Clinical trial results:
TACTI-002 (Two ACTive Immunotherapeutics): A multicenter, open label, Phase II study in patients with previously untreated unresectable or metastatic non-small cell lung cancer (NSCLC), or recurrent PD-X refractory NSCLC or with recurrent or metastatic squamous head and neck cancer (HNSCC) receiving the soluble LAG-3 fusion protein eftilagimod alpha (IMP321) in combination with pembrolizumab (PD-1 antagonist)

Summary

EudraCT number	2018-001994-25
Trial protocol	GB ES PL
Global end of trial date	25 November 2024

Results information

Result version number	v1
This version publication date	11 December 2025
First version publication date	11 December 2025

Trial information

Trial identification

Sponsor protocol code	TACTI-002(P015);Keynote-PN798

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03625323
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Immutep S.A.S.
Sponsor organisation address	Parc Les Algorithmes Bâtiment 7- Le Pythagore Route de l'Orme – RD128 , SAINT-AUBIN, France, 91190
Public contact	Clinical Trial Disclosure Enquiries, Immutep S.A.S., +33 160 123 250, enquiries@immutep.com
Scientific contact	Clinical Trial Disclosure Enquiries, Immutep S.A.S., +33 160 123 250, enquiries@immutep.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	30 November 2024
Is this the analysis of the primary completion data?	Yes
Primary completion date	02 June 2022
Global end of trial reached?	Yes
Global end of trial date	25 November 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the response rate of eftilagimod alpha in combination with pembrolizumab in patients with advanced, metastatic, recurrent NSCLC and HNSCC

Protection of trial subjects:

The study was conducted in accordance with the most recent version of the Declaration of Helsinki and the International Council for Harmonization (ICH) E6 Good Clinical Practices (GCP) guidelines.
At regular intervals, the Data Monitoring Committee (DMC) monitored the available safety and efficacy data and demographics of all subjects (Parts A-C). Additionally, the DMC reviewed the efficacy and safety data after the minimum number of responses was reached for each part of the study. Subjects included in this decision required at least one tumor imaging after initiating treatment. The DMC then made a recommendation for each part of the study, whether stage 2 or an extension could be independently opened

Background therapy:

No background therapy was given during the study

Evidence for comparator:

No comparator was used during the study

Actual start date of recruitment	21 February 2019
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	12 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Poland: 2
Country: Number of subjects enrolled	Spain: 107
Country: Number of subjects enrolled	United Kingdom: 32
Country: Number of subjects enrolled	United States: 18
Country: Number of subjects enrolled	Ukraine: 12
Country: Number of subjects enrolled	Australia: 16
Worldwide total number of subjects	187
EEA total number of subjects	109

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)	74
From 65 to 84 years	112
85 years and over	1

Subject disposition

Recruitment

Recruitment details:

The first ICF for the study was signed on February 21, 2019. Recruitment ended on November 30, 2021. 18 sites in 6 countries.
Number of sites per country: Australia (2), Poland (1), Spain (8), UK (3), Ukraine (2) and US (2).

Pre-assignment

Screening details:

Participants could enrol in the study if: NSCLC previously untreated for stage IIIB or stage IV disease (Part A); NSCLC after confirmed progression on first-line treatment and proven resistance to PD (L)1 inhibitors (Part B) or HNSCC of the oral cavity, oropharynx, hypopharynx, or larynx after failure of prior platinum-based therapy (Part C)

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Part A: 1st Line NSCLC

Arm description:

1st line, PD (L)1 naïve participants in metastatic setting NSCLC: histologically- or cytologically-confirmed diagnosis of NSCLC stage IIIB not amenable to curative treatment or stage IV not amenable to EGFR/ALK based therapy, treatment-naïve for systemic therapy given for advanced/metastatic disease (previous palliative radiotherapy for advanced/metastatic disease acceptable).

Arm type	Experimental
Investigational medicinal product name	eftilagimod alpha
Investigational medicinal product code	IMP321
Other name	eftilagimod alfa, efti
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Eftilagimod alpha (efti; IMP321) was injected every 2 weeks until end of Cycle 8 (12 doses). Thereafter efti was administered every 3 weeks starting Cycle 9 until end of Cycle 18 (10 doses). Efti was administered as a s.c. injection (single anatomical site) on the anterior face of the thigh

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

Dosage and administration details:

Pembrolizumab was administered at a dose of 200 mg using a 30-minute i.v. infusion on Day 1 of each 3-week treatment Cycle after all procedures and assessments had been completed. Pembrolizumab was given on Day 1 from Cycle 1 to Cycle 35.

Arm title	Part B: 2nd line NSCLC

Arm description:

2nd line, PD (L)1 refractory NSCLC: Histologically- or cytologically-confirmed diagnosis of NSCLC after failure of first-line treatment (for metastatic disease) with at least two cycles of any PD 1/PD L1 containing based therapy (e.g., nivolumab, pembrolizumab, avelumab, durvalumab, etc.) alone, or in combination with any other immunotherapeutic or chemotherapy given as part of first-line treatment.

Arm type	Experimental

Investigational medicinal product name	eftilagimod alpha
Investigational medicinal product code	IMP321
Other name	eftilagimod alfa, efti
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Eftilagimod alpha (efti; IMP321) was injected every 2 weeks until end of Cycle 8 (12 doses). Thereafter efti was administered every 3 weeks starting Cycle 9 until end of Cycle 18 (10 doses). Efti was administered as a s.c. injection (single anatomical site) on the anterior face of the thigh

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

Dosage and administration details:

Pembrolizumab was administered at a dose of 200 mg using a 30-minute i.v. infusion on Day 1 of each 3-week treatment Cycle after all procedures and assessments had been completed. Pembrolizumab was given on Day 1 from Cycle 1 to Cycle 35.

Arm title	Part C: 2nd line HNSCC

Arm description:

2nd line PD (L)1-naïve HNSCC: Histologically- or cytologically-confirmed recurrent disease not amenable to curative treatment with local or systemic therapy, or metastatic (disseminated) head and HNSCC of the oral cavity, oropharynx, hypopharynx, or larynx that was considered incurable by local therapies after failure of prior platinum-based therapy.

Arm type	Experimental
Investigational medicinal product name	eftilagimod alpha
Investigational medicinal product code	IMP321
Other name	eftilagimod alfa, efti
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Eftilagimod alpha (efti; IMP321) was injected every 2 weeks until end of Cycle 8 (12 doses). Thereafter efti was administered every 3 weeks starting Cycle 9 until end of Cycle 18 (10 doses). Efti was administered as a s.c. injection (single anatomical site) on the anterior face of the thigh

Investigational medicinal product name	pembrolizumab KEYTRUDA®
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Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Pembrolizumab was administered at a dose of 200 mg using a 30-minute i.v. infusion on Day 1 of each 3-week treatment Cycle after all procedures and assessments had been completed. Pembrolizumab was given on Day 1 from Cycle 1 to Cycle 35.

Number of subjects in period 1	Part A: 1st Line NSCLC	Part B: 2nd line NSCLC	Part C: 2nd line HNSCC
Started	114	36	37
Completed	22	2	4
Not completed	92	34	33
Physician decision	3	-	2
Consent withdrawn by subject	2	-	1

Disease progression	47	31	19
Death	11	1	6
Other	14	2	-
Adverse event	14	-	5
Prohibited medication	1	-	-

Baseline characteristics

Reporting groups	
Reporting group title	Part A: 1st Line NSCLC
Reporting group description:	
1st line, PD (L)1 naïve participants in metastatic setting NSCLC: histologically- or cytologically-confirmed diagnosis of NSCLC stage IIIB not amenable to curative treatment or stage IV not amenable to EGFR/ALK based therapy, treatment-naïve for systemic therapy given for advanced/metastatic disease (previous palliative radiotherapy for advanced/metastatic disease acceptable).	
Reporting group title	Part B: 2nd line NSCLC
Reporting group description:	
2nd line, PD (L)1 refractory NSCLC: Histologically- or cytologically-confirmed diagnosis of NSCLC after failure of first-line treatment (for metastatic disease) with at least two cycles of any PD 1/PD L1 containing based therapy (e.g., nivolumab, pembrolizumab, avelumab, durvalumab, etc.) alone, or in combination with any other immunotherapeutic or chemotherapy given as part of first-line treatment.	
Reporting group title	Part C: 2nd line HNSCC
Reporting group description:	
2nd line PD (L)1-naïve HNSCC: Histologically- or cytologically-confirmed recurrent disease not amenable to curative treatment with local or systemic therapy, or metastatic (disseminated) head and HNSCC of the oral cavity, oropharynx, hypopharynx, or larynx that was considered incurable by local therapies after failure of prior platinum-based therapy.	

Reporting group values	Part A: 1st Line NSCLC	Part B: 2nd line NSCLC	Part C: 2nd line HNSCC
Number of subjects	114	36	37
Age categorical Units: Subjects			
Adults (18-64 years)	39	15	20
From 65 years	75	21	17
Age continuous Units: years			
median	67.0	67.0	63.0
full range (min-max)	44 to 85	46 to 84	48 to 84
Gender categorical Units: Subjects			
Female	30	14	4
Male	84	22	33
Race Units: Subjects			
White	109	34	35
Black or African American	2	2	0
Asian	1	0	1
Unknown	2	0	1
Smoking history Units: Subjects			
Non-smoker	6	5	5
Ex- or current smoker	108	31	32

Reporting group values	Total		
Number of subjects	187		

Age categorical Units: Subjects			
Adults (18-64 years)	74		
From 65 years	113		
Age continuous Units: years median full range (min-max)	 -		
Gender categorical Units: Subjects			
Female	48		
Male	139		
Race Units: Subjects			
White	178		
Black or African American	4		
Asian	2		
Unknown	3		
Smoking history Units: Subjects			
Non-smoker	16		
Ex- or current smoker	171		

End points

End points reporting groups

Reporting group title	Part A: 1st Line NSCLC

Reporting group description:

1st line, PD (L)1 naïve participants in metastatic setting NSCLC: histologically- or cytologically-confirmed diagnosis of NSCLC stage IIIB not amenable to curative treatment or stage IV not amenable to EGFR/ALK based therapy, treatment-naïve for systemic therapy given for advanced/metastatic disease (previous palliative radiotherapy for advanced/metastatic disease acceptable).

Reporting group title	Part B: 2nd line NSCLC

Reporting group description:

2nd line, PD (L)1 refractory NSCLC: Histologically- or cytologically-confirmed diagnosis of NSCLC after failure of first-line treatment (for metastatic disease) with at least two cycles of any PD 1/PD L1 containing based therapy (e.g., nivolumab, pembrolizumab, avelumab, durvalumab, etc.) alone, or in combination with any other immunotherapeutic or chemotherapy given as part of first-line treatment.

Reporting group title	Part C: 2nd line HNSCC

Reporting group description:

2nd line PD (L)1-naïve HNSCC: Histologically- or cytologically-confirmed recurrent disease not amenable to curative treatment with local or systemic therapy, or metastatic (disseminated) head and HNSCC of the oral cavity, oropharynx, hypopharynx, or larynx that was considered incurable by local therapies after failure of prior platinum-based therapy.

Primary: Overall Response Rate Unconfirmed

End point title	Overall Response Rate Unconfirmed[1]

End point description:

ORR was defined as the number of participants for each dose level whose best overall response is rated as iCR or iPR per immune Response Evaluation Criteria In Solid Tumors (iRECIST) for target lesions and assessed by CT or MRI per local assessment.
iCR was defined as disappearance of all target and non-target lesions and any pathological lymph nodes must be <10 mm in the short axis.
iPR was defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference, the baseline sum of the diameters.
95% Confidence interval calculated using Clopper-Pearson method.

End point type	Primary

End point timeframe:

Radiological assessments according to iRECIST. from screening onwards every 9 weeks until week 36, then every 12 weeks thereafter.

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 analyses were planned for this endpoint

End point values	Part A: 1st Line NSCLC	Part B: 2nd line NSCLC	Part C: 2nd line HNSCC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	36	37	
Units: Number of patients	46	3	11	

Statistical analyses

No statistical analyses for this end point

Primary: Overall Response Rate Confirmed

End point title	Overall Response Rate Confirmed[2]

End point description:

ORR was defined as the number of participants for each dose level whose best overall response is rated as iCR or iPR per immune Response Evaluation Criteria In Solid Tumors (iRECIST) for target lesions and assessed by CT or MRI per local assessment.
iCR was defined as disappearance of all target and non-target lesions and any pathological lymph nodes must be <10 mm in the short axis.
iPR was defined as at least a 30% decrease in the sum of the diameters of target lesions, taking as a reference, the baseline sum of the diameters.
95% Confidence interval calculated using Clopper-Pearson method.

End point type	Primary

End point timeframe:

Radiological assessments according to iRECIST. from screening onwards every 9 weeks until week 36, then every 12 weeks thereafter.

Notes:

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

End point values	Part A: 1st Line NSCLC	Part B: 2nd line NSCLC	Part C: 2nd line HNSCC	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	114	36	37	
Units: Number of paticipants	40	3	10	

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Up to 27 months	
Assessment type	Systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	21.1

Reporting groups	
Reporting group title	Part A: 1st Line NSCLC
Reporting group description:	
Reported data is based on adverse events with onset dates on or after the first dose of study drug regardless of causality	
Reporting group title	Part B: 2nd line NSCLC
Reporting group description:	
Reported data is based on adverse events with onset dates on or after the first dose of study drug regardless of causality	
Reporting group title	Part C: 2nd line HNSCC
Reporting group description:	
Reported data is based on adverse events with onset dates on or after the first dose of study drug regardless of causality	

Serious adverse events	Part A: 1st Line NSCLC	Part B: 2nd line NSCLC	Part C: 2nd line HNSCC
Total subjects affected by serious adverse events			
subjects affected / exposed	54 / 114 (47.37%)	9 / 36 (25.00%)	20 / 37 (54.05%)
number of deaths (all causes)	84	30	31
number of deaths resulting from adverse events	14	2	7
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	1 / 114 (0.88%)	1 / 36 (2.78%)	2 / 37 (5.41%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bladder transitional cell carcinoma			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Lymphoma			

subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Prostate cancer			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tumour haemorrhage			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
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 disorders			
Arterial thrombosis			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Hypertension			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral ischaemia			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
General disorders and administration site conditions			
Death			
subjects affected / exposed	3 / 114 (2.63%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	1 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	1 / 3	0 / 0	0 / 0
Fatigue			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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

Gait disturbance			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
General physical health deterioration			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Reproductive system and breast disorders			
Asthma			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	8 / 114 (7.02%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 8	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 1	0 / 0
Pneumonitis			
subjects affected / exposed	4 / 114 (3.51%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	4 / 5	0 / 0	1 / 1
deaths causally related to treatment / all	1 / 1	0 / 0	0 / 0
Haemoptysis			
subjects affected / exposed	4 / 114 (3.51%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 4	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Chronic obstructive pulmonary disease			

subjects affected / exposed	1 / 114 (0.88%)	1 / 36 (2.78%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 3	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory failure			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	2 / 37 (5.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Acute respiratory failure			
subjects affected / exposed	0 / 114 (0.00%)	1 / 36 (2.78%)	0 / 37 (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
Bronchial fistula			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Bronchospasm			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Immune-mediated pneumonitis			
subjects affected / exposed	0 / 114 (0.00%)	1 / 36 (2.78%)	0 / 37 (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
Pleural effusion			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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 aspiration			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			

subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Biopsy lymph gland			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Injury, poisoning and procedural complications			
Femur fracture			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal stoma complication			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Procedural pain			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Subdural haematoma			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1

Toxicity to various agents			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac disorders			
Atrial fibrillation			
subjects affected / exposed	3 / 114 (2.63%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	1 / 5	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure			
subjects affected / exposed	2 / 114 (1.75%)	0 / 36 (0.00%)	0 / 37 (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
Atrial thrombosis			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Atrioventricular block			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Cardiac failure congestive			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Cardiac tamponade			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Myocardial ischaemia			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Nervous system disorders			

Seizure			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 1	0 / 0	0 / 0
Syncope			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	2 / 37 (5.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolic encephalopathy			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	3 / 114 (2.63%)	1 / 36 (2.78%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	1 / 4	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	1 / 114 (0.88%)	1 / 36 (2.78%)	0 / 37 (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
Abdominal pain upper			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Ascites			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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

Colitis			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dysphagia			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
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	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Pancreatitis			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Hepatobiliary disorders			
Bile duct stone			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Cholangitis			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Immune-mediated hepatitis			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Skin and subcutaneous tissue disorders			

Pruritus			
subjects affected / exposed	0 / 114 (0.00%)	1 / 36 (2.78%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 0	1 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash			
subjects affected / exposed	0 / 114 (0.00%)	1 / 36 (2.78%)	0 / 37 (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
Toxic skin eruption			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Neck pain			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pain in extremity			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Lower respiratory tract infection			

subjects affected / exposed	2 / 114 (1.75%)	1 / 36 (2.78%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 2	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia			
subjects affected / exposed	3 / 114 (2.63%)	1 / 36 (2.78%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 1	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19			
subjects affected / exposed	3 / 114 (2.63%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 3	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	1 / 114 (0.88%)	1 / 36 (2.78%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 1	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	2 / 114 (1.75%)	0 / 36 (0.00%)	0 / 37 (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
Urinary tract infection			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	2 / 37 (5.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Achromobacter infection			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Atypical pneumonia			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Bronchitis			

subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Device related infection			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Endocarditis enterococcal			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Large intestine infection			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Otitis media			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural infection			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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 viral			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Prostate infection			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary sepsis			

subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Sepsis			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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
Skin infection			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Metabolism and nutrition disorders			
Hypercalcaemia			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	2 / 37 (5.41%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	1 / 37 (2.70%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyponatraemia			
subjects affected / exposed	0 / 114 (0.00%)	1 / 36 (2.78%)	0 / 37 (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
Type 2 diabetes mellitus			

subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	0 / 37 (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

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

Non-serious adverse events	Part A: 1st Line NSCLC	Part B: 2nd line NSCLC	Part C: 2nd line HNSCC
Total subjects affected by non-serious adverse events			
subjects affected / exposed	114 / 114 (100.00%)	35 / 36 (97.22%)	36 / 37 (97.30%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	6 / 114 (5.26%)	1 / 36 (2.78%)	3 / 37 (8.11%)
occurrences (all)	8	1	5
Vascular disorders			
Hypotension			
subjects affected / exposed	6 / 114 (5.26%)	0 / 36 (0.00%)	4 / 37 (10.81%)
occurrences (all)	7	0	5
Hypertension			
subjects affected / exposed	6 / 114 (5.26%)	0 / 36 (0.00%)	3 / 37 (8.11%)
occurrences (all)	6	0	8
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	39 / 114 (34.21%)	8 / 36 (22.22%)	8 / 37 (21.62%)
occurrences (all)	91	14	12
Fatigue			
subjects affected / exposed	26 / 114 (22.81%)	8 / 36 (22.22%)	6 / 37 (16.22%)
occurrences (all)	47	11	11
Pyrexia			
subjects affected / exposed	17 / 114 (14.91%)	2 / 36 (5.56%)	2 / 37 (5.41%)
occurrences (all)	24	5	2
Oedema peripheral			
subjects affected / exposed	11 / 114 (9.65%)	6 / 36 (16.67%)	0 / 37 (0.00%)
occurrences (all)	20	6	0
Injection site pain			

subjects affected / exposed	10 / 114 (8.77%)	5 / 36 (13.89%)	0 / 37 (0.00%)
occurrences (all)	38	9	0
Non-cardiac chest pain			
subjects affected / exposed	10 / 114 (8.77%)	5 / 36 (13.89%)	0 / 37 (0.00%)
occurrences (all)	12	6	0
Injection site erythema			
subjects affected / exposed	8 / 114 (7.02%)	5 / 36 (13.89%)	0 / 37 (0.00%)
occurrences (all)	14	17	0
Injection site reaction			
subjects affected / exposed	7 / 114 (6.14%)	4 / 36 (11.11%)	0 / 37 (0.00%)
occurrences (all)	28	4	0
Injection site swelling			
subjects affected / exposed	4 / 114 (3.51%)	3 / 36 (8.33%)	0 / 37 (0.00%)
occurrences (all)	6	3	0
Injection site pruritus			
subjects affected / exposed	4 / 114 (3.51%)	2 / 36 (5.56%)	0 / 37 (0.00%)
occurrences (all)	11	2	0
Malaise			
subjects affected / exposed	2 / 114 (1.75%)	3 / 36 (8.33%)	0 / 37 (0.00%)
occurrences (all)	2	3	0
Chest pain			
subjects affected / exposed	1 / 114 (0.88%)	2 / 36 (5.56%)	0 / 37 (0.00%)
occurrences (all)	1	2	0
Facial pain			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	2 / 37 (5.41%)
occurrences (all)	1	0	2
Pain			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	2 / 37 (5.41%)
occurrences (all)	1	0	2
Face oedema			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	4
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			

subjects affected / exposed	39 / 114 (34.21%)	13 / 36 (36.11%)	3 / 37 (8.11%)
occurrences (all)	64	18	4
Cough			
subjects affected / exposed	34 / 114 (29.82%)	11 / 36 (30.56%)	7 / 37 (18.92%)
occurrences (all)	54	12	10
Haemoptysis			
subjects affected / exposed	15 / 114 (13.16%)	1 / 36 (2.78%)	2 / 37 (5.41%)
occurrences (all)	22	1	2
Productive cough			
subjects affected / exposed	12 / 114 (10.53%)	3 / 36 (8.33%)	0 / 37 (0.00%)
occurrences (all)	19	3	0
Dysphonia			
subjects affected / exposed	3 / 114 (2.63%)	2 / 36 (5.56%)	2 / 37 (5.41%)
occurrences (all)	3	3	2
Dyspnoea exertional			
subjects affected / exposed	2 / 114 (1.75%)	2 / 36 (5.56%)	0 / 37 (0.00%)
occurrences (all)	2	2	0
Wheezing			
subjects affected / exposed	1 / 114 (0.88%)	2 / 36 (5.56%)	0 / 37 (0.00%)
occurrences (all)	1	2	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	11 / 114 (9.65%)	2 / 36 (5.56%)	1 / 37 (2.70%)
occurrences (all)	14	2	1
Investigations			
Weight decreased			
subjects affected / exposed	6 / 114 (5.26%)	6 / 36 (16.67%)	7 / 37 (18.92%)
occurrences (all)	9	6	7
Amylase increased			
subjects affected / exposed	13 / 114 (11.40%)	3 / 36 (8.33%)	1 / 37 (2.70%)
occurrences (all)	24	8	4
Aspartate aminotransferase increased			
subjects affected / exposed	6 / 114 (5.26%)	3 / 36 (8.33%)	3 / 37 (8.11%)
occurrences (all)	6	3	4
Alanine aminotransferase increased			

subjects affected / exposed	7 / 114 (6.14%)	2 / 36 (5.56%)	1 / 37 (2.70%)
occurrences (all)	11	2	1
Blood creatine increased			
subjects affected / exposed	7 / 114 (6.14%)	1 / 36 (2.78%)	0 / 37 (0.00%)
occurrences (all)	9	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	5 / 114 (4.39%)	2 / 36 (5.56%)	0 / 37 (0.00%)
occurrences (all)	7	2	0
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	1 / 114 (0.88%)	2 / 36 (5.56%)	0 / 37 (0.00%)
occurrences (all)	1	2	0
Nervous system disorders			
Dizziness			
subjects affected / exposed	7 / 114 (6.14%)	4 / 36 (11.11%)	2 / 37 (5.41%)
occurrences (all)	9	4	2
Headache			
subjects affected / exposed	7 / 114 (6.14%)	4 / 36 (11.11%)	2 / 37 (5.41%)
occurrences (all)	7	4	2
Paraesthesia			
subjects affected / exposed	4 / 114 (3.51%)	2 / 36 (5.56%)	0 / 37 (0.00%)
occurrences (all)	5	2	0
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	28 / 114 (24.56%)	1 / 36 (2.78%)	7 / 37 (18.92%)
occurrences (all)	46	5	9
Gastrointestinal disorders			
Nausea			
subjects affected / exposed	19 / 114 (16.67%)	6 / 36 (16.67%)	4 / 37 (10.81%)
occurrences (all)	28	9	5
Diarrhoea			
subjects affected / exposed	20 / 114 (17.54%)	3 / 36 (8.33%)	5 / 37 (13.51%)
occurrences (all)	38	3	8
Constipation			
subjects affected / exposed	21 / 114 (18.42%)	4 / 36 (11.11%)	2 / 37 (5.41%)
occurrences (all)	31	7	2

Vomiting			
subjects affected / exposed	13 / 114 (11.40%)	5 / 36 (13.89%)	3 / 37 (8.11%)
occurrences (all)	16	6	3
Abdominal pain			
subjects affected / exposed	6 / 114 (5.26%)	3 / 36 (8.33%)	2 / 37 (5.41%)
occurrences (all)	8	7	2
Abdominal pain upper			
subjects affected / exposed	7 / 114 (6.14%)	2 / 36 (5.56%)	0 / 37 (0.00%)
occurrences (all)	8	2	0
Dysphagia			
subjects affected / exposed	7 / 114 (6.14%)	1 / 36 (2.78%)	1 / 37 (2.70%)
occurrences (all)	8	1	2
Stomatitis			
subjects affected / exposed	2 / 114 (1.75%)	1 / 36 (2.78%)	4 / 37 (10.81%)
occurrences (all)	3	1	5
Dry mouth			
subjects affected / exposed	6 / 114 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	12	0	0
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	27 / 114 (23.68%)	5 / 36 (13.89%)	4 / 37 (10.81%)
occurrences (all)	60	7	6
Rash			
subjects affected / exposed	18 / 114 (15.79%)	0 / 36 (0.00%)	3 / 37 (8.11%)
occurrences (all)	46	0	4
Dry skin			
subjects affected / exposed	9 / 114 (7.89%)	2 / 36 (5.56%)	2 / 37 (5.41%)
occurrences (all)	11	2	2
Rash erythematous			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	2 / 37 (5.41%)
occurrences (all)	2	0	2
Renal and urinary disorders			
Urinary retention			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	2
Endocrine disorders			

Hypothyroidism			
subjects affected / exposed	11 / 114 (9.65%)	1 / 36 (2.78%)	7 / 37 (18.92%)
occurrences (all)	11	1	9
Hyperthyroidism			
subjects affected / exposed	7 / 114 (6.14%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	8	0	0
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	19 / 114 (16.67%)	7 / 36 (19.44%)	4 / 37 (10.81%)
occurrences (all)	29	8	10
Back pain			
subjects affected / exposed	15 / 114 (13.16%)	3 / 36 (8.33%)	5 / 37 (13.51%)
occurrences (all)	30	3	7
Musculoskeletal pain			
subjects affected / exposed	13 / 114 (11.40%)	4 / 36 (11.11%)	2 / 37 (5.41%)
occurrences (all)	18	4	2
Neck pain			
subjects affected / exposed	8 / 114 (7.02%)	1 / 36 (2.78%)	3 / 37 (8.11%)
occurrences (all)	9	1	3
Pain in extremity			
subjects affected / exposed	8 / 114 (7.02%)	1 / 36 (2.78%)	2 / 37 (5.41%)
occurrences (all)	15	1	2
Musculoskeletal chest pain			
subjects affected / exposed	6 / 114 (5.26%)	3 / 36 (8.33%)	0 / 37 (0.00%)
occurrences (all)	6	3	0
Myalgia			
subjects affected / exposed	8 / 114 (7.02%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	11	0	0
Pain in jaw			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	2 / 37 (5.41%)
occurrences (all)	1	0	4
Infections and infestations			
Pneumonia			
subjects affected / exposed	8 / 114 (7.02%)	2 / 36 (5.56%)	2 / 37 (5.41%)
occurrences (all)	10	5	3
COVID-19			

subjects affected / exposed	8 / 114 (7.02%)	2 / 36 (5.56%)	1 / 37 (2.70%)
occurrences (all)	9	2	1
Upper respiratory tract infection			
subjects affected / exposed	5 / 114 (4.39%)	3 / 36 (8.33%)	4 / 37 (10.81%)
occurrences (all)	5	3	4
Urinary tract infection			
subjects affected / exposed	7 / 114 (6.14%)	1 / 36 (2.78%)	3 / 37 (8.11%)
occurrences (all)	9	1	3
Respiratory tract infection			
subjects affected / exposed	5 / 114 (4.39%)	1 / 36 (2.78%)	2 / 37 (5.41%)
occurrences (all)	5	1	3
Bronchitis			
subjects affected / exposed	4 / 114 (3.51%)	1 / 36 (2.78%)	2 / 37 (5.41%)
occurrences (all)	6	1	2
Lower respiratory tract infection			
subjects affected / exposed	3 / 114 (2.63%)	2 / 36 (5.56%)	1 / 37 (2.70%)
occurrences (all)	4	3	1
Oral candidiasis			
subjects affected / exposed	4 / 114 (3.51%)	1 / 36 (2.78%)	2 / 37 (5.41%)
occurrences (all)	6	1	2
Nasopharyngitis			
subjects affected / exposed	6 / 114 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	9	0	0
Rhinitis			
subjects affected / exposed	3 / 114 (2.63%)	2 / 36 (5.56%)	0 / 37 (0.00%)
occurrences (all)	6	3	0
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	30 / 114 (26.32%)	13 / 36 (36.11%)	4 / 37 (10.81%)
occurrences (all)	40	14	4
Hyperglycaemia			
subjects affected / exposed	9 / 114 (7.89%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	12	0	0
Hypercalcaemia			
subjects affected / exposed	3 / 114 (2.63%)	2 / 36 (5.56%)	1 / 37 (2.70%)
occurrences (all)	4	3	2

Hyponatraemia			
subjects affected / exposed	4 / 114 (3.51%)	3 / 36 (8.33%)	1 / 37 (2.70%)
occurrences (all)	6	5	2
Hyperkalaemia			
subjects affected / exposed	6 / 114 (5.26%)	0 / 36 (0.00%)	0 / 37 (0.00%)
occurrences (all)	7	0	0
Dehydration			
subjects affected / exposed	2 / 114 (1.75%)	1 / 36 (2.78%)	2 / 37 (5.41%)
occurrences (all)	2	1	2
Hypokalaemia			
subjects affected / exposed	1 / 114 (0.88%)	1 / 36 (2.78%)	2 / 37 (5.41%)
occurrences (all)	1	1	2
Hypoalbuminaemia			
subjects affected / exposed	1 / 114 (0.88%)	0 / 36 (0.00%)	2 / 37 (5.41%)
occurrences (all)	1	0	3
Hypomagnesaemia			
subjects affected / exposed	0 / 114 (0.00%)	0 / 36 (0.00%)	2 / 37 (5.41%)
occurrences (all)	0	0	7

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
31 January 2019	• Update on pembrolizumab's relevant approved indication • Update of clinical data of eftilagimod alpha • Study Stopping Rules updated according to CA comments • Inclusion criteria updated to specify NSCLC patient population eligible for the study e.g. clarification on the prior use of durvalumab • Exclusion criteria updated #´specifing NSCLC patient population e.g. clarification on the wash-out for patients receiving pembrolizumab and clarification on the definition/detection of hepatitis • Additional safety data added and update of related risk language • Update to management and discontinuation guidelines
28 July 2020	• Part A cohort extension • Clarifications regarding Part B patient selection and inclusion exclusion criteria • Clarification on rules of efti treatment delay and allowed study treatment interruptions • Update to pembrolizumab dose modification rules • Clarification on patient rescreening, pregnancy testing and laboratory analyses used for tumour tissue • Additions to allow for adapting to COVID-19, replacement of patients who discontinue early due to COVID, remote monitoring under special circumstances • PK sampling window extended for late PK timepoints • Clarification on interim analyses and timing
08 June 2021	• Update to Sponsor's address and other contact details • Clarification to reporting deadline for Events of Clinical Interest
18 August 2023	• Update on study timelines, extending study end by 12 month to collect additional PFS/OS FU data

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

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

Limitations include lack of randomization and a control group, and a small sample size

Notes: