31 (0.00%)	2 / 31 (6.45%)	0 / 99 (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
Cholecystitis acute			

subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cirrhosis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	1 / 31 (3.23%)	0 / 31 (0.00%)	0 / 99 (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
Hyperbilirubinaemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertransaminasaemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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 hepatitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			

subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	2 / 99 (2.02%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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			
Nephrotic syndrome			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Urinary tract obstruction			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	0 / 99 (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

Ureterolithiasis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 31 (3.23%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophysitis			
subjects affected / exposed	1 / 31 (3.23%)	0 / 31 (0.00%)	2 / 99 (2.02%)
occurrences causally related to treatment / all	1 / 1	0 / 0	3 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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 chest pain			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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			
Abscess limb			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall abscess			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal infection			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	0 / 99 (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
Abdominal abscess			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary sepsis			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	0 / 99 (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
Bacteroides infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteraemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
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 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Anal abscess			

subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	1 / 31 (3.23%)	0 / 31 (0.00%)	0 / 99 (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
Device related infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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 sepsis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			

subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural abscess			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	0 / 99 (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
Escherichia sepsis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective aneurysm			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			

subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lower respiratory tract infection			
subjects affected / exposed	1 / 31 (3.23%)	0 / 31 (0.00%)	0 / 99 (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
Meningitis viral			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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 sepsis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peritonitis			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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 / 31 (3.23%)	2 / 31 (6.45%)	2 / 99 (2.02%)
occurrences causally related to treatment / all	0 / 1	0 / 2	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			

subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Scrotal infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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 / 31 (0.00%)	2 / 31 (6.45%)	0 / 99 (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
Tooth abscess			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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 infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Septic shock			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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 / 31 (3.23%)	1 / 31 (3.23%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
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 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	1 / 31 (3.23%)	2 / 31 (6.45%)	0 / 99 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 2	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Pancreatic (Lenva + Pembro)	CRC (Lenva)	GBM (Lenva + Pembro)
Total subjects affected by serious adverse events			
subjects affected / exposed	49 / 103 (47.57%)	12 / 30 (40.00%)	30 / 101 (29.70%)
number of deaths (all causes)	101	30	99
number of deaths resulting from adverse events	7	2	3
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Transitional cell carcinoma			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Thyroid cancer			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour pain			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolism			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertension			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Hypertensive crisis			

subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypertensive urgency			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypovolaemic shock			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Iliac artery occlusion			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasculitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Venous haemorrhage			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Surgical and medical procedures			
Assisted suicide			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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

Asthenia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Death			
subjects affected / exposed	0 / 103 (0.00%)	1 / 30 (3.33%)	0 / 101 (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
Pain			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyrexia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	4 / 101 (3.96%)
occurrences causally related to treatment / all	0 / 1	0 / 0	2 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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 physical health deterioration			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Mucosal inflammation			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Multiple organ dysfunction syndrome			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Social circumstances			

Loss of personal independence in daily activities			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	0 / 103 (0.00%)	1 / 30 (3.33%)	0 / 101 (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
Dyspnoea			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Acute respiratory failure			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung consolidation			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Pneumothorax			
subjects affected / exposed	2 / 103 (1.94%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	2 / 101 (1.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Pleural effusion			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Lung disorder			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Psychiatric disorders			
Confusional state			
subjects affected / exposed	0 / 103 (0.00%)	1 / 30 (3.33%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Delirium			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Disorientation			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Product issues			
Stent malfunction			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Device dislocation			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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			
Blood creatinine increased			
subjects affected / exposed	0 / 103 (0.00%)	1 / 30 (3.33%)	0 / 101 (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
Blood bilirubin increased			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemoglobin decreased			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Platelet count decreased			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Weight decreased			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Transaminases increased			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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			
Cervical vertebral fracture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Craniocerebral injury			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infusion related reaction			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal anastomosis complication			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pelvic fracture			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Rib fracture			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal fracture			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Stoma site haemorrhage			
subjects affected / exposed	0 / 103 (0.00%)	1 / 30 (3.33%)	0 / 101 (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

Stomal hernia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Toxicity to various agents			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Urinary tract stoma complication			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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			
Cardiac arrest			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bradycardia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Angina pectoris			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute coronary syndrome			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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 failure			

subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiomyopathy			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypersensitivity myocarditis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Left ventricular dysfunction			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myocardial infarction			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Myocarditis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Sinus tachycardia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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			
Aphasia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	1 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cognitive disorder			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Embolic stroke			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Epilepsy			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	2 / 101 (1.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalopathy			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemorrhage intracranial			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Headache			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic encephalopathy			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Intracranial pressure increased			

subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ischaemic stroke			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Leukoencephalopathy			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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 encephalopathy			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Myasthenic syndrome			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Neurotoxicity			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Paraneoplastic neurological syndrome			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord compression			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Somnolence			

subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Seizure			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	2 / 101 (1.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Spinal cord haemorrhage			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Status epilepticus			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vasogenic cerebral oedema			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular encephalopathy			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Syncope			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	2 / 101 (1.98%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Wernicke's encephalopathy			

subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Febrile neutropenia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Thrombotic microangiopathy			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancytopenia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Haemolytic uraemic syndrome			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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	2 / 103 (1.94%)	0 / 30 (0.00%)	0 / 101 (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
Ascites			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Abdominal wall haematoma			

subjects affected / exposed	0 / 103 (0.00%)	1 / 30 (3.33%)	0 / 101 (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
Abdominal pain upper			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Abdominal pain			
subjects affected / exposed	5 / 103 (4.85%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 6	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis ischaemic			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal perforation			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Duodenal obstruction			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulum intestinal			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Diarrhoea			
subjects affected / exposed	0 / 103 (0.00%)	2 / 30 (6.67%)	0 / 101 (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
Constipation			

subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Duodenal stenosis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Gastric ulcer haemorrhage			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric perforation			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastric haemorrhage			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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 haemorrhage			
subjects affected / exposed	0 / 103 (0.00%)	1 / 30 (3.33%)	0 / 101 (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
Haematemesis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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 obstruction			

subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Ileus			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated pancreatitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal dilatation			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal obstruction			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intestinal perforation			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 1	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	1 / 1
Intestinal pseudo-obstruction			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Intra-abdominal haemorrhage			

subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jejunal perforation			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Large intestinal obstruction			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Melaena			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine perforation			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Nausea			
subjects affected / exposed	2 / 103 (1.94%)	0 / 30 (0.00%)	0 / 101 (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
Oesophageal stenosis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Oesophageal perforation			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Obstruction gastric			

subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pancreatitis acute			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rectal haemorrhage			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Small intestinal obstruction			
subjects affected / exposed	1 / 103 (0.97%)	1 / 30 (3.33%)	0 / 101 (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
Stomatitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subileus			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Varices oesophageal			

subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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	1 / 103 (0.97%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Bile duct stone			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract disorder			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cholangitis acute			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Cholecystitis			
subjects affected / exposed	0 / 103 (0.00%)	1 / 30 (3.33%)	0 / 101 (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
Cholecystitis acute			

subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic cirrhosis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatic failure			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperbilirubinaemia			
subjects affected / exposed	0 / 103 (0.00%)	2 / 30 (6.67%)	0 / 101 (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
Hypertransaminasaemia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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 hepatitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Jaundice cholestatic			

subjects affected / exposed	0 / 103 (0.00%)	1 / 30 (3.33%)	0 / 101 (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
Skin and subcutaneous tissue disorders			
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal and urinary disorders			
Nephrotic syndrome			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Haematuria			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute kidney injury			
subjects affected / exposed	1 / 103 (0.97%)	1 / 30 (3.33%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	1 / 1	0 / 1	2 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Renal failure			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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 obstruction			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Ureterolithiasis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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			
Adrenal insufficiency			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypophysitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bone pain			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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 chest pain			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myositis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Myalgia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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			
Abscess limb			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal wall abscess			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Abdominal infection			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Abdominal abscess			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary sepsis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bacteroides infection			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Bacteraemia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Anal abscess			

subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cellulitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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	1 / 103 (0.97%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Device related sepsis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Biliary tract infection			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Diverticulitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Encephalitis			

subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Enterocolitis infectious			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Herpes zoster			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Extradural abscess			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastroenteritis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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 sepsis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Infection			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infective aneurysm			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Liver abscess			

subjects affected / exposed	2 / 103 (1.94%)	0 / 30 (0.00%)	0 / 101 (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
Lower respiratory tract infection			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Meningitis viral			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Periorbital cellulitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Peritonitis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Pneumonia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pneumonia aspiration			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Postoperative wound infection			

subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Scrotal infection			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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	1 / 103 (0.97%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tooth abscess			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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 infection			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Septic shock			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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	0 / 103 (0.00%)	1 / 30 (3.33%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 1	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Vascular device infection			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (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
Hyperkalaemia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypernatraemia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypoglycaemia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypokalaemia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
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	BTC (Lenva + Pembro)	CRC (Lenva + Pembro)	
Total subjects affected by serious adverse events			
subjects affected / exposed	62 / 102 (60.78%)	55 / 105 (52.38%)	
number of deaths (all causes)	98	97	
number of deaths resulting from adverse events	5	3	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Transitional cell carcinoma			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thyroid cancer			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour pain			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolism			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertension			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive crisis			

subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertensive urgency			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypovolaemic shock			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Iliac artery occlusion			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasculitis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Surgical and medical procedures			
Assisted suicide			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Chest pain			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Asthenia			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	7 / 102 (6.86%)	2 / 105 (1.90%)	
occurrences causally related to treatment / all	2 / 9	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mucosal inflammation			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Multiple organ dysfunction syndrome			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Social circumstances			

Loss of personal independence in daily activities			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Epistaxis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung consolidation			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Pneumonitis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung disorder			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 102 (0.98%)	2 / 105 (1.90%)	
occurrences causally related to treatment / all	1 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Disorientation			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Product issues			
Stent malfunction			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device dislocation			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Investigations			
Blood creatinine increased			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood bilirubin increased			
subjects affected / exposed	1 / 102 (0.98%)	2 / 105 (1.90%)	
occurrences causally related to treatment / all	1 / 1	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Alanine aminotransferase increased			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoglobin decreased			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Platelet count decreased			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Weight decreased			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Transaminases increased			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Injury, poisoning and procedural complications			
Cervical vertebral fracture			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Craniocerebral injury			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion related reaction			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal anastomosis complication			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pelvic fracture			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rib fracture			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal fracture			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stoma site haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Stomal hernia			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subdural haematoma			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxicity to various agents			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract stoma complication			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Cardiac arrest			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bradycardia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute coronary syndrome			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			

subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiomyopathy			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypersensitivity myocarditis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular dysfunction			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocarditis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Aphasia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			

subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cognitive disorder			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Embolic stroke			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Epilepsy			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic encephalopathy			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intracranial pressure increased			

subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			
subjects affected / exposed	1 / 102 (0.98%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukoencephalopathy			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolic encephalopathy			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myasthenic syndrome			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neurotoxicity			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraneoplastic neurological syndrome			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord compression			
subjects affected / exposed	1 / 102 (0.98%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Somnolence			

subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal cord haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Status epilepticus			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subarachnoid haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vasogenic cerebral oedema			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular encephalopathy			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Wernicke's encephalopathy			

subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombotic microangiopathy			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancytopenia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemolytic uraemic syndrome			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Colitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ascites			
subjects affected / exposed	2 / 102 (1.96%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall haematoma			

subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	6 / 102 (5.88%)	2 / 105 (1.90%)	
occurrences causally related to treatment / all	1 / 8	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis ischaemic			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal perforation			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal obstruction			
subjects affected / exposed	1 / 102 (0.98%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulum intestinal			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	2 / 102 (1.96%)	3 / 105 (2.86%)	
occurrences causally related to treatment / all	2 / 2	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			

subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal stenosis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric ulcer haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric perforation			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastric haemorrhage			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal haemorrhage			
subjects affected / exposed	1 / 102 (0.98%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematemesis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal obstruction			

subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ileus			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated enterocolitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated pancreatitis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal dilatation			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	0 / 102 (0.00%)	3 / 105 (2.86%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			
subjects affected / exposed	2 / 102 (1.96%)	2 / 105 (1.90%)	
occurrences causally related to treatment / all	0 / 2	2 / 2	
deaths causally related to treatment / all	0 / 1	1 / 1	
Intestinal pseudo-obstruction			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intra-abdominal haemorrhage			

subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jejunal perforation			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestinal obstruction			
subjects affected / exposed	0 / 102 (0.00%)	2 / 105 (1.90%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Melaena			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	1 / 102 (0.98%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal stenosis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal perforation			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Obstruction gastric			

subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis acute			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rectal haemorrhage			
subjects affected / exposed	1 / 102 (0.98%)	2 / 105 (1.90%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	2 / 102 (1.96%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomatitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Varices oesophageal			

subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	2 / 102 (1.96%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Biliary obstruction			
subjects affected / exposed	5 / 102 (4.90%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 5	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bile duct stone			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary tract disorder			
subjects affected / exposed	2 / 102 (1.96%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholangitis			
subjects affected / exposed	6 / 102 (5.88%)	3 / 105 (2.86%)	
occurrences causally related to treatment / all	0 / 6	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Cholangitis acute			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Cholecystitis acute			

subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic cirrhosis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatic failure			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hepatitis			
subjects affected / exposed	2 / 102 (1.96%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperbilirubinaemia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypertransaminasaemia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune-mediated hepatitis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Jaundice cholestatic			

subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash			
subjects affected / exposed	1 / 102 (0.98%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Nephrotic syndrome			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute kidney injury			
subjects affected / exposed	4 / 102 (3.92%)	2 / 105 (1.90%)	
occurrences causally related to treatment / all	4 / 4	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract obstruction			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Ureterolithiasis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypophysitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	1 / 102 (0.98%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone pain			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	2 / 102 (1.96%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myositis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Infections and infestations			
Abscess limb			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal wall abscess			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal infection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal abscess			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary sepsis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteroides infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacteraemia			
subjects affected / exposed	2 / 102 (1.96%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anorectal infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Anal abscess			

subjects affected / exposed	1 / 102 (0.98%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
COVID-19			
subjects affected / exposed	1 / 102 (0.98%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related sepsis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Biliary tract infection			
subjects affected / exposed	4 / 102 (3.92%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 5	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Diverticulitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis			

subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enterocolitis infectious			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Herpes zoster			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Extradural abscess			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Escherichia sepsis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective aneurysm			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Liver abscess			

subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis viral			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Periorbital cellulitis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary sepsis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peritonitis			
subjects affected / exposed	2 / 102 (1.96%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pneumonia			
subjects affected / exposed	2 / 102 (1.96%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Postoperative wound infection			

subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Scrotal infection			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 102 (0.00%)	3 / 105 (2.86%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tooth abscess			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin infection			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Septic shock			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 102 (0.00%)	2 / 105 (1.90%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Vascular device infection			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Metabolism and nutrition disorders			
Dehydration			

subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperkalaemia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypernatraemia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	2 / 102 (1.96%)	1 / 105 (0.95%)	
occurrences causally related to treatment / all	2 / 2	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	TNBC (Lenva + Pembro)	Ovarian (Lenva + Pembro)	Gastric (Lenva + Pembro)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	30 / 31 (96.77%)	31 / 31 (100.00%)	95 / 99 (95.96%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	2 / 31 (6.45%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences (all)	2	0	0
Vascular disorders			

Hypertension			
subjects affected / exposed	16 / 31 (51.61%)	21 / 31 (67.74%)	37 / 99 (37.37%)
occurrences (all)	25	28	42
Hypotension			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	2 / 99 (2.02%)
occurrences (all)	0	1	2
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	7 / 31 (22.58%)	6 / 31 (19.35%)	30 / 99 (30.30%)
occurrences (all)	8	8	34
Chest pain			
subjects affected / exposed	3 / 31 (9.68%)	1 / 31 (3.23%)	5 / 99 (5.05%)
occurrences (all)	3	1	5
Oedema peripheral			
subjects affected / exposed	2 / 31 (6.45%)	5 / 31 (16.13%)	5 / 99 (5.05%)
occurrences (all)	3	5	5
Mucosal inflammation			
subjects affected / exposed	7 / 31 (22.58%)	10 / 31 (32.26%)	9 / 99 (9.09%)
occurrences (all)	10	10	10
Influenza like illness			
subjects affected / exposed	0 / 31 (0.00%)	2 / 31 (6.45%)	0 / 99 (0.00%)
occurrences (all)	0	2	0
Fatigue			
subjects affected / exposed	13 / 31 (41.94%)	14 / 31 (45.16%)	21 / 99 (21.21%)
occurrences (all)	14	16	22
Chills			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	2 / 99 (2.02%)
occurrences (all)	0	0	2
Peripheral swelling			
subjects affected / exposed	0 / 31 (0.00%)	2 / 31 (6.45%)	0 / 99 (0.00%)
occurrences (all)	0	2	0
Pyrexia			
subjects affected / exposed	4 / 31 (12.90%)	3 / 31 (9.68%)	8 / 99 (8.08%)
occurrences (all)	4	3	9
Reproductive system and breast disorders			

Breast pain			
subjects affected / exposed	3 / 31 (9.68%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences (all)	4	0	0
Respiratory, thoracic and mediastinal disorders			
Dysphonia			
subjects affected / exposed	5 / 31 (16.13%)	3 / 31 (9.68%)	20 / 99 (20.20%)
occurrences (all)	5	3	20
Cough			
subjects affected / exposed	6 / 31 (19.35%)	4 / 31 (12.90%)	6 / 99 (6.06%)
occurrences (all)	6	5	6
Dyspnoea			
subjects affected / exposed	4 / 31 (12.90%)	4 / 31 (12.90%)	6 / 99 (6.06%)
occurrences (all)	4	5	6
Epistaxis			
subjects affected / exposed	3 / 31 (9.68%)	2 / 31 (6.45%)	8 / 99 (8.08%)
occurrences (all)	3	2	8
Productive cough			
subjects affected / exposed	0 / 31 (0.00%)	2 / 31 (6.45%)	3 / 99 (3.03%)
occurrences (all)	0	2	3
Wheezing			
subjects affected / exposed	2 / 31 (6.45%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences (all)	2	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 31 (6.45%)	5 / 31 (16.13%)	2 / 99 (2.02%)
occurrences (all)	2	6	2
Depression			
subjects affected / exposed	1 / 31 (3.23%)	2 / 31 (6.45%)	2 / 99 (2.02%)
occurrences (all)	1	2	2
Insomnia			
subjects affected / exposed	3 / 31 (9.68%)	1 / 31 (3.23%)	5 / 99 (5.05%)
occurrences (all)	3	1	5
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	2 / 31 (6.45%)	6 / 31 (19.35%)	14 / 99 (14.14%)
occurrences (all)	2	7	14

Blood bilirubin increased			
subjects affected / exposed	1 / 31 (3.23%)	2 / 31 (6.45%)	7 / 99 (7.07%)
occurrences (all)	3	2	8
Blood cholesterol increased			
subjects affected / exposed	1 / 31 (3.23%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences (all)	4	0	0
Blood creatine phosphokinase increased			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	3 / 99 (3.03%)
occurrences (all)	0	1	3
Blood creatinine increased			
subjects affected / exposed	1 / 31 (3.23%)	1 / 31 (3.23%)	5 / 99 (5.05%)
occurrences (all)	1	1	7
Blood albumin decreased			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	2 / 99 (2.02%)
occurrences (all)	0	1	2
Aspartate aminotransferase increased			
subjects affected / exposed	6 / 31 (19.35%)	8 / 31 (25.81%)	18 / 99 (18.18%)
occurrences (all)	11	17	25
Amylase increased			
subjects affected / exposed	1 / 31 (3.23%)	2 / 31 (6.45%)	7 / 99 (7.07%)
occurrences (all)	1	2	9
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	4 / 99 (4.04%)
occurrences (all)	0	1	4
Alanine aminotransferase increased			
subjects affected / exposed	5 / 31 (16.13%)	7 / 31 (22.58%)	12 / 99 (12.12%)
occurrences (all)	12	17	18
Blood magnesium decreased			
subjects affected / exposed	1 / 31 (3.23%)	1 / 31 (3.23%)	2 / 99 (2.02%)
occurrences (all)	1	1	4
Blood sodium increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Blood thyroid stimulating hormone increased			

subjects affected / exposed	1 / 31 (3.23%)	3 / 31 (9.68%)	3 / 99 (3.03%)
occurrences (all)	6	3	3
Blood urea increased			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	2 / 99 (2.02%)
occurrences (all)	0	0	2
Gamma-glutamyltransferase increased			
subjects affected / exposed	2 / 31 (6.45%)	2 / 31 (6.45%)	7 / 99 (7.07%)
occurrences (all)	2	2	7
Lipase increased			
subjects affected / exposed	2 / 31 (6.45%)	3 / 31 (9.68%)	8 / 99 (8.08%)
occurrences (all)	2	4	9
Lymphocyte count decreased			
subjects affected / exposed	1 / 31 (3.23%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences (all)	1	0	1
Neutrophil count decreased			
subjects affected / exposed	5 / 31 (16.13%)	1 / 31 (3.23%)	1 / 99 (1.01%)
occurrences (all)	10	1	1
Platelet count decreased			
subjects affected / exposed	5 / 31 (16.13%)	3 / 31 (9.68%)	9 / 99 (9.09%)
occurrences (all)	7	3	10
Platelet count increased			
subjects affected / exposed	1 / 31 (3.23%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences (all)	1	0	1
Protein total decreased			
subjects affected / exposed	1 / 31 (3.23%)	0 / 31 (0.00%)	3 / 99 (3.03%)
occurrences (all)	1	0	4
Weight decreased			
subjects affected / exposed	8 / 31 (25.81%)	7 / 31 (22.58%)	15 / 99 (15.15%)
occurrences (all)	9	8	15
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	1 / 31 (3.23%)	1 / 31 (3.23%)	1 / 99 (1.01%)
occurrences (all)	1	1	1
Cardiac disorders			

Tachycardia			
subjects affected / exposed	2 / 31 (6.45%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences (all)	2	0	1
Nervous system disorders			
Dizziness			
subjects affected / exposed	0 / 31 (0.00%)	5 / 31 (16.13%)	4 / 99 (4.04%)
occurrences (all)	0	5	4
Aphasia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences (all)	0	0	0
Dysgeusia			
subjects affected / exposed	2 / 31 (6.45%)	4 / 31 (12.90%)	5 / 99 (5.05%)
occurrences (all)	2	5	5
Tremor			
subjects affected / exposed	0 / 31 (0.00%)	3 / 31 (9.68%)	0 / 99 (0.00%)
occurrences (all)	0	3	0
Headache			
subjects affected / exposed	10 / 31 (32.26%)	10 / 31 (32.26%)	7 / 99 (7.07%)
occurrences (all)	16	16	8
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	5 / 31 (16.13%)	4 / 31 (12.90%)	17 / 99 (17.17%)
occurrences (all)	9	5	20
Thrombocytopenia			
subjects affected / exposed	2 / 31 (6.45%)	2 / 31 (6.45%)	10 / 99 (10.10%)
occurrences (all)	2	3	14
Leukopenia			
subjects affected / exposed	0 / 31 (0.00%)	0 / 31 (0.00%)	5 / 99 (5.05%)
occurrences (all)	0	0	5
Neutropenia			
subjects affected / exposed	1 / 31 (3.23%)	2 / 31 (6.45%)	6 / 99 (6.06%)
occurrences (all)	1	3	7
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	0 / 31 (0.00%)	5 / 31 (16.13%)	2 / 99 (2.02%)
occurrences (all)	0	6	2
Abdominal pain			

subjects affected / exposed	5 / 31 (16.13%)	10 / 31 (32.26%)	17 / 99 (17.17%)
occurrences (all)	7	11	19
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 31 (9.68%)	3 / 31 (9.68%)	4 / 99 (4.04%)
occurrences (all)	4	4	4
Flatulence			
subjects affected / exposed	0 / 31 (0.00%)	3 / 31 (9.68%)	0 / 99 (0.00%)
occurrences (all)	0	3	0
Dysphagia			
subjects affected / exposed	2 / 31 (6.45%)	0 / 31 (0.00%)	6 / 99 (6.06%)
occurrences (all)	2	0	6
Dyspepsia			
subjects affected / exposed	5 / 31 (16.13%)	2 / 31 (6.45%)	4 / 99 (4.04%)
occurrences (all)	6	3	4
Dry mouth			
subjects affected / exposed	1 / 31 (3.23%)	8 / 31 (25.81%)	2 / 99 (2.02%)
occurrences (all)	1	9	2
Diarrhoea			
subjects affected / exposed	14 / 31 (45.16%)	19 / 31 (61.29%)	30 / 99 (30.30%)
occurrences (all)	34	38	40
Constipation			
subjects affected / exposed	7 / 31 (22.58%)	11 / 31 (35.48%)	17 / 99 (17.17%)
occurrences (all)	7	11	18
Ascites			
subjects affected / exposed	0 / 31 (0.00%)	4 / 31 (12.90%)	4 / 99 (4.04%)
occurrences (all)	0	5	4
Nausea			
subjects affected / exposed	13 / 31 (41.94%)	15 / 31 (48.39%)	31 / 99 (31.31%)
occurrences (all)	17	21	32
Abdominal pain upper			
subjects affected / exposed	3 / 31 (9.68%)	8 / 31 (25.81%)	7 / 99 (7.07%)
occurrences (all)	3	10	7
Vomiting			
subjects affected / exposed	10 / 31 (32.26%)	13 / 31 (41.94%)	15 / 99 (15.15%)
occurrences (all)	18	22	17
Toothache			

subjects affected / exposed	1 / 31 (3.23%)	3 / 31 (9.68%)	0 / 99 (0.00%)
occurrences (all)	1	3	0
Stomatitis			
subjects affected / exposed	4 / 31 (12.90%)	6 / 31 (19.35%)	9 / 99 (9.09%)
occurrences (all)	4	6	9
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	3 / 31 (9.68%)	5 / 31 (16.13%)	4 / 99 (4.04%)
occurrences (all)	3	5	4
Dry skin			
subjects affected / exposed	1 / 31 (3.23%)	3 / 31 (9.68%)	6 / 99 (6.06%)
occurrences (all)	1	3	6
Hyperkeratosis			
subjects affected / exposed	2 / 31 (6.45%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences (all)	2	0	1
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	8 / 31 (25.81%)	6 / 31 (19.35%)	10 / 99 (10.10%)
occurrences (all)	8	6	10
Pruritus			
subjects affected / exposed	2 / 31 (6.45%)	6 / 31 (19.35%)	13 / 99 (13.13%)
occurrences (all)	3	7	13
Rash maculo-papular			
subjects affected / exposed	0 / 31 (0.00%)	2 / 31 (6.45%)	0 / 99 (0.00%)
occurrences (all)	0	2	0
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	0 / 31 (0.00%)	3 / 31 (9.68%)	2 / 99 (2.02%)
occurrences (all)	0	3	2
Haematuria			
subjects affected / exposed	1 / 31 (3.23%)	2 / 31 (6.45%)	3 / 99 (3.03%)
occurrences (all)	1	2	3
Leukocyturia			
subjects affected / exposed	0 / 31 (0.00%)	2 / 31 (6.45%)	0 / 99 (0.00%)
occurrences (all)	0	2	0
Proteinuria			

subjects affected / exposed	6 / 31 (19.35%)	13 / 31 (41.94%)	12 / 99 (12.12%)
occurrences (all)	8	18	13
Hydronephrosis			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	0 / 99 (0.00%)
occurrences (all)	0	1	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	14 / 31 (45.16%)	14 / 31 (45.16%)	25 / 99 (25.25%)
occurrences (all)	15	14	25
Hyperthyroidism			
subjects affected / exposed	4 / 31 (12.90%)	2 / 31 (6.45%)	6 / 99 (6.06%)
occurrences (all)	4	2	6
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	3 / 31 (9.68%)	2 / 31 (6.45%)	1 / 99 (1.01%)
occurrences (all)	3	4	1
Flank pain			
subjects affected / exposed	1 / 31 (3.23%)	3 / 31 (9.68%)	1 / 99 (1.01%)
occurrences (all)	1	3	1
Back pain			
subjects affected / exposed	5 / 31 (16.13%)	4 / 31 (12.90%)	13 / 99 (13.13%)
occurrences (all)	5	4	14
Musculoskeletal chest pain			
subjects affected / exposed	4 / 31 (12.90%)	0 / 31 (0.00%)	2 / 99 (2.02%)
occurrences (all)	4	0	2
Arthralgia			
subjects affected / exposed	11 / 31 (35.48%)	11 / 31 (35.48%)	10 / 99 (10.10%)
occurrences (all)	18	17	13
Pain in extremity			
subjects affected / exposed	2 / 31 (6.45%)	2 / 31 (6.45%)	4 / 99 (4.04%)
occurrences (all)	2	2	6
Neck pain			
subjects affected / exposed	4 / 31 (12.90%)	2 / 31 (6.45%)	1 / 99 (1.01%)
occurrences (all)	4	2	1
Myalgia			

subjects affected / exposed	6 / 31 (19.35%)	7 / 31 (22.58%)	6 / 99 (6.06%)
occurrences (all)	6	7	6
Musculoskeletal pain			
subjects affected / exposed	1 / 31 (3.23%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences (all)	1	0	0
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	2 / 31 (6.45%)	5 / 31 (16.13%)	4 / 99 (4.04%)
occurrences (all)	3	10	4
Upper respiratory tract infection			
subjects affected / exposed	5 / 31 (16.13%)	0 / 31 (0.00%)	0 / 99 (0.00%)
occurrences (all)	5	0	0
Tooth infection			
subjects affected / exposed	0 / 31 (0.00%)	2 / 31 (6.45%)	3 / 99 (3.03%)
occurrences (all)	0	3	3
Gingivitis			
subjects affected / exposed	1 / 31 (3.23%)	2 / 31 (6.45%)	2 / 99 (2.02%)
occurrences (all)	1	2	2
Cystitis			
subjects affected / exposed	2 / 31 (6.45%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences (all)	2	0	1
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	2 / 31 (6.45%)	0 / 31 (0.00%)	4 / 99 (4.04%)
occurrences (all)	2	0	5
Hyperglycaemia			
subjects affected / exposed	3 / 31 (9.68%)	1 / 31 (3.23%)	3 / 99 (3.03%)
occurrences (all)	6	3	3
Hypoalbuminaemia			
subjects affected / exposed	2 / 31 (6.45%)	4 / 31 (12.90%)	9 / 99 (9.09%)
occurrences (all)	2	5	9
Hypertriglyceridaemia			
subjects affected / exposed	1 / 31 (3.23%)	0 / 31 (0.00%)	1 / 99 (1.01%)
occurrences (all)	4	0	1
Decreased appetite			

subjects affected / exposed	9 / 31 (29.03%)	15 / 31 (48.39%)	30 / 99 (30.30%)
occurrences (all)	12	20	31
Dehydration			
subjects affected / exposed	1 / 31 (3.23%)	4 / 31 (12.90%)	0 / 99 (0.00%)
occurrences (all)	1	5	0
Hypokalaemia			
subjects affected / exposed	4 / 31 (12.90%)	3 / 31 (9.68%)	4 / 99 (4.04%)
occurrences (all)	4	6	4
Hypophosphataemia			
subjects affected / exposed	0 / 31 (0.00%)	1 / 31 (3.23%)	5 / 99 (5.05%)
occurrences (all)	0	1	5
Hyponatraemia			
subjects affected / exposed	0 / 31 (0.00%)	2 / 31 (6.45%)	8 / 99 (8.08%)
occurrences (all)	0	2	8
Hypomagnesaemia			
subjects affected / exposed	4 / 31 (12.90%)	5 / 31 (16.13%)	1 / 99 (1.01%)
occurrences (all)	5	17	1

Non-serious adverse events	Pancreatic (Lenva + Pembro)	CRC (Lenva)	GBM (Lenva + Pembro)
Total subjects affected by non-serious adverse events			
subjects affected / exposed	101 / 103 (98.06%)	29 / 30 (96.67%)	98 / 101 (97.03%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	2 / 103 (1.94%)	1 / 30 (3.33%)	0 / 101 (0.00%)
occurrences (all)	2	1	0
Vascular disorders			
Hypertension			
subjects affected / exposed	55 / 103 (53.40%)	17 / 30 (56.67%)	51 / 101 (50.50%)
occurrences (all)	65	22	65
Hypotension			
subjects affected / exposed	1 / 103 (0.97%)	1 / 30 (3.33%)	0 / 101 (0.00%)
occurrences (all)	1	1	0
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	23 / 103 (22.33%)	7 / 30 (23.33%)	29 / 101 (28.71%)
occurrences (all)	25	8	36

Chest pain			
subjects affected / exposed	1 / 103 (0.97%)	1 / 30 (3.33%)	3 / 101 (2.97%)
occurrences (all)	1	1	3
Oedema peripheral			
subjects affected / exposed	19 / 103 (18.45%)	0 / 30 (0.00%)	5 / 101 (4.95%)
occurrences (all)	20	0	5
Mucosal inflammation			
subjects affected / exposed	5 / 103 (4.85%)	2 / 30 (6.67%)	11 / 101 (10.89%)
occurrences (all)	5	2	14
Influenza like illness			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	2 / 101 (1.98%)
occurrences (all)	1	0	2
Fatigue			
subjects affected / exposed	31 / 103 (30.10%)	9 / 30 (30.00%)	20 / 101 (19.80%)
occurrences (all)	35	11	22
Chills			
subjects affected / exposed	6 / 103 (5.83%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences (all)	6	0	0
Peripheral swelling			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Pyrexia			
subjects affected / exposed	19 / 103 (18.45%)	2 / 30 (6.67%)	8 / 101 (7.92%)
occurrences (all)	23	2	13
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Respiratory, thoracic and mediastinal disorders			
Dysphonia			
subjects affected / exposed	17 / 103 (16.50%)	12 / 30 (40.00%)	11 / 101 (10.89%)
occurrences (all)	18	14	12
Cough			
subjects affected / exposed	5 / 103 (4.85%)	1 / 30 (3.33%)	9 / 101 (8.91%)
occurrences (all)	5	1	9
Dyspnoea			

subjects affected / exposed	7 / 103 (6.80%)	2 / 30 (6.67%)	5 / 101 (4.95%)
occurrences (all)	8	2	5
Epistaxis			
subjects affected / exposed	2 / 103 (1.94%)	0 / 30 (0.00%)	5 / 101 (4.95%)
occurrences (all)	2	0	6
Productive cough			
subjects affected / exposed	0 / 103 (0.00%)	1 / 30 (3.33%)	1 / 101 (0.99%)
occurrences (all)	0	1	1
Wheezing			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Psychiatric disorders			
Anxiety			
subjects affected / exposed	2 / 103 (1.94%)	0 / 30 (0.00%)	5 / 101 (4.95%)
occurrences (all)	2	0	6
Depression			
subjects affected / exposed	4 / 103 (3.88%)	0 / 30 (0.00%)	4 / 101 (3.96%)
occurrences (all)	4	0	4
Insomnia			
subjects affected / exposed	8 / 103 (7.77%)	0 / 30 (0.00%)	5 / 101 (4.95%)
occurrences (all)	10	0	5
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	9 / 103 (8.74%)	11 / 30 (36.67%)	4 / 101 (3.96%)
occurrences (all)	13	14	4
Blood bilirubin increased			
subjects affected / exposed	8 / 103 (7.77%)	6 / 30 (20.00%)	7 / 101 (6.93%)
occurrences (all)	9	8	7
Blood cholesterol increased			
subjects affected / exposed	1 / 103 (0.97%)	1 / 30 (3.33%)	6 / 101 (5.94%)
occurrences (all)	1	1	6
Blood creatine phosphokinase increased			
subjects affected / exposed	2 / 103 (1.94%)	3 / 30 (10.00%)	0 / 101 (0.00%)
occurrences (all)	4	3	0
Blood creatinine increased			

subjects affected / exposed	11 / 103 (10.68%)	3 / 30 (10.00%)	3 / 101 (2.97%)
occurrences (all)	11	6	3
Blood albumin decreased			
subjects affected / exposed	2 / 103 (1.94%)	2 / 30 (6.67%)	0 / 101 (0.00%)
occurrences (all)	2	3	0
Aspartate aminotransferase increased			
subjects affected / exposed	19 / 103 (18.45%)	7 / 30 (23.33%)	20 / 101 (19.80%)
occurrences (all)	24	8	27
Amylase increased			
subjects affected / exposed	6 / 103 (5.83%)	3 / 30 (10.00%)	6 / 101 (5.94%)
occurrences (all)	8	3	10
Blood lactate dehydrogenase increased			
subjects affected / exposed	4 / 103 (3.88%)	2 / 30 (6.67%)	5 / 101 (4.95%)
occurrences (all)	4	2	9
Alanine aminotransferase increased			
subjects affected / exposed	14 / 103 (13.59%)	10 / 30 (33.33%)	22 / 101 (21.78%)
occurrences (all)	17	14	33
Blood magnesium decreased			
subjects affected / exposed	0 / 103 (0.00%)	3 / 30 (10.00%)	0 / 101 (0.00%)
occurrences (all)	0	4	0
Blood sodium increased			
subjects affected / exposed	0 / 103 (0.00%)	2 / 30 (6.67%)	1 / 101 (0.99%)
occurrences (all)	0	2	1
Blood thyroid stimulating hormone increased			
subjects affected / exposed	3 / 103 (2.91%)	4 / 30 (13.33%)	7 / 101 (6.93%)
occurrences (all)	3	5	11
Blood urea increased			
subjects affected / exposed	3 / 103 (2.91%)	2 / 30 (6.67%)	1 / 101 (0.99%)
occurrences (all)	4	2	1
Gamma-glutamyltransferase increased			
subjects affected / exposed	1 / 103 (0.97%)	1 / 30 (3.33%)	3 / 101 (2.97%)
occurrences (all)	1	1	3
Lipase increased			

subjects affected / exposed	7 / 103 (6.80%)	3 / 30 (10.00%)	5 / 101 (4.95%)
occurrences (all)	10	3	5
Lymphocyte count decreased			
subjects affected / exposed	2 / 103 (1.94%)	2 / 30 (6.67%)	7 / 101 (6.93%)
occurrences (all)	3	2	11
Neutrophil count decreased			
subjects affected / exposed	5 / 103 (4.85%)	0 / 30 (0.00%)	3 / 101 (2.97%)
occurrences (all)	6	0	3
Platelet count decreased			
subjects affected / exposed	12 / 103 (11.65%)	6 / 30 (20.00%)	7 / 101 (6.93%)
occurrences (all)	17	8	8
Platelet count increased			
subjects affected / exposed	0 / 103 (0.00%)	2 / 30 (6.67%)	0 / 101 (0.00%)
occurrences (all)	0	2	0
Protein total decreased			
subjects affected / exposed	4 / 103 (3.88%)	2 / 30 (6.67%)	4 / 101 (3.96%)
occurrences (all)	7	3	9
Weight decreased			
subjects affected / exposed	22 / 103 (21.36%)	8 / 30 (26.67%)	6 / 101 (5.94%)
occurrences (all)	23	9	6
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	3 / 103 (2.91%)	0 / 30 (0.00%)	9 / 101 (8.91%)
occurrences (all)	3	0	9
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	5 / 103 (4.85%)	0 / 30 (0.00%)	4 / 101 (3.96%)
occurrences (all)	5	0	4
Aphasia			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	8 / 101 (7.92%)
occurrences (all)	0	0	8
Dysgeusia			

subjects affected / exposed	9 / 103 (8.74%)	1 / 30 (3.33%)	4 / 101 (3.96%)
occurrences (all)	9	1	4
Tremor			
subjects affected / exposed	3 / 103 (2.91%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences (all)	3	0	2
Headache			
subjects affected / exposed	22 / 103 (21.36%)	6 / 30 (20.00%)	25 / 101 (24.75%)
occurrences (all)	25	11	29
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	15 / 103 (14.56%)	6 / 30 (20.00%)	3 / 101 (2.97%)
occurrences (all)	17	8	8
Thrombocytopenia			
subjects affected / exposed	10 / 103 (9.71%)	3 / 30 (10.00%)	7 / 101 (6.93%)
occurrences (all)	13	3	8
Leukopenia			
subjects affected / exposed	2 / 103 (1.94%)	0 / 30 (0.00%)	2 / 101 (1.98%)
occurrences (all)	2	0	3
Neutropenia			
subjects affected / exposed	4 / 103 (3.88%)	0 / 30 (0.00%)	2 / 101 (1.98%)
occurrences (all)	5	0	2
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	5 / 103 (4.85%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences (all)	6	0	0
Abdominal pain			
subjects affected / exposed	29 / 103 (28.16%)	5 / 30 (16.67%)	12 / 101 (11.88%)
occurrences (all)	34	7	14
Gastrooesophageal reflux disease			
subjects affected / exposed	2 / 103 (1.94%)	1 / 30 (3.33%)	2 / 101 (1.98%)
occurrences (all)	2	1	2
Flatulence			
subjects affected / exposed	3 / 103 (2.91%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences (all)	4	0	0
Dysphagia			

subjects affected / exposed	3 / 103 (2.91%)	2 / 30 (6.67%)	1 / 101 (0.99%)
occurrences (all)	3	2	1
Dyspepsia			
subjects affected / exposed	3 / 103 (2.91%)	0 / 30 (0.00%)	3 / 101 (2.97%)
occurrences (all)	3	0	3
Dry mouth			
subjects affected / exposed	8 / 103 (7.77%)	1 / 30 (3.33%)	4 / 101 (3.96%)
occurrences (all)	9	1	4
Diarrhoea			
subjects affected / exposed	25 / 103 (24.27%)	16 / 30 (53.33%)	26 / 101 (25.74%)
occurrences (all)	41	44	43
Constipation			
subjects affected / exposed	19 / 103 (18.45%)	3 / 30 (10.00%)	14 / 101 (13.86%)
occurrences (all)	24	3	15
Ascites			
subjects affected / exposed	4 / 103 (3.88%)	1 / 30 (3.33%)	0 / 101 (0.00%)
occurrences (all)	4	1	0
Nausea			
subjects affected / exposed	37 / 103 (35.92%)	5 / 30 (16.67%)	19 / 101 (18.81%)
occurrences (all)	50	7	21
Abdominal pain upper			
subjects affected / exposed	7 / 103 (6.80%)	2 / 30 (6.67%)	4 / 101 (3.96%)
occurrences (all)	8	2	4
Vomiting			
subjects affected / exposed	19 / 103 (18.45%)	8 / 30 (26.67%)	13 / 101 (12.87%)
occurrences (all)	26	11	13
Toothache			
subjects affected / exposed	3 / 103 (2.91%)	0 / 30 (0.00%)	2 / 101 (1.98%)
occurrences (all)	3	0	2
Stomatitis			
subjects affected / exposed	9 / 103 (8.74%)	4 / 30 (13.33%)	6 / 101 (5.94%)
occurrences (all)	9	5	6
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	15 / 103 (14.56%)	2 / 30 (6.67%)	14 / 101 (13.86%)
occurrences (all)	17	3	18

Dry skin			
subjects affected / exposed	7 / 103 (6.80%)	1 / 30 (3.33%)	4 / 101 (3.96%)
occurrences (all)	7	1	4
Hyperkeratosis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences (all)	0	0	1
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	12 / 103 (11.65%)	5 / 30 (16.67%)	10 / 101 (9.90%)
occurrences (all)	14	6	10
Pruritus			
subjects affected / exposed	8 / 103 (7.77%)	0 / 30 (0.00%)	4 / 101 (3.96%)
occurrences (all)	11	0	4
Rash maculo-papular			
subjects affected / exposed	4 / 103 (3.88%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences (all)	4	0	1
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	3 / 103 (2.91%)	1 / 30 (3.33%)	6 / 101 (5.94%)
occurrences (all)	4	1	6
Haematuria			
subjects affected / exposed	2 / 103 (1.94%)	2 / 30 (6.67%)	4 / 101 (3.96%)
occurrences (all)	2	2	5
Leukocyturia			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences (all)	1	0	4
Proteinuria			
subjects affected / exposed	22 / 103 (21.36%)	11 / 30 (36.67%)	12 / 101 (11.88%)
occurrences (all)	25	12	15
Hydronephrosis			
subjects affected / exposed	0 / 103 (0.00%)	2 / 30 (6.67%)	0 / 101 (0.00%)
occurrences (all)	0	2	0
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	28 / 103 (27.18%)	12 / 30 (40.00%)	28 / 101 (27.72%)
occurrences (all)	29	13	30
Hyperthyroidism			

subjects affected / exposed	3 / 103 (2.91%)	1 / 30 (3.33%)	6 / 101 (5.94%)
occurrences (all)	3	1	8
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	3 / 103 (2.91%)	1 / 30 (3.33%)	3 / 101 (2.97%)
occurrences (all)	3	1	3
Flank pain			
subjects affected / exposed	2 / 103 (1.94%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences (all)	2	0	0
Back pain			
subjects affected / exposed	12 / 103 (11.65%)	1 / 30 (3.33%)	4 / 101 (3.96%)
occurrences (all)	12	1	4
Musculoskeletal chest pain			
subjects affected / exposed	1 / 103 (0.97%)	1 / 30 (3.33%)	1 / 101 (0.99%)
occurrences (all)	1	1	1
Arthralgia			
subjects affected / exposed	16 / 103 (15.53%)	4 / 30 (13.33%)	12 / 101 (11.88%)
occurrences (all)	19	4	15
Pain in extremity			
subjects affected / exposed	1 / 103 (0.97%)	2 / 30 (6.67%)	6 / 101 (5.94%)
occurrences (all)	2	2	7
Neck pain			
subjects affected / exposed	2 / 103 (1.94%)	2 / 30 (6.67%)	1 / 101 (0.99%)
occurrences (all)	2	2	1
Myalgia			
subjects affected / exposed	5 / 103 (4.85%)	3 / 30 (10.00%)	8 / 101 (7.92%)
occurrences (all)	5	3	8
Musculoskeletal pain			
subjects affected / exposed	3 / 103 (2.91%)	1 / 30 (3.33%)	0 / 101 (0.00%)
occurrences (all)	4	1	0
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	5 / 103 (4.85%)	3 / 30 (10.00%)	6 / 101 (5.94%)
occurrences (all)	5	5	8
Upper respiratory tract infection			

subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	1 / 101 (0.99%)
occurrences (all)	1	0	1
Tooth infection			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences (all)	1	0	0
Gingivitis			
subjects affected / exposed	1 / 103 (0.97%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences (all)	2	0	0
Cystitis			
subjects affected / exposed	0 / 103 (0.00%)	0 / 30 (0.00%)	0 / 101 (0.00%)
occurrences (all)	0	0	0
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	0 / 103 (0.00%)	3 / 30 (10.00%)	1 / 101 (0.99%)
occurrences (all)	0	5	1
Hyperglycaemia			
subjects affected / exposed	7 / 103 (6.80%)	3 / 30 (10.00%)	5 / 101 (4.95%)
occurrences (all)	9	4	11
Hypoalbuminaemia			
subjects affected / exposed	9 / 103 (8.74%)	5 / 30 (16.67%)	2 / 101 (1.98%)
occurrences (all)	11	5	3
Hypertriglyceridaemia			
subjects affected / exposed	2 / 103 (1.94%)	1 / 30 (3.33%)	2 / 101 (1.98%)
occurrences (all)	2	2	5
Decreased appetite			
subjects affected / exposed	33 / 103 (32.04%)	6 / 30 (20.00%)	19 / 101 (18.81%)
occurrences (all)	40	6	20
Dehydration			
subjects affected / exposed	4 / 103 (3.88%)	2 / 30 (6.67%)	2 / 101 (1.98%)
occurrences (all)	4	3	2
Hypokalaemia			
subjects affected / exposed	13 / 103 (12.62%)	2 / 30 (6.67%)	9 / 101 (8.91%)
occurrences (all)	15	2	11
Hypophosphataemia			
subjects affected / exposed	0 / 103 (0.00%)	2 / 30 (6.67%)	4 / 101 (3.96%)
occurrences (all)	0	2	4

Hyponatraemia			
subjects affected / exposed	12 / 103 (11.65%)	1 / 30 (3.33%)	2 / 101 (1.98%)
occurrences (all)	15	1	3
Hypomagnesaemia			
subjects affected / exposed	4 / 103 (3.88%)	6 / 30 (20.00%)	5 / 101 (4.95%)
occurrences (all)	5	9	9

Non-serious adverse events	BTC (Lenva + Pembro)	CRC (Lenva + Pembro)	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	100 / 102 (98.04%)	103 / 105 (98.10%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	1 / 102 (0.98%)	1 / 105 (0.95%)	
occurrences (all)	1	1	
Vascular disorders			
Hypertension			
subjects affected / exposed	58 / 102 (56.86%)	59 / 105 (56.19%)	
occurrences (all)	74	92	
Hypotension			
subjects affected / exposed	6 / 102 (5.88%)	3 / 105 (2.86%)	
occurrences (all)	7	4	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	23 / 102 (22.55%)	27 / 105 (25.71%)	
occurrences (all)	29	35	
Chest pain			
subjects affected / exposed	4 / 102 (3.92%)	2 / 105 (1.90%)	
occurrences (all)	4	2	
Oedema peripheral			
subjects affected / exposed	13 / 102 (12.75%)	15 / 105 (14.29%)	
occurrences (all)	13	16	
Mucosal inflammation			
subjects affected / exposed	15 / 102 (14.71%)	10 / 105 (9.52%)	
occurrences (all)	18	12	
Influenza like illness			

subjects affected / exposed	0 / 102 (0.00%)	2 / 105 (1.90%)	
occurrences (all)	0	2	
Fatigue			
subjects affected / exposed	40 / 102 (39.22%)	41 / 105 (39.05%)	
occurrences (all)	52	47	
Chills			
subjects affected / exposed	6 / 102 (5.88%)	1 / 105 (0.95%)	
occurrences (all)	6	1	
Peripheral swelling			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences (all)	0	0	
Pyrexia			
subjects affected / exposed	11 / 102 (10.78%)	11 / 105 (10.48%)	
occurrences (all)	15	14	
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences (all)	0	0	
Respiratory, thoracic and mediastinal disorders			
Dysphonia			
subjects affected / exposed	31 / 102 (30.39%)	21 / 105 (20.00%)	
occurrences (all)	34	21	
Cough			
subjects affected / exposed	11 / 102 (10.78%)	10 / 105 (9.52%)	
occurrences (all)	15	10	
Dyspnoea			
subjects affected / exposed	14 / 102 (13.73%)	7 / 105 (6.67%)	
occurrences (all)	15	8	
Epistaxis			
subjects affected / exposed	9 / 102 (8.82%)	4 / 105 (3.81%)	
occurrences (all)	11	4	
Productive cough			
subjects affected / exposed	2 / 102 (1.96%)	2 / 105 (1.90%)	
occurrences (all)	2	2	
Wheezing			

subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences (all)	1	0	
Psychiatric disorders			
Anxiety			
subjects affected / exposed	1 / 102 (0.98%)	9 / 105 (8.57%)	
occurrences (all)	1	9	
Depression			
subjects affected / exposed	2 / 102 (1.96%)	0 / 105 (0.00%)	
occurrences (all)	2	0	
Insomnia			
subjects affected / exposed	6 / 102 (5.88%)	9 / 105 (8.57%)	
occurrences (all)	6	10	
Investigations			
Blood alkaline phosphatase increased			
subjects affected / exposed	14 / 102 (13.73%)	13 / 105 (12.38%)	
occurrences (all)	14	15	
Blood bilirubin increased			
subjects affected / exposed	15 / 102 (14.71%)	15 / 105 (14.29%)	
occurrences (all)	17	24	
Blood cholesterol increased			
subjects affected / exposed	1 / 102 (0.98%)	6 / 105 (5.71%)	
occurrences (all)	1	12	
Blood creatine phosphokinase increased			
subjects affected / exposed	1 / 102 (0.98%)	2 / 105 (1.90%)	
occurrences (all)	2	2	
Blood creatinine increased			
subjects affected / exposed	6 / 102 (5.88%)	12 / 105 (11.43%)	
occurrences (all)	8	17	
Blood albumin decreased			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences (all)	0	1	
Aspartate aminotransferase increased			
subjects affected / exposed	26 / 102 (25.49%)	24 / 105 (22.86%)	
occurrences (all)	31	35	
Amylase increased			

subjects affected / exposed	3 / 102 (2.94%)	7 / 105 (6.67%)	
occurrences (all)	4	10	
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 102 (0.00%)	3 / 105 (2.86%)	
occurrences (all)	0	3	
Alanine aminotransferase increased			
subjects affected / exposed	21 / 102 (20.59%)	24 / 105 (22.86%)	
occurrences (all)	25	34	
Blood magnesium decreased			
subjects affected / exposed	1 / 102 (0.98%)	1 / 105 (0.95%)	
occurrences (all)	1	1	
Blood sodium increased			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences (all)	0	1	
Blood thyroid stimulating hormone increased			
subjects affected / exposed	3 / 102 (2.94%)	8 / 105 (7.62%)	
occurrences (all)	3	17	
Blood urea increased			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences (all)	0	2	
Gamma-glutamyltransferase increased			
subjects affected / exposed	4 / 102 (3.92%)	3 / 105 (2.86%)	
occurrences (all)	4	4	
Lipase increased			
subjects affected / exposed	6 / 102 (5.88%)	12 / 105 (11.43%)	
occurrences (all)	8	14	
Lymphocyte count decreased			
subjects affected / exposed	4 / 102 (3.92%)	4 / 105 (3.81%)	
occurrences (all)	5	5	
Neutrophil count decreased			
subjects affected / exposed	1 / 102 (0.98%)	2 / 105 (1.90%)	
occurrences (all)	1	2	
Platelet count decreased			

subjects affected / exposed	7 / 102 (6.86%)	8 / 105 (7.62%)	
occurrences (all)	7	10	
Platelet count increased			
subjects affected / exposed	0 / 102 (0.00%)	3 / 105 (2.86%)	
occurrences (all)	0	5	
Protein total decreased			
subjects affected / exposed	1 / 102 (0.98%)	3 / 105 (2.86%)	
occurrences (all)	1	5	
Weight decreased			
subjects affected / exposed	10 / 102 (9.80%)	13 / 105 (12.38%)	
occurrences (all)	10	13	
Injury, poisoning and procedural complications			
Fall			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences (all)	0	1	
Nervous system disorders			
Dizziness			
subjects affected / exposed	3 / 102 (2.94%)	7 / 105 (6.67%)	
occurrences (all)	4	7	
Aphasia			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences (all)	0	1	
Dysgeusia			
subjects affected / exposed	5 / 102 (4.90%)	2 / 105 (1.90%)	
occurrences (all)	5	2	
Tremor			
subjects affected / exposed	2 / 102 (1.96%)	2 / 105 (1.90%)	
occurrences (all)	2	2	
Headache			
subjects affected / exposed	25 / 102 (24.51%)	18 / 105 (17.14%)	
occurrences (all)	28	21	
Blood and lymphatic system disorders			

Anaemia			
subjects affected / exposed	11 / 102 (10.78%)	12 / 105 (11.43%)	
occurrences (all)	13	19	
Thrombocytopenia			
subjects affected / exposed	4 / 102 (3.92%)	9 / 105 (8.57%)	
occurrences (all)	5	10	
Leukopenia			
subjects affected / exposed	1 / 102 (0.98%)	2 / 105 (1.90%)	
occurrences (all)	1	2	
Neutropenia			
subjects affected / exposed	3 / 102 (2.94%)	1 / 105 (0.95%)	
occurrences (all)	3	1	
Gastrointestinal disorders			
Abdominal distension			
subjects affected / exposed	4 / 102 (3.92%)	3 / 105 (2.86%)	
occurrences (all)	4	3	
Abdominal pain			
subjects affected / exposed	32 / 102 (31.37%)	25 / 105 (23.81%)	
occurrences (all)	44	28	
Gastrooesophageal reflux disease			
subjects affected / exposed	3 / 102 (2.94%)	5 / 105 (4.76%)	
occurrences (all)	3	5	
Flatulence			
subjects affected / exposed	1 / 102 (0.98%)	3 / 105 (2.86%)	
occurrences (all)	1	3	
Dysphagia			
subjects affected / exposed	2 / 102 (1.96%)	0 / 105 (0.00%)	
occurrences (all)	2	0	
Dyspepsia			
subjects affected / exposed	8 / 102 (7.84%)	9 / 105 (8.57%)	
occurrences (all)	9	9	
Dry mouth			
subjects affected / exposed	11 / 102 (10.78%)	7 / 105 (6.67%)	
occurrences (all)	11	9	
Diarrhoea			

subjects affected / exposed	42 / 102 (41.18%)	47 / 105 (44.76%)	
occurrences (all)	67	74	
Constipation			
subjects affected / exposed	24 / 102 (23.53%)	22 / 105 (20.95%)	
occurrences (all)	27	25	
Ascites			
subjects affected / exposed	6 / 102 (5.88%)	1 / 105 (0.95%)	
occurrences (all)	6	1	
Nausea			
subjects affected / exposed	37 / 102 (36.27%)	34 / 105 (32.38%)	
occurrences (all)	55	45	
Abdominal pain upper			
subjects affected / exposed	10 / 102 (9.80%)	8 / 105 (7.62%)	
occurrences (all)	10	9	
Vomiting			
subjects affected / exposed	20 / 102 (19.61%)	26 / 105 (24.76%)	
occurrences (all)	43	34	
Toothache			
subjects affected / exposed	3 / 102 (2.94%)	2 / 105 (1.90%)	
occurrences (all)	3	2	
Stomatitis			
subjects affected / exposed	12 / 102 (11.76%)	12 / 105 (11.43%)	
occurrences (all)	15	13	
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	16 / 102 (15.69%)	13 / 105 (12.38%)	
occurrences (all)	19	16	
Dry skin			
subjects affected / exposed	7 / 102 (6.86%)	6 / 105 (5.71%)	
occurrences (all)	7	6	
Hyperkeratosis			
subjects affected / exposed	0 / 102 (0.00%)	1 / 105 (0.95%)	
occurrences (all)	0	1	
Palmar-plantar erythrodysaesthesia syndrome			

subjects affected / exposed	12 / 102 (11.76%)	8 / 105 (7.62%)	
occurrences (all)	13	8	
Pruritus			
subjects affected / exposed	15 / 102 (14.71%)	9 / 105 (8.57%)	
occurrences (all)	20	10	
Rash maculo-papular			
subjects affected / exposed	4 / 102 (3.92%)	5 / 105 (4.76%)	
occurrences (all)	5	5	
Renal and urinary disorders			
Dysuria			
subjects affected / exposed	1 / 102 (0.98%)	3 / 105 (2.86%)	
occurrences (all)	1	3	
Haematuria			
subjects affected / exposed	2 / 102 (1.96%)	4 / 105 (3.81%)	
occurrences (all)	2	4	
Leukocyturia			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences (all)	0	0	
Proteinuria			
subjects affected / exposed	23 / 102 (22.55%)	39 / 105 (37.14%)	
occurrences (all)	24	52	
Hydronephrosis			
subjects affected / exposed	0 / 102 (0.00%)	0 / 105 (0.00%)	
occurrences (all)	0	0	
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	34 / 102 (33.33%)	46 / 105 (43.81%)	
occurrences (all)	35	53	
Hyperthyroidism			
subjects affected / exposed	6 / 102 (5.88%)	9 / 105 (8.57%)	
occurrences (all)	6	9	
Musculoskeletal and connective tissue disorders			
Muscular weakness			
subjects affected / exposed	3 / 102 (2.94%)	4 / 105 (3.81%)	
occurrences (all)	3	4	
Flank pain			

subjects affected / exposed	1 / 102 (0.98%)	1 / 105 (0.95%)	
occurrences (all)	1	1	
Back pain			
subjects affected / exposed	15 / 102 (14.71%)	20 / 105 (19.05%)	
occurrences (all)	15	23	
Musculoskeletal chest pain			
subjects affected / exposed	1 / 102 (0.98%)	3 / 105 (2.86%)	
occurrences (all)	1	3	
Arthralgia			
subjects affected / exposed	18 / 102 (17.65%)	21 / 105 (20.00%)	
occurrences (all)	22	26	
Pain in extremity			
subjects affected / exposed	5 / 102 (4.90%)	6 / 105 (5.71%)	
occurrences (all)	6	8	
Neck pain			
subjects affected / exposed	3 / 102 (2.94%)	1 / 105 (0.95%)	
occurrences (all)	3	1	
Myalgia			
subjects affected / exposed	6 / 102 (5.88%)	17 / 105 (16.19%)	
occurrences (all)	7	17	
Musculoskeletal pain			
subjects affected / exposed	4 / 102 (3.92%)	6 / 105 (5.71%)	
occurrences (all)	4	6	
Infections and infestations			
Urinary tract infection			
subjects affected / exposed	7 / 102 (6.86%)	7 / 105 (6.67%)	
occurrences (all)	7	8	
Upper respiratory tract infection			
subjects affected / exposed	0 / 102 (0.00%)	2 / 105 (1.90%)	
occurrences (all)	0	2	
Tooth infection			
subjects affected / exposed	1 / 102 (0.98%)	1 / 105 (0.95%)	
occurrences (all)	1	1	
Gingivitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences (all)	1	0	

Cystitis			
subjects affected / exposed	1 / 102 (0.98%)	0 / 105 (0.00%)	
occurrences (all)	1	0	
Metabolism and nutrition disorders			
Hyperkalaemia			
subjects affected / exposed	1 / 102 (0.98%)	4 / 105 (3.81%)	
occurrences (all)	4	4	
Hyperglycaemia			
subjects affected / exposed	3 / 102 (2.94%)	6 / 105 (5.71%)	
occurrences (all)	3	7	
Hypoalbuminaemia			
subjects affected / exposed	6 / 102 (5.88%)	11 / 105 (10.48%)	
occurrences (all)	7	11	
Hypertriglyceridaemia			
subjects affected / exposed	1 / 102 (0.98%)	6 / 105 (5.71%)	
occurrences (all)	1	17	
Decreased appetite			
subjects affected / exposed	37 / 102 (36.27%)	46 / 105 (43.81%)	
occurrences (all)	44	50	
Dehydration			
subjects affected / exposed	2 / 102 (1.96%)	1 / 105 (0.95%)	
occurrences (all)	2	1	
Hypokalaemia			
subjects affected / exposed	8 / 102 (7.84%)	4 / 105 (3.81%)	
occurrences (all)	12	7	
Hypophosphataemia			
subjects affected / exposed	3 / 102 (2.94%)	5 / 105 (4.76%)	
occurrences (all)	4	5	
Hyponatraemia			
subjects affected / exposed	12 / 102 (11.76%)	5 / 105 (4.76%)	
occurrences (all)	14	6	
Hypomagnesaemia			
subjects affected / exposed	7 / 102 (6.86%)	5 / 105 (4.76%)	
occurrences (all)	9	6	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
31 July 2019	AM 01: Amended to incorporate changes requested by Health Authorities and correct minor errors.
12 August 2020	AM 02: Amended to update and clarify language for progression of the study to the expansion phase and to correct minor errors.
14 January 2021	AM 03: Amended to add lenvatinib monotherapy arms to the ovarian and colorectal cancer (CRC) cohorts to obtain contribution of component data and to add a pancreatic cancer cohort.
09 July 2021	AM 04: Amended to indicate that the triple-negative breast cancer (TNBC) and the ovarian cancer cohort will not enroll participants in the expansion phase and to correct minor errors.
30 November 2022	AM 05: Sponsor underwent an entity name change and update to the address.
04 March 2024	AM 06: This change provides an option for participants to continue in an extension study.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported