Clinical trial results:
A Randomized, Multicenter, Phase Ib/III Study to Investigate the Pharmacokinetics, Efficacy, and Safety of Atezolizumab Subcutaneous Compared With Atezolizumab Intravenous in Patients With Previously Treated Locally Advanced or Metastatic Non-small Cell Lung Cancer

Summary

EudraCT number	2018-002328-18
Trial protocol	LV PL HU GR BG IT
Global end of trial date	22 November 2024

Results information

Result version number	v3 (current)
This version publication date	20 November 2025
First version publication date	12 May 2023
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	BP40657

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT03735121
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche AG
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, CH-4058
Public contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, + 41 616878333, global.trial_information@roche.com
Scientific contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, + 41 616878333, global.trial_information@roche.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	22 November 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	22 November 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main purpose of Part 1 of the study was to determine the dose of atezolizumab (atezo) given as subcutaneous (SC) injection that was predicted to yield drug exposure that is comparable to that of atezolizumab intravenous (IV) infusion. The main purpose of Part 2 of the study was to demonstrate non-inferiority of exposure to atezolizumab SC compared with atezolizumab IV.

Protection of trial subjects:

All participants were required to sign the informed consent form (ICF).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	27 December 2018
Long term follow-up planned	No
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 7
Country: Number of subjects enrolled	Brazil: 22
Country: Number of subjects enrolled	Chile: 50
Country: Number of subjects enrolled	China: 10
Country: Number of subjects enrolled	Costa Rica: 8
Country: Number of subjects enrolled	France: 7
Country: Number of subjects enrolled	Greece: 9
Country: Number of subjects enrolled	Guatemala: 7
Country: Number of subjects enrolled	Hungary: 7
Country: Number of subjects enrolled	Italy: 2
Country: Number of subjects enrolled	Korea, Republic of: 5
Country: Number of subjects enrolled	Latvia: 13
Country: Number of subjects enrolled	Mexico: 8
Country: Number of subjects enrolled	New Zealand: 17
Country: Number of subjects enrolled	Peru: 18
Country: Number of subjects enrolled	Poland: 11
Country: Number of subjects enrolled	Russian Federation: 44
Country: Number of subjects enrolled	South Africa: 3
Country: Number of subjects enrolled	Spain: 37
Country: Number of subjects enrolled	Thailand: 69

Country: Number of subjects enrolled	Türkiye: 54
Country: Number of subjects enrolled	Ukraine: 28
Country: Number of subjects enrolled	United Kingdom: 2
Worldwide total number of subjects	438
EEA total number of subjects	86

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)	229
From 65 to 84 years	207
85 years and over	2

Subject disposition

Recruitment

Recruitment details:

Total of 438 participants with previously treated locally advanced or metastatic non-small cell lung cancer (NSCLC) who were cancer immunotherapy (CIT)-naïve & for whom prior platinum-based therapy failed took part in the study across 23 countries from 27 Dec 2018 to 22 Nov 2024. Study had 2 parts: Part 1(Dose Finding) & Part 2(Dose Confirmation).

Pre-assignment

Screening details:

Health care professionals (HCPs) who administered atezo to participants were not enrolled in the study. To evaluate HCPs experience with administration of atezo SC & IV, they were asked to complete 2 questionnaires: HCP SC Vs IV Perspective; HCP SC Perspective. No data other than HCP's responses to these Questionnaires were collected in the study.

Period 1

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

Blinding implementation details:

Open-label study, with allocation for Part 1 being non-randomized, whereas for Part 2 it is randomized.

Arms

Are arms mutually exclusive?	Yes
Arm title	Part 1 Cohort 1: Atezolizumab SC Co-mix 1800 mg

Arm description:

Participants received atezolizumab, 1800 milligrams (mg), co-mixed with rHuPH20, as SC injection on Cycle 1 Day 1 (1 cycle=21 days), followed by atezolizumab, 1200 mg, as an IV infusion, every 3 weeks (Q3W) on Day 1 of subsequent cycles (1 cycle=21 days) until disease progression (PD), loss of clinical benefit, unacceptable toxicity, or withdrawal of consent.

Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Atezolizumab, 1200 mg, as an IV infusion, Q3W (1 cycle=21 days).

Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267/F01
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Atezolizumab, 1800 mg, co-mixed with rHuPH20, as SC injection on Cycle 1 Day 1 (1 cycle=21 days).

Arm title	Part 1 Cohort 2: Atezolizumab SC Co-mix 1200 mg

Arm description:

Participants received atezolizumab, 1200 mg, co-mixed with rHuPH20, as SC injection, Q2W, on Day 1 of the first 3 cycles (Cycle 1-3=14 days), followed by atezolizumab, 1200 mg, as an IV infusion, Q3W, on Day 1 of subsequent cycles (1 cycle=21 days) until PD, loss of clinical benefit, unacceptable toxicity, or withdrawal of consent.

Arm type	Experimental

Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Atezolizumab, 1200 mg, as an IV infusion, Q3W (1 cycle=21 days).

Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267/F01
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Atezolizumab, 1200 mg, co-mixed with rHuPH20, as SC injection, Q2W, on Day 1 of the first 3 cycles (1 Cycle = 21 days).

Arm title	Part 1 Cohort 3: Atezolizumab SC Co-mix 1800 mg

Arm description:

Participants received atezolizumab, 1800 mg, co-mixed with rHuPH20, as SC injection, Q3W, on Day 1 of first 3 cycles, followed by atezolizumab, 1200 mg, as an IV infusion, Q3W on Day 1 for subsequent cycles (1 cycle=21 days) until PD, loss of clinical benefit, unacceptable toxicity, or withdrawal of consent.

Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Atezolizumab, 1200 mg, as an IV infusion, Q3W (1 cycle=21 days).

Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267/F01
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Atezolizumab, 1800 mg, co-mixed with rHuPH20, as SC injection, Q3W, on Day 1 of first 3 cycles (1 Cycle = 21 days).

Arm title	Part 2: Atezolizumab IV 1200 mg

Arm description:

Participants received atezolizumab, 1200 mg, as an IV infusion, Q3W, on Day 1 of each cycle (1 cycle=21 days) until PD, loss of clinical benefit, or unacceptable toxicity.

Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267/F03
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Atezolizumab, 1200 mg, as an IV infusion, Q3W, on Day 1 of each cycle (1 cycle=21 days).

Arm title	Part 2: Atezolizumab SC 1875 mg

Arm description:

Participants received atezolizumab, 1875 mg, co-formulated with rHuPH20, as SC injection, on Day 1 of each cycle (1 cycle=21 days) until PD, loss of clinical benefit, or unacceptable toxicity.

Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	RO5541267/F01
Other name	
Pharmaceutical forms	Solution for injection
Routes of administration	Subcutaneous use

Dosage and administration details:

Atezolizumab, 1875 mg, co-formulated with rHuPH20, as SC injection, on Day 1 of each cycle (1 cycle=21 days).

Number of subjects in period 1	Part 1 Cohort 1: Atezolizumab SC Co-mix 1800 mg	Part 1 Cohort 2: Atezolizumab SC Co-mix 1200 mg	Part 1 Cohort 3: Atezolizumab SC Co-mix 1800 mg
Started	13	15	39
Completed	8	7	13
Not completed	5	8	26
Consent withdrawn by subject	1	1	6
Study Ended by Sponsor	1	-	1
Death	3	6	19
New Therapy	-	1	-
Lost to follow-up	-	-	-

Number of subjects in period 1	Part 2: Atezolizumab IV 1200 mg	Part 2: Atezolizumab SC 1875 mg
Started	124	247
Completed	0	0
Not completed	124	247
Consent withdrawn by subject	8	11
Study Ended by Sponsor	17	28
Death	97	205
New Therapy	-	-
Lost to follow-up	2	3

Baseline characteristics

Reporting groups	
Reporting group title	Part 1 Cohort 1: Atezolizumab SC Co-mix 1800 mg
Reporting group description:	
Participants received atezolizumab, 1800 milligrams (mg), co-mixed with rHuPH20, as SC injection on Cycle 1 Day 1 (1 cycle=21 days), followed by atezolizumab, 1200 mg, as an IV infusion, every 3 weeks (Q3W) on Day 1 of subsequent cycles (1 cycle=21 days) until disease progression (PD), loss of clinical benefit, unacceptable toxicity, or withdrawal of consent.	
Reporting group title	Part 1 Cohort 2: Atezolizumab SC Co-mix 1200 mg
Reporting group description:	
Participants received atezolizumab, 1200 mg, co-mixed with rHuPH20, as SC injection, Q2W, on Day 1 of the first 3 cycles (Cycle 1-3=14 days), followed by atezolizumab, 1200 mg, as an IV infusion, Q3W, on Day 1 of subsequent cycles (1 cycle=21 days) until PD, loss of clinical benefit, unacceptable toxicity, or withdrawal of consent.	
Reporting group title	Part 1 Cohort 3: Atezolizumab SC Co-mix 1800 mg
Reporting group description:	
Participants received atezolizumab, 1800 mg, co-mixed with rHuPH20, as SC injection, Q3W, on Day 1 of first 3 cycles, followed by atezolizumab, 1200 mg, as an IV infusion, Q3W on Day 1 for subsequent cycles (1 cycle=21 days) until PD, loss of clinical benefit, unacceptable toxicity, or withdrawal of consent.	
Reporting group title	Part 2: Atezolizumab IV 1200 mg
Reporting group description:	
Participants received atezolizumab, 1200 mg, as an IV infusion, Q3W, on Day 1 of each cycle (1 cycle=21 days) until PD, loss of clinical benefit, or unacceptable toxicity.	
Reporting group title	Part 2: Atezolizumab SC 1875 mg
Reporting group description:	
Participants received atezolizumab, 1875 mg, co-formulated with rHuPH20, as SC injection, on Day 1 of each cycle (1 cycle=21 days) until PD, loss of clinical benefit, or unacceptable toxicity.	

Reporting group values	Part 1 Cohort 1: Atezolizumab SC Co-mix 1800 mg	Part 1 Cohort 2: Atezolizumab SC Co-mix 1200 mg	Part 1 Cohort 3: Atezolizumab SC Co-mix 1800 mg
Number of subjects	13	15	39
Age Categorical Units: participants			
<=18 years	0	0	0
Between 18 and 65 years	8	7	19
>=65 years	5	8	20
Sex: Female, Male Units: participants			
Female	8	6	12
Male	5	9	27
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	0	0	0
Asian	2	2	1
Native Hawaiian or Other Pacific Islander	0	0	0
Black or African American	0	0	0
White	8	11	36
More than one race	0	0	0
Unknown or Not Reported	3	2	2

Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	1	5	12
Not Hispanic or Latino	9	7	25
Not Stated	3	3	2
Unknown	0	0	0

Reporting group values	Part 2: Atezolizumab IV 1200 mg	Part 2: Atezolizumab SC 1875 mg	Total
Number of subjects	124	247	438
Age Categorical Units: participants			
<=18 years	0	0	0
Between 18 and 65 years	58	137	229
>=65 years	66	110	209
Sex: Female, Male Units: participants			
Female	42	72	140
Male	82	175	298
Race (NIH/OMB) Units: Subjects			
American Indian or Alaska Native	9	15	24
Asian	33	47	85
Native Hawaiian or Other Pacific Islander	2	1	3
Black or African American	1	2	3
White	74	174	303
More than one race	5	6	11
Unknown or Not Reported	0	2	9
Race/Ethnicity, Customized Units: Subjects			
Hispanic or Latino	36	61	115
Not Hispanic or Latino	88	185	314
Not Stated	0	0	8
Unknown	0	1	1

End points

End points reporting groups

Reporting group title	Part 1 Cohort 1: Atezolizumab SC Co-mix 1800 mg

Reporting group description:

Participants received atezolizumab, 1800 milligrams (mg), co-mixed with rHuPH20, as SC injection on Cycle 1 Day 1 (1 cycle=21 days), followed by atezolizumab, 1200 mg, as an IV infusion, every 3 weeks (Q3W) on Day 1 of subsequent cycles (1 cycle=21 days) until disease progression (PD), loss of clinical benefit, unacceptable toxicity, or withdrawal of consent.

Reporting group title	Part 1 Cohort 2: Atezolizumab SC Co-mix 1200 mg

Reporting group description:

Participants received atezolizumab, 1200 mg, co-mixed with rHuPH20, as SC injection, Q2W, on Day 1 of the first 3 cycles (Cycle 1-3=14 days), followed by atezolizumab, 1200 mg, as an IV infusion, Q3W, on Day 1 of subsequent cycles (1 cycle=21 days) until PD, loss of clinical benefit, unacceptable toxicity, or withdrawal of consent.

Reporting group title	Part 1 Cohort 3: Atezolizumab SC Co-mix 1800 mg

Reporting group description:

Participants received atezolizumab, 1800 mg, co-mixed with rHuPH20, as SC injection, Q3W, on Day 1 of first 3 cycles, followed by atezolizumab, 1200 mg, as an IV infusion, Q3W on Day 1 for subsequent cycles (1 cycle=21 days) until PD, loss of clinical benefit, unacceptable toxicity, or withdrawal of consent.

Reporting group title	Part 2: Atezolizumab IV 1200 mg

Reporting group description:

Participants received atezolizumab, 1200 mg, as an IV infusion, Q3W, on Day 1 of each cycle (1 cycle=21 days) until PD, loss of clinical benefit, or unacceptable toxicity.

Reporting group title	Part 2: Atezolizumab SC 1875 mg

Reporting group description:

Participants received atezolizumab, 1875 mg, co-formulated with rHuPH20, as SC injection, on Day 1 of each cycle (1 cycle=21 days) until PD, loss of clinical benefit, or unacceptable toxicity.

Subject analysis set title	Part 2: Atezolizumab IV/Atezolizumab SC
Subject analysis set type	Per protocol

Subject analysis set description:

Participants received atezolizumab, 1200 mg, as an IV infusion, Q3W, or atezolizumab, 1875 mg, co-formulated with rHuPH20, as SC injection, on Day 1 of each cycle (1 cycle=21 days) until PD, loss of clinical benefit, or unacceptable toxicity. HCPs who administered the IV or SC formulations completed the HCP SC versus IV Perspective Questionnaire and the HCP SC Perspective Questionnaire.

Primary: Part 1: Serum Trough Concentration (Ctrough) of Atezolizumab at Cycle 1

End point title	Part 1: Serum Trough Concentration (Ctrough) of Atezolizumab at Cycle 1[1][2]

End point description:

Pharmacokinetic (PK)-evaluable population included all participants who received at least one dose of atezolizumab and had at least 1 evaluable post dose PK sample that could affect PK results. Number analyzed is the number of participants with data available for analysis.

End point type	Primary

End point timeframe:

Pre-dose on Day 1 of Cycle 2 (Cycle length =21 days for cohorts 1 and 3 and 14 days for cohort 2)

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 analysis 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: No statistical analysis for this endpoint.

End point values	Part 1 Cohort 1: Atezolizumab SC Co-mix 1800 mg	Part 1 Cohort 2: Atezolizumab SC Co-mix 1200 mg	Part 1 Cohort 3: Atezolizumab SC Co-mix 1800 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	15	35	
Units: micrograms per milliliter (µg/mL)				
geometric mean (geometric coefficient of variation)	121 (± 42.8)	77.5 (± 51.4)	78.3 (± 88.6)	

Statistical analyses

No statistical analyses for this end point

Primary: Part 2: Observed Serum Ctrough of Atezolizumab at Cycle 1

End point title	Part 2: Observed Serum Ctrough of Atezolizumab at Cycle 1[3]

End point description:

Per Protocol PK evaluable population included all participants randomized to the atezolizumab SC and atezolizumab IV treatment arms who did not have protocol deviations that could affect Cycle 1 observed Ctrough results.

End point type	Primary

End point timeframe:

Predose on Day 1 of Cycle 2 (Cycle length =21 days)

Notes:

[3] - 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: No statistical analysis for this endpoint.

End point values	Part 2: Atezolizumab IV 1200 mg	Part 2: Atezolizumab SC 1875 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	97	205		
Units: µg/mL				
geometric mean (geometric coefficient of variation)	85.4 (± 34.1)	89.4 (± 127.1)		

Statistical analyses

Statistical analysis title	Analysis of Co-primary Endpoint Ctrough
Comparison groups	Part 2: Atezolizumab IV 1200 mg v Part 2: Atezolizumab SC 1875 mg
Number of subjects included in analysis	302
Analysis specification	Pre-specified
Analysis type	non-inferiority[4]
Parameter estimate	Geometric mean ratio
Point estimate	1.05

Confidence interval	
level	90 %
sides	2-sided
lower limit	0.88
upper limit	1.24

Notes:

[4] - The null hypothesis that atezolizumab SC is inferior to atezolizumab IV is rejected if the lower bound of the 2-sided 90% confidence interval [CI] of the geometric mean ratio is greater than or equal to (≥) the non-inferiority margin 0.8.

Primary: Part 2: Area Under the Concentration-Time Curve from Time Zero to 21 Days (AUC 0-21 d) at Cycle 1

End point title	Part 2: Area Under the Concentration-Time Curve from Time Zero to 21 Days (AUC 0-21 d) at Cycle 1[5]

End point description:

PK-evaluable population included all participants who received at least one dose of atezolizumab and had at least 1 evaluable post dose PK sample that could affect PK results. Number analyzed is the number of participants with data available for analysis.

End point type	Primary

End point timeframe:

From start of dosing up to Day 21 in Cycle 1 (Cycle length = 21 days)

Notes:

[5] - 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: No statistical analysis for this endpoint.

End point values	Part 2: Atezolizumab IV 1200 mg	Part 2: Atezolizumab SC 1875 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	122	246		
Units: micrograms day per mL (µg*day/mL)				
geometric mean (geometric coefficient of variation)	3327.9 (± 19.4)	2907.1 (± 35.9)		

Statistical analyses

Statistical analysis title	Analysis of Co-primary Endpoint AUC
Comparison groups	Part 2: Atezolizumab IV 1200 mg v Part 2: Atezolizumab SC 1875 mg
Number of subjects included in analysis	368
Analysis specification	Pre-specified
Analysis type	non-inferiority[6]
Parameter estimate	Geometric mean ratio
Point estimate	0.87
Confidence interval	
level	90 %
sides	2-sided
lower limit	0.83
upper limit	0.92

Notes:

[6] - The null hypothesis that atezolizumab SC is inferior to atezolizumab IV is rejected if the lower bound of the 2-sided 90% CI of the geometric mean ratio is ≥ the non-inferiority margin 0.8.

Secondary: Part 1: Maximum Observed Serum Concentration (Cmax) of Atezolizumab

End point title	Part 1: Maximum Observed Serum Concentration (Cmax) of Atezolizumab[7]

End point description:

PK-evaluable population included all participants who received at least one dose of atezolizumab and had at least 1 evaluable post dose PK sample that could affect PK results. Number analyzed is the number of participants with data available for analysis.

End point type	Secondary

End point timeframe:

Predose and post dose on Day 1 of Cycle 1 and post dose on Days 3 and 8 of Cycle 1 (Cycle length = 21 days for cohorts 1 and 3 and 14 days for cohort 2)

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: No statistical analysis for this endpoint.

End point values	Part 1 Cohort 1: Atezolizumab SC Co-mix 1800 mg	Part 1 Cohort 2: Atezolizumab SC Co-mix 1200 mg	Part 1 Cohort 3: Atezolizumab SC Co-mix 1800 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	14	30	
Units: µg/mL				
geometric mean (geometric coefficient of variation)	251 (± 40.9)	129 (± 42.5)	181 (± 38.3)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Time to Maximum Serum Concentration (Tmax) of Atezolizumab

End point title	Part 1: Time to Maximum Serum Concentration (Tmax) of Atezolizumab[8]

End point description:

PK-evaluable population included all participants who received at least one dose of atezolizumab and had at least 1 evaluable post dose PK sample that could affect PK results. Number analyzed is the number of participants with data available for analysis.

End point type	Secondary

End point timeframe:

Predose and post dose on Day 1 of Cycle 1 and post dose on Days 3 and 8 of Cycle 1 (Cycle length = 21 days for cohorts 1 and 3 and 14 days for cohort 2)

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: No statistical analysis for this endpoint.

End point values	Part 1 Cohort 1: Atezolizumab SC Co-mix 1800 mg	Part 1 Cohort 2: Atezolizumab SC Co-mix 1200 mg	Part 1 Cohort 3: Atezolizumab SC Co-mix 1800 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	14	30	
Units: days				
median (full range (min-max))	3.02 (2.93 to 7.80)	3.45 (3.00 to 8.95)	3.92 (2.99 to 7.11)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Serum Atezolizumab Concentration at Specified Timepoint During SC Administration

End point title	Part 1: Serum Atezolizumab Concentration at Specified Timepoint During SC Administration[9]

End point description:

PK-evaluable population included all participants who received at least one dose of atezolizumab and had at least 1 evaluable post dose PK sample that could affect PK results. Number analyzed is the number of participants with data available for analysis. n = number of participants with data available for analysis at a given timepoint. 99999 = no participants were analyzed for this endpoint at the specified timepoint; 9999 = data was not evaluable as all the samples were below lower limit of quantification (BLLQ); 999999 = Since only 1 participant was analyzed the geometric coefficient of variation could not be calculated.
Cycle length = 21 days for cohorts 1 and 3 and 14 days for cohort 2. Day=D; Cycle=C.

End point type	Secondary

End point timeframe:

Cohort 1: Predose: D1 & postdose: D1, 3, 8 of C1; Cohort 2: Pre & postdose: D1 of C1, 3 & postdose: D3, 8 of C1, Predose: D1 of C2; Cohort 3: Pre & postdose: D1 of C1, 2 & postdose: D3, 8 of C1, D2, 4 & 9 of C2 & pre dose: D1 of C3

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: No statistical analysis for this endpoint.

End point values	Part 1 Cohort 1: Atezolizumab SC Co-mix 1800 mg	Part 1 Cohort 2: Atezolizumab SC Co-mix 1200 mg	Part 1 Cohort 3: Atezolizumab SC Co-mix 1800 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	15	39	
Units: µg/mL				
geometric mean (geometric coefficient of variation)				
Cycle 1 Day 1: Pre-dose (n=13,15,39)	9999 (± 9999)	9999 (± 9999)	9999 (± 9999)	
Cycle 1 Day 1: Post-dose (n=13,15,39)	116 (± 57.8)	61.7 (± 70.9)	108 (± 57.6)	
Cycle 1 Day 3: Post-dose (n=13,15,38)	247 (± 40.5)	123 (± 44.3)	166 (± 45.7)	
Cycle 1 Day 8: Post-dose (n=13,15,37)	230 (± 36.6)	110 (± 45.0)	162 (± 43.5)	
Cycle 2 Day 1: Pre-dose (n=0,15,35)	99999 (± 99999)	77.5 (± 51.4)	78.3 (± 88.6)	
Cycle 2 Day 1: Post-dose (n=0,0,36)	99999 (± 99999)	99999 (± 99999)	87.7 (± 64.7)	

Cycle 2 Day 2: Post-dose (n=0,0,36)	99999 (± 99999)	99999 (± 99999)	183 (± 46.1)	
Cycle 2 Day 4: Post-dose (n=0,0,34)	99999 (± 99999)	99999 (± 99999)	245 (± 42.0)	
Cycle 2 Day 9: Post-dose (n=0,0,35)	99999 (± 99999)	99999 (± 99999)	225 (± 37.2)	
Cycle 3 Day 1: Pre-dose (n=0,14,33)	99999 (± 99999)	104 (± 47.8)	123 (± 57.2)	
Cycle 3 Day 1: Post-dose (n=0,1,0)	99999 (± 99999)	189 (± 999999)	99999 (± 99999)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Area Under the Concentration-time Curve (AUClast) of Atezolizumab

End point title	Part 1: Area Under the Concentration-time Curve (AUClast) of Atezolizumab[10]

End point description:

PK-evaluable population included all participants who received at least one dose of atezolizumab and had at least 1 evaluable post dose PK sample that could affect PK results. Number analyzed is the number of participants with data available for analysis.

End point type	Secondary

End point timeframe:

Predose and up to 21 days post dose in Cycle 1 for cohorts 1 and 3 and from predose up to 14 days post last dose in Cycle 1 for cohort 2 (Cycle length= 21 days for cohorts 1 and 3 and 14 days for cohort 2)

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: No statistical analysis for this endpoint.

End point values	Part 1 Cohort 1: Atezolizumab SC Co-mix 1800 mg	Part 1 Cohort 2: Atezolizumab SC Co-mix 1200 mg	Part 1 Cohort 3: Atezolizumab SC Co-mix 1800 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	14	30	
Units: µg*day/mL				
geometric mean (geometric coefficient of variation)	3870 (± 38.6)	1410 (± 41.8)	2820 (± 38.6)	

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Model Predicted Ctrough at Steady State (Ctrough,ss) of Atezolizumab

End point title	Part 2: Model Predicted Ctrough at Steady State (Ctrough,ss) of Atezolizumab[11]

End point description:

PK-evaluable population included all participants who received at least one dose of atezolizumab (atezolizumab SC or atezolizumab IV) and had at least 1 evaluable post dose PK sample. Number analyzed is the number of participants with data available for analysis.
1 cycle=21 days.
Abbreviations used-Cycle=C; Day =D; Atezolizumab=atezo.

End point type	Secondary

End point timeframe:

Atezo SC: Pre&postdose C1D1, postdose C1 Days 2,4,8, Pre&postdose C2,D1 and Predose on D1 of C3,4,8,12 and 16 ; Atezo IV: Pre&postdose on C1D1, postdose C1 Days 2,4,8; Pre&postdose C2D1, Predose on D1 of C3,4,8,12, and 16 (up to approximately 16 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: No statistical analysis for this endpoint.

End point values	Part 2: Atezolizumab IV 1200 mg	Part 2: Atezolizumab SC 1875 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	122	246		
Units: µg/mL				
geometric mean (geometric coefficient of variation)	179 (± 38.8)	205 (± 58.1)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Model Predicted Ctrough of Atezolizumab at Cycle 1

End point title	Part 2: Model Predicted Ctrough of Atezolizumab at Cycle 1[12]

End point description:

PK evaluable population included all participants randomized to the atezolizumab SC and atezolizumab IV treatment arms with at least one post-baseline PK sample. Number analyzed is the number of participants with data available for analysis.

End point type	Secondary

End point timeframe:

Cycle 1 (Cycle length=21 days)

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: No statistical analysis for this endpoint.

End point values	Part 2: Atezolizumab IV 1200 mg	Part 2: Atezolizumab SC 1875 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	122	246		
Units: µg/mL				
geometric mean (geometric coefficient of variation)	88.7 (± 26.2)	97.2 (± 42.3)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of Participants with AEs

End point title	Part 2: Percentage of Participants with AEs[13]

End point description:

An AE was any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with the treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a pharmaceutical product, whether or not considered related to the pharmaceutical product. Preexisting conditions which worsen during a study are also considered as AEs. AEs were reported based on the NCI-CTCAE, V5.0. Safety-evaluable population included all participants who received at least one dose of atezolizumab (IV or SC), with participants grouped according to treatment received. Percentages have been rounded to one decimal place.

End point type	Secondary

End point timeframe:

From initiation of study treatment up to approximately 44.7 months

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: No statistical analysis for this endpoint.

End point values	Part 2: Atezolizumab IV 1200 mg	Part 2: Atezolizumab SC 1875 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	124	247		
Units: percentage of participants				
number (not applicable)	85.5	89.9		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 1: Percentage of Participants with Adverse Events (AEs)

End point title	Part 1: Percentage of Participants with Adverse Events (AEs)[14]

End point description:

An AE was any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with the treatment. An AE can therefore be any unfavorable and unintended sign (including an abnormal laboratory finding, for example), symptom, or disease temporally associated with the use of a pharmaceutical product, whether or not considered related to the pharmaceutical product. Preexisting conditions which worsen during a study are also considered as AEs. AEs were reported based on the National Cancer Institute Common Terminology Criteria for AEs, version 5.0 (NCI-CTCAE, v5.0). Safety-evaluable population included all participants who received at least one dose of atezolizumab (IV or SC), with participants grouped

according to treatment received. Percentages have been rounded to one decimal place.

End point type	Secondary

End point timeframe:

From initiation of study treatment up to approximately 69 months

Notes:

[14] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis for this endpoint.

End point values	Part 1 Cohort 1: Atezolizumab SC Co-mix 1800 mg	Part 1 Cohort 2: Atezolizumab SC Co-mix 1200 mg	Part 1 Cohort 3: Atezolizumab SC Co-mix 1800 mg	
Subject group type	Reporting group	Reporting group	Reporting group	
Number of subjects analysed	13	15	39	
Units: percentage of participants				
number (not applicable)	100	86.7	84.6	

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Model Predicted AUC at Steady State (AUCss) of Atezolizumab

End point title	Part 2: Model Predicted AUC at Steady State (AUCss) of Atezolizumab[15]

End point description:

PK-evaluable population included all participants who received at least one dose of atezolizumab (atezolizumab SC or atezolizumab IV) and had at least 1 evaluable post dose PK sample. Number analyzed is the number of participants with data available for analysis.
1 cycle=21 days.
Abbreviations used-Cycle=C; Day =D; Atezolizumab=atezo

End point type	Secondary

End point timeframe:

Atezo SC: Pre&postdose C1D1, postdose C1 Days 2,4,8, Pre&postdose C2,D1 and Predose on D1 of C3,4,8,12 and 16 ; Atezo IV: Pre&postdose on C1D1, postdose C1 Days 2,4,8; Pre&postdose C2D1, Predose on D1 of C3,4,8,12, and 16 (up to approximately 16 months)

Notes:

[15] - 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: No statistical analysis for this endpoint.

End point values	Part 2: Atezolizumab IV 1200 mg	Part 2: Atezolizumab SC 1875 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	122	246		
Units: ug*day/mL				
geometric mean (geometric coefficient of variation)	6107 (± 27.3)	6163 (± 46.7)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Progression-free Survival (PFS)

End point title	Part 2: Progression-free Survival (PFS)[16]

End point description:

PFS was defined as the time from study start to the first occurrence of PD, as determined by the investigator according to RECIST v1.1 or death from any cause (whichever occurs first). PD was defined as at least a 20% increase in the SOD of target lesions, taking as reference the smallest SOD at prior timepoints (including baseline). In addition to the relative increase of 20%, the SOD must also demonstrate an absolute increase of ≥ 5 mm. PFS was analyzed using the Kaplan-Meier method. FAS included all randomized participants, with participants grouped according to their assigned treatment.

End point type	Secondary

End point timeframe:

Up to approximately 25 months

Notes:

[16] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis for this endpoint.

End point values	Part 2: Atezolizumab IV 1200 mg	Part 2: Atezolizumab SC 1875 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	124	247		
Units: months				
median (confidence interval 95%)	2.9 (1.8 to 4.2)	2.8 (2.7 to 4.1)		

Statistical analyses

Statistical analysis title	Atezolizumab IV 1200 mg vs Atezolizumab SC 1875 mg
Comparison groups	Part 2: Atezolizumab IV 1200 mg v Part 2: Atezolizumab SC 1875 mg
Number of subjects included in analysis	371
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6906
Method	Logrank
Parameter estimate	Odds ratio (OR)
Point estimate	1.05

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.83
upper limit	1.33

Secondary: Part 2: Objective Response Rate (ORR)

End point title	Part 2: Objective Response Rate (ORR)[17]

End point description:

ORR was defined as the percentage of participants having a complete response (CR) or partial response (PR) as determined by investigator assessment of radiographic disease per Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST V1.1). CR was defined as the disappearance of all target lesions and any pathological lymph nodes must have reduction in short axis to < 10 millimeters (mm). PR was defined as at least a 30% decrease in the sum of diameters (SOD) of all target lesions, taking as reference the baseline SOD in the absence of CR. Response-evaluable population included all participants with measurable disease at baseline. Percentage of participants who achieved confirmed objective response (CR or PR) have been reported. Percentages have been rounded to one decimal place.

End point type	Secondary

End point timeframe:

Up to approximately 25 months

Notes:

[17] - 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: No statistical analysis for this endpoint.

End point values	Part 2: Atezolizumab IV 1200 mg	Part 2: Atezolizumab SC 1875 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	124	245		
Units: percentage of participants				
number (confidence interval 95%)	10.5 (5.7 to 17.3)	11.0 (7.4 to 15.6)		

Statistical analyses

Statistical analysis title	Atezolizumab IV 1200 mg vs Atezolizumab SC 1875 mg
Comparison groups	Part 2: Atezolizumab IV 1200 mg v Part 2: Atezolizumab SC 1875 mg
Number of subjects included in analysis	369
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8757
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in ORR
Point estimate	0.54

Confidence interval	
level	95 %
sides	2-sided
lower limit	-6.56
upper limit	7.63

Secondary: Part 2: Duration of response (DOR)

End point title	Part 2: Duration of response (DOR)[18]

End point description:

DOR was defined as the time from first occurrence of a confirmed objective response (CR or PR) to PD as determined by the investigator according to RECIST v1.1. or death from any cause, whichever occurs first. CR was defined as the disappearance of all target lesions and any pathological lymph nodes must have a reduction in short axis to < 10 mm. PR was defined as at least a 30% decrease in the SOD of target lesions, taking as reference the baseline SOD in the absence of CR. PD was defined as at least a 20% increase in the SOD of target lesions, taking as reference the smallest SOD at prior timepoints (including baseline). In addition to the relative increase of 20%, the SODs must also demonstrate an absolute increase of ≥ 5 mm. DOR-evaluable population included all participants with a measurable disease at baseline and a post-baseline confirmed objective response (CR/PR). 9999 = upper limit of the 95% CI was not estimable due to an insufficient number of participants with events.

End point type	Secondary

End point timeframe:

Up to approximately 25 months

Notes:

[18] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis for this endpoint.

End point values	Part 2: Atezolizumab IV 1200 mg	Part 2: Atezolizumab SC 1875 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	13	27		
Units: months				
median (confidence interval 95%)	11.2 (4.2 to 9999)	15.1 (5.6 to 9999)		

Statistical analyses

Statistical analysis title	Atezolizumab IV 1200 mg vs Atezolizumab SC 1875 mg
Comparison groups	Part 2: Atezolizumab IV 1200 mg v Part 2: Atezolizumab SC 1875 mg
Number of subjects included in analysis	40
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8375
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.9

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.34
upper limit	2.42

Secondary: Part 2: Overall Survival (OS)

End point title	Part 2: Overall Survival (OS)[19]

End point description:

OS was defined as the time from the date of study randomization to the date of death from any cause. FAS included all randomized participants, with participants grouped according to their assigned treatment.

End point type	Secondary

End point timeframe:

Up to approximately 44.7 months

Notes:

[19] - 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: No statistical analysis for this endpoint.

End point values	Part 2: Atezolizumab IV 1200 mg	Part 2: Atezolizumab SC 1875 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	124	247		
Units: months				
median (confidence interval 95%)	10.1 (7.5 to 12.3)	10.9 (8.5 to 14.4)		

Statistical analyses

Statistical analysis title	Atezolizumab IV 1200 mg vs Atezolizumab SC 1875 mg
Comparison groups	Part 2: Atezolizumab IV 1200 mg v Part 2: Atezolizumab SC 1875 mg
Number of subjects included in analysis	371
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.9766
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.78
upper limit	1.27

Secondary: Part 2: Change From Baseline in European Organization for Research and Treatment of Cancer (EORTC) Item Library (IL) 57 Physical Functioning Score

End point title	Part 2: Change From Baseline in European Organization for Research and Treatment of Cancer (EORTC) Item Library (IL) 57 Physical Functioning Score[20]

End point description:

EORTC IL57 questionnaire has 10 items and covers 3 scales: physical functioning (PF), role functioning (RF) and global health status/quality of life (GHS/QoL) and 1 item from EORTC IL. PF scale has 5 items evaluating the extent to which participants have trouble doing strenuous activities; taking long walks and short walks; need to stay in bed or a chair; need help with eating, dressing, bathing or using toilet. Questions are answered on a 4-point Likert scale (where 1="Not at all" to 4="Very much") for physical function scale. For this scale, mean of the items are linearly transformed to obtain scores from 0-100, where 100 = best possible score. Higher score indicates better outcome. FAS. Number analyzed is the number of participants with data available for analysis. n = number analyzed at specified time point. 9999 = No participants were analyzed at specified time point. 99999 = Standard deviation (SD) was not estimable for since only 1 participant was evaluated.

End point type	Secondary

End point timeframe:

Baseline, Day 1 of Cycles 2, 3, 4, 5, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64 (Cycle length = 21 days), and Treatment Discontinuation Visit (TDV) (up to approximately 44 months)

Notes:

[20] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis for this endpoint.

End point values	Part 2: Atezolizumab IV 1200 mg	Part 2: Atezolizumab SC 1875 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	117	243		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=117,243)	74.53 (± 20.37)	72.15 (± 21.94)		
Change at Day 1 Cycle 2 (n=106,219)	-6.23 (± 19.17)	-4.23 (± 17.01)		
Change at Day 1 Cycle 3 (n=86,183)	-4.55 (± 19.04)	-4.99 (± 17.63)		
Change at Day 1 Cycle 4 (n=80,167)	-5.75 (± 22.04)	-4.47 (± 20.86)		
Change at Day 1 Cycle 5 (n=64,134)	-1.46 (± 21.40)	-2.14 (± 20.05)		
Change at Day 1 Cycle 6 (n=58,120)	-2.76 (± 25.68)	-0.67 (± 20.09)		
Change at Day 1 Cycle 8 (n=47,95)	-0.14 (± 19.24)	-0.42 (± 19.76)		
Change at Day 1 Cycle 10 (n=41,81)	-1.46 (± 22.39)	0.82 (± 20.96)		
Change at Day 1 Cycle 12 (n=35,70)	0.95 (± 22.64)	1.14 (± 20.43)		
Change at Day 1 Cycle 14 (n=30,60)	0.67 (± 19.37)	1.11 (± 18.82)		
Change at Day 1 Cycle 16 (n=28,53)	-2.14 (± 23.38)	2.26 (± 19.30)		
Change at Day 1 Cycle 18 (n=23,50)	-0.87 (± 19.10)	0.67 (± 19.30)		

Change at Day 1 Cycle 20 (n=21,44)	-1.59 (± 22.30)	-0.15 (± 19.53)		
Change at Day 1 Cycle 22 (n=18,36)	-2.22 (± 23.54)	-1.67 (± 23.66)		
Change at Day 1 Cycle 24 (n=16,34)	-0.83 (± 22.69)	-1.76 (± 20.97)		
Change at Day 1 Cycle 26 (n=16,31)	0.83 (± 17.36)	-1.94 (± 23.61)		
Change at Day 1 Cycle 28 (n=14,23)	2.38 (± 14.70)	0.51 (± 19.46)		
Change at Day 1 Cycle 30 (n=13,21)	2.05 (± 16.42)	0.95 (± 18.89)		
Change at Day 1 Cycle 32 (n=12,22)	-6.67 (± 21.27)	0.61 (± 22.34)		
Change at Day 1 Cycle 34 (n=11,20)	-2.42 (± 16.40)	3.00 (± 26.62)		
Change at Day 1 Cycle 36 (n=11,20)	0.61 (± 17.24)	6.00 (± 23.59)		
Change at Day 1 Cycle 38 (n=11,18)	3.64 (± 17.22)	4.07 (± 24.96)		
Change at Day 1 Cycle 40 (n=11,18)	0.00 (± 25.65)	1.11 (± 23.79)		
Change at Day 1 Cycle 42 (n=8,18)	1.67 (± 19.76)	2.96 (± 21.36)		
Change at Day 1 Cycle 44 (n=8,16)	5.83 (± 12.57)	5.00 (± 21.15)		
Change at Day 1 Cycle 46 (n=8,17)	5.83 (± 16.88)	5.88 (± 26.34)		
Change at Day 1 Cycle 48 (n=7,14)	8.57 (± 10.69)	8.10 (± 24.13)		
Change at Day 1 Cycle 50 (n=7,11)	4.76 (± 14.76)	9.09 (± 29.25)		
Change at Day 1 Cycle 52 (n=6,10)	12.22 (± 12.94)	5.33 (± 24.30)		
Change at Day 1 Cycle 54 (n=3,8)	11.11 (± 10.18)	6.67 (± 29.81)		
Change at Day 1 Cycle 56 (n=2,3)	10.00 (± 4.71)	8.89 (± 13.88)		
Change at Day 1 Cycle 58 (n=1,2)	6.67 (± 99999)	3.33 (± 14.14)		
Change at Day 1 Cycle 60 (n=1,1)	20.00 (± 99999)	13.33 (± 99999)		
Change at Day 1 Cycle 62 (n=1,1)	13.33 (± 99999)	13.33 (± 99999)		
Change at Day 1 Cycle 64 (n=0,1)	9999 (± 9999)	13.33 (± 99999)		
Change at TDV (n=74,149)	-19.01 (± 28.26)	-15.68 (± 25.67)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change From Baseline in EORTC IL57 Role Functioning Score

End point title	Part 2: Change From Baseline in EORTC IL57 Role Functioning Score[21]

End point description:

EORTC IL57 questionnaire has 10 items and covers 3 scales: PF, RF and GHS/QoL and 1 item from EORTC IL. RF scale has 2 items evaluating extent to which participants are limited in doing work and pursuing leisure activities in the previous week. Questions are answered on a 4-point Likert scale (where 1="Not at all" to 4="Very much") for the role functioning scale. For this scale, mean of the items are linearly transformed to obtain scores from 0-100, where 100 = best possible score. Higher score indicates better outcome. FAS included all randomized participants, with participants grouped according to their assigned treatment. Number analyzed is the number of participants with data available for analysis. n = number of participants with data available for analysis at the specified time point. 9999 = No participants were analyzed at the specified time point. 99999 = SD was not estimable for since only 1 participant was evaluated.

End point type	Secondary

End point timeframe:

Baseline, Day 1 of Cycles 2, 3, 4, 5, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64 (Cycle length = 21 days), and Treatment Discontinuation Visit (up to approximately 44 months)

Notes:

[21] - 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: No statistical analysis for this endpoint.

End point values	Part 2: Atezolizumab IV 1200 mg	Part 2: Atezolizumab SC 1875 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	117	242		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=117,242)	74.93 (± 25.67)	74.86 (± 27.51)		
Change at Day 1 Cycle 2 (n=106,218)	0.31 (± 29.46)	-4.36 (± 24.48)		
Change at Day 1 Cycle 3 (n=86,182)	-3.29 (± 27.51)	-4.67 (± 25.83)		
Change at Day 1 Cycle 4 (n=80,167)	-0.83 (± 26.90)	-6.59 (± 28.63)		
Change at Day 1 Cycle 5 (n=64,134)	2.34 (± 31.13)	-5.22 (± 30.27)		
Change at Day 1 Cycle 6 (n=58,119)	0.00 (± 32.14)	-5.74 (± 29.39)		
Change at Day 1 Cycle 8 (n=47,94)	4.96 (± 29.47)	-1.95 (± 25.50)		
Change at Day 1 Cycle 10 (n=41,81)	1.63 (± 29.06)	-0.82 (± 24.71)		
Change at Day 1 Cycle 12 (n=35,69)	4.29 (± 29.80)	-2.66 (± 30.20)		
Change at Day 1 Cycle 14 (n=30,60)	6.11 (± 22.09)	-3.61 (± 30.24)		
Change at Day 1 Cycle 16 (n=28,53)	-0.60 (± 29.91)	-1.26 (± 27.12)		
Change at Day 1 Cycle 18 (n=23,50)	0.72 (± 21.60)	-2.00 (± 27.90)		
Change at Day 1 Cycle 20 (n=21,44)	7.94 (± 30.10)	-2.65 (± 27.83)		
Change at Day 1 Cycle 22 (n=18,36)	6.48 (± 28.66)	-5.09 (± 34.23)		
Change at Day 1 Cycle 24 (n=16,34)	3.13 (± 24.51)	-4.41 (± 29.39)		
Change at Day 1 Cycle 26 (n=16,31)	4.17 (± 36.77)	0.54 (± 27.38)		
Change at Day 1 Cycle 28 (n=14,23)	7.14 (± 16.94)	5.07 (± 29.91)		
Change at Day 1 Cycle 30 (n=13,21)	-2.56 (± 20.24)	3.17 (± 31.01)		
Change at Day 1 Cycle 32 (n=12,22)	-6.94 (± 19.41)	-0.76 (± 31.49)		
Change at Day 1 Cycle 34 (n=11,20)	-6.06 (± 22.70)	0.00 (± 34.20)		
Change at Day 1 Cycle 36 (n=11,20)	-3.03 (± 17.98)	1.67 (± 31.48)		
Change at Day 1 Cycle 38 (n=11,18)	4.55 (± 16.82)	5.56 (± 26.20)		
Change at Day 1 Cycle 40 (n=11,18)	1.52 (± 24.10)	1.85 (± 28.52)		

Change at Day 1 Cycle 42 (n=8,18)	-6.25 (± 23.46)	3.70 (± 32.11)		
Change at Day 1 Cycle 44 (n=8,16)	-2.08 (± 16.52)	7.29 (± 31.60)		
Change at Day 1 Cycle 46 (n=8,17)	0.00 (± 23.57)	4.90 (± 32.68)		
Change at Day 1 Cycle 48 (n=7,14)	2.38 (± 20.25)	8.33 (± 31.86)		
Change at Day 1 Cycle 50 (n=7,11)	2.38 (± 20.25)	13.64 (± 36.38)		
Change at Day 1 Cycle 52 (n=6,10)	2.78 (± 28.71)	1.67 (± 24.15)		
Change at Day 1 Cycle 54 (n=3,8)	-11.11 (± 34.69)	2.08 (± 36.12)		
Change at Day 1 Cycle 56 (n=2,3)	0.00 (± 23.57)	-5.56 (± 19.25)		
Change at Day 1 Cycle 58 (n=1,2)	-33.33 (± 99999)	0.00 (± 23.57)		
Change at Day 1 Cycle 60 (n=1,1)	16.67 (± 99999)	16.67 (± 99999)		
Change at Day 1 Cycle 62 (n=1,1)	16.67 (± 99999)	16.67 (± 99999)		
Change at Day 1 Cycle 64 (n=0,1)	9999 (± 9999)	16.67 (± 99999)		
Change at TDV (n=74,149)	-20.27 (± 33.70)	-21.14 (± 34.80)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Change From Baseline in EORTC IL57 Global Health Status Score

End point title	Part 2: Change From Baseline in EORTC IL57 Global Health Status Score[22]

End point description:

EORTC IL57 questionnaire has 10 items and covers 3 scales: PF, RF and GHS/QoL and 1 item from EORTC IL. GHS/QoL scale has 2 items evaluating participants' overall health and QoL in previous week. Questions are answered on a 7-point scale (where 1="Very poor" to 7="Excellent") for GHS/QoL. For this scale, mean of the items are linearly transformed to obtain scores from 0-100, where 100 = best possible score. Higher score indicates better outcome. FAS included all randomized participants, with participants grouped according to their assigned treatment. Number analyzed is the number of participants with data available for analysis. n = number of participants with data available for analysis at the specified time point. 9999 = No participants were analyzed at the specified time point. 99999 = SD was not estimable since only 1 participant was evaluated.

End point type	Secondary

End point timeframe:

Baseline, Day 1 of Cycles 2, 3, 4, 5, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, 64 (Cycle length = 21 days), and Treatment Discontinuation Visit (up to approximately 44 months)

Notes:

[22] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis for this endpoint.

End point values	Part 2: Atezolizumab IV 1200 mg	Part 2: Atezolizumab SC 1875 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	117	242		
Units: score on a scale				
arithmetic mean (standard deviation)				
Baseline (n=117,242)	66.52 (± 17.68)	63.50 (± 22.00)		
Change at Day 1 Cycle 2 (n=106,218)	-3.54 (± 21.33)	-2.48 (± 21.77)		
Change at Day 1 Cycle 3 (n=86,182)	-2.91 (± 20.92)	-1.83 (± 23.04)		
Change at Day 1 Cycle 4 (n=80,167)	-2.71 (± 19.61)	-2.25 (± 22.21)		
Change at Day 1 Cycle 5 (n=64,134)	0.65 (± 19.26)	-1.43 (± 25.35)		
Change at Day 1 Cycle 6 (n=58,119)	-0.14 (± 21.99)	0.14 (± 22.94)		
Change at Day 1 Cycle 8 (n=47,94)	3.01 (± 18.26)	1.86 (± 22.74)		
Change at Day 1 Cycle 10 (n=41,81)	5.28 (± 19.87)	0.72 (± 23.17)		
Change at Day 1 Cycle 12 (n=35,69)	6.19 (± 18.45)	-2.78 (± 18.56)		
Change at Day 1 Cycle 14 (n=30,60)	7.50 (± 17.42)	1.94 (± 19.67)		
Change at Day 1 Cycle 16 (n=28,53)	6.55 (± 17.77)	1.73 (± 18.52)		
Change at Day 1 Cycle 18 (n=23,50)	4.71 (± 19.11)	0.67 (± 17.56)		
Change at Day 1 Cycle 20 (n=21,44)	9.52 (± 16.73)	-0.95 (± 18.52)		
Change at Day 1 Cycle 22 (n=18,36)	5.56 (± 21.20)	0.00 (± 19.92)		
Change at Day 1 Cycle 24 (n=16,34)	7.29 (± 28.20)	-2.70 (± 18.99)		
Change at Day 1 Cycle 26 (n=16,31)	1.56 (± 24.95)	-2.15 (± 21.51)		
Change at Day 1 Cycle 28 (n=14,23)	1.79 (± 16.72)	1.81 (± 21.17)		
Change at Day 1 Cycle 30 (n=13,21)	5.77 (± 16.45)	3.17 (± 21.81)		
Change at Day 1 Cycle 32 (n=12,22)	0.00 (± 18.46)	0.38 (± 17.91)		
Change at Day 1 Cycle 34 (n=11,20)	0.00 (± 20.07)	2.50 (± 19.70)		
Change at Day 1 Cycle 36 (n=11,20)	-1.52 (± 15.73)	1.67 (± 20.52)		
Change at Day 1 Cycle 38 (n=11,18)	2.27 (± 21.11)	3.70 (± 20.66)		
Change at Day 1 Cycle 40 (n=11,18)	5.30 (± 21.50)	1.39 (± 19.85)		
Change at Day 1 Cycle 42 (n=8,18)	0.00 (± 17.25)	2.31 (± 20.37)		
Change at Day 1 Cycle 44 (n=8,16)	2.08 (± 18.23)	3.65 (± 19.95)		
Change at Day 1 Cycle 46 (n=8,17)	2.08 (± 25.88)	2.45 (± 21.60)		
Change at Day 1 Cycle 48 (n=7,14)	7.14 (± 15.54)	4.17 (± 20.35)		
Change at Day 1 Cycle 50 (n=7,11)	-2.38 (± 17.16)	3.03 (± 21.82)		
Change at Day 1 Cycle 52 (n=6,10)	8.33 (± 12.91)	-3.33 (± 16.76)		
Change at Day 1 Cycle 54 (n=3,8)	-2.78 (± 12.73)	0.00 (± 22.27)		
Change at Day 1 Cycle 56 (n=2,3)	4.17 (± 5.89)	2.78 (± 4.81)		
Change at Day 1 Cycle 58 (n=1,2)	0.00 (± 99999)	0.00 (± 0.00)		
Change at Day 1 Cycle 60 (n=1,1)	8.33 (± 99999)	0.00 (± 99999)		
Change at Day 1 Cycle 62 (n=1,1)	-8.33 (± 99999)	0.00 (± 99999)		
Change at Day 1 Cycle 64 (n=0,1)	9999 (± 9999)	0.00 (± 99999)		

Change at TDV (n=74,149)	-14.53 (± 26.28)	-13.37 (± 25.42)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Overall Satisfaction with Treatment Over Time, Assessed by the Modified Satisfaction With Therapy (SWT) Scale of the Cancer Therapy Satisfaction Questionnaire (CTSQ)

End point title	Part 2: Overall Satisfaction with Treatment Over Time, Assessed by the Modified Satisfaction With Therapy (SWT) Scale of the Cancer Therapy Satisfaction Questionnaire (CTSQ)[23]

End point description:

Modified SWT scale of the CTSQ consisted of seven items that measured seven domains related to satisfaction with cancer therapy. These include worthwhile, difficulty, benefits, feelings about side effects, form of therapy, overall satisfaction, and if participants would choose the therapy taking everything into consideration. Each domain is rated on a 5-point scale, with 1 representing the worst response and 5 representing the best response, except in the case of one reverse-scored item. Mean of the items were linearly transformed to obtain scores from 0-100, where 100 was the best possible score. Higher scores indicate higher satisfaction. FAS included all randomized participants, with participants grouped according to their assigned treatment. Number analyzed is the number of participants with data available for analysis. n = number of participants with data available for analysis at the specified time point. Here, data for 'overall satisfaction' domain has been presented.

End point type	Secondary

End point timeframe:

Day 1 Cycle 3 or TDV (if treatment discontinued at any visit before Cycle 3) (Cycle length = 21 days)

Notes:

[23] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis for this endpoint.

End point values	Part 2: Atezolizumab IV 1200 mg	Part 2: Atezolizumab SC 1875 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	98	191		
Units: score on a scale				
arithmetic mean (standard deviation)				
Day 1 Cycle 3 (n=83,162)	77.29 (± 16.08)	75.56 (± 18.61)		
TDV (n=15,29)	50.67 (± 19.90)	61.21 (± 19.81)		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of Participants by Their Responses to AE's Burden

Over Time, Assessed by the Treatment-related Symptom Burden Item from the EORTC IL57

End point title	Part 2: Percentage of Participants by Their Responses to AE's Burden Over Time, Assessed by the Treatment-related Symptom Burden Item from the EORTC IL57[24]

End point description:

The overall patient-reported AE burden was assessed using a single item from the EORTC IL57 questionnaire i.e "To what extent have you been troubled with side-effects from your treatment?" The questions were answered on a 4-point Likert scale, where 1="Not at all" to 4="Very much". Higher scores indicated greater AE burden. Percentages have been rounded to one decimal place. FAS included all randomized participants, with participants grouped according to their assigned treatment. Number analyzed is the number of participants with data available for analysis. n = number of participants with data available for analysis at the specified time point. 9999 = No participants were analyzed at the specified time point.

End point type	Secondary

End point timeframe:

Baseline, Day 1 of Cycles 2, 3, 4, 5, 6, 8, 10, 12, 14, 16, 18, 20, 22, 24, 26, 28, 30, 32, 34, 36, 38, 40, 42, 44, 46, 48, 50, 52, 54, 56, 58, 60, 62, and 64 (Cycle length = 21 days)

Notes:

[24] - 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: No statistical analysis for this endpoint.

End point values	Part 2: Atezolizumab IV 1200 mg	Part 2: Atezolizumab SC 1875 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	113	238		
Units: percentage of participants				
number (not applicable)				
Baseline - Not at all (n=113,238)	49.6	56.7		
Baseline - A little (n=113,238)	36.3	28.6		
Baseline - Quite a bit (n=113,238)	8.0	10.1		
Baseline - Very much (n=113,238)	6.2	4.6		
Day 1 Cycle 2 - Not at all (n=108,222)	47.2	49.5		
Day 1 Cycle 2 - A little (n=108,222)	39.8	35.6		
Day 1 Cycle 2 - Quite a bit (n=108,222)	9.3	12.6		
Day 1 Cycle 2 - Very much (n=108,222)	3.7	2.3		
Day 1 Cycle 3 - Not at all (n=88,184)	43.2	46.7		
Day 1 Cycle 3 - A little (n=88,184)	45.5	41.8		
Day 1 Cycle 3 - Quite a bit (n=88,184)	10.2	8.7		
Day 1 Cycle 3 - Very much (n=88,184)	1.1	2.7		
Day 1 Cycle 4 - Not at all (n=82,169)	48.8	46.7		
Day 1 Cycle 4 - A little (n=82,169)	36.6	36.1		
Day 1 Cycle 4 - Quite a bit (n=82,169)	14.6	15.4		
Day 1 Cycle 4 - Very much (n=82,169)	0	1.8		
Day 1 Cycle 5 - Not at all (n=64,136)	56.3	55.9		
Day 1 Cycle 5 - A little (n=64,136)	35.9	36.0		
Day 1 Cycle 5 - Quite a bit (n=64,136)	7.8	5.9		
Day 1 Cycle 5 - Very much (n=64,136)	0	2.2		
Day 1 Cycle 6 - Not at all (n=59,122)	54.2	49.2		
Day 1 Cycle 6 - A little (n=59,122)	37.3	40.2		
Day 1 Cycle 6 - Quite a bit (n=59,122)	8.5	8.2		
Day 1 Cycle 6 - Very much (n=59,122)	0	2.5		
Day 1 Cycle 8 - Not at all (n=48,96)	62.5	58.3		

Day 1 Cycle 8 - A little (n=48,96)	33.3	37.5		
Day 1 Cycle 8 - Quite a bit (n=48,96)	4.2	4.2		
Day 1 Cycle 10 - Not at all (n=42,81)	66.7	54.3		
Day 1 Cycle 10 - A little (n=42,81)	28.6	44.4		
Day 1 Cycle 10 - Quite a bit (n=42,81)	4.8	1.2		
Day 1 Cycle 12 - Not at all (n=36,70)	63.9	50.0		
Day 1 Cycle 12 - A little (n=36,70)	30.6	45.7		
Day 1 Cycle 12 - Quite a bit (n=36,70)	5.6	4.3		
Day 1 Cycle 14 - Not at all (n=31,60)	61.3	53.3		
Day 1 Cycle 14 - A little (n=31,60)	25.8	45.0		
Day 1 Cycle 14 - Quite a bit (n=31,60)	12.9	1.7		
Day 1 Cycle 16 - Not at all (n=28,53)	60.7	56.6		
Day 1 Cycle 16 - A little (n=28,53)	28.6	35.8		
Day 1 Cycle 16 - Quite a bit (n=28,53)	10.7	7.5		
Day 1 Cycle 18 - Not at all (n=23,50)	69.6	58.0		
Day 1 Cycle 18 - A little (n=23,50)	30.4	36.0		
Day 1 Cycle 18 - Quite a bit (n=23,50)	0	6.0		
Day 1 Cycle 20 - Not at all (n=21,44)	71.4	59.1		
Day 1 Cycle 20 - A little (n=21,44)	28.6	31.8		
Day 1 Cycle 20 - Quite a bit (n=21,44)	0	9.1		
Day 1 Cycle 22 - Not at all (n=18,36)	55.6	52.8		
Day 1 Cycle 22 - A little (n=18,36)	38.9	36.1		
Day 1 Cycle 22 - Quite a bit (n=18,36)	5.6	11.1		
Day 1 Cycle 24 - Not at all (n=16,34)	75.0	55.9		
Day 1 Cycle 24 - A little (n=16,34)	25.0	38.2		
Day 1 Cycle 24 - Quite a bit (n=16,34)	0	5.9		
Day 1 Cycle 26 - Not at all (n=15,31)	73.3	51.6		
Day 1 Cycle 26 - A little (n=15,31)	26.7	41.9		
Day 1 Cycle 26 - Quite a bit (n=15,31)	0	6.5		
Day 1 Cycle 28 - Not at all (n=14,23)	64.3	56.5		
Day 1 Cycle 28 - A little (n=14,23)	35.7	39.1		
Day 1 Cycle 28 - Quite a bit (n=14,23)	0	4.3		
Day 1 Cycle 30 - Not at all (n=13,20)	69.2	70.0		
Day 1 Cycle 30 - A little (n=13,20)	30.8	25.0		
Day 1 Cycle 30 - Quite a bit (n=13,20)	0	5.0		
Day 1 Cycle 32 - Not at all (n=12,22)	50.0	59.1		
Day 1 Cycle 32 - A little (n=12,22)	41.7	36.4		
Day 1 Cycle 32 - Quite a bit (n=12,22)	8.3	4.5		
Day 1 Cycle 34 - Not at all (n=11,20)	72.7	65.0		
Day 1 Cycle 34 - A little (n=11,20)	27.3	35.0		
Day 1 Cycle 36 - Not at all (n=11,20)	63.6	65.0		
Day 1 Cycle 36 - A little (n=11,20)	36.4	35.0		
Day 1 Cycle 38 - Not at all (n=11,18)	72.7	61.1		
Day 1 Cycle 38 - A little (n=11,18)	27.3	33.3		
Day 1 Cycle 38 - Quite a bit (n=11,18)	0	5.6		
Day 1 Cycle 40 - Not at all (n=11,18)	72.7	55.6		
Day 1 Cycle 40 - A little (n=11,18)	27.3	38.9		
Day 1 Cycle 40 - Quite a bit (n=11,18)	0	5.6		
Day 1 Cycle 42 - Not at all (n=8,18)	75.0	66.7		
Day 1 Cycle 42 - A little (n=8,18)	25.0	33.3		
Day 1 Cycle 44 - Not at all (n=8,16)	75.0	68.8		
Day 1 Cycle 44 - A little (n=8,16)	25.0	31.3		

Day 1 Cycle 46 - Not at all (n=8,17)	87.5	76.5		
Day 1 Cycle 46 - A little (n=8,17)	0	23.5		
Day 1 Cycle 46 - Quite a bit (n=8,17)	12.5	0		
Day 1 Cycle 48 - Not at all (n=7,14)	100	71.4		
Day 1 Cycle 48 - A little (n=7,14)	0	28.6		
Day 1 Cycle 50 - Not at all (n=7,11)	100	63.6		
Day 1 Cycle 50 - A little (n=7,11)	0	36.4		
Day 1 Cycle 52 - Not at all (n=6,10)	100	60.0		
Day 1 Cycle 52 - A little (n=6,10)	0	40.0		
Day 1 Cycle 54 - Not at all (n=3,8)	100	50.0		
Day 1 Cycle 54 - A little (n=3,8)	0	50.0		
Day 1 Cycle 56 - Not at all (n=2,3)	100	0		
Day 1 Cycle 56 - A little (n=2,3)	0	100		
Day 1 Cycle 58 - Not at all (n=1,2)	100	50.0		
Day 1 Cycle 58 - A little (n=1,2)	0	50.0		
Day 1 Cycle 60 - Not at all (n=1,1)	100	0		
Day 1 Cycle 60 - A little (n=1,1)	0	100		
Day 1 Cycle 62 - Not at all (n=1,1)	100	0		
Day 1 Cycle 62 - A little (n=1,1)	0	100		
Day 1 Cycle 64 - A little (n=0,1)	9999	100		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of Health Care Professionals (HCPs) by Their Response to Question 2 of HCP SC Versus IV Perspective Questionnaire

End point title	Part 2: Percentage of Health Care Professionals (HCPs) by Their Response to Question 2 of HCP SC Versus IV Perspective Questionnaire

End point description:

The HCP SC versus IV Perspective Questionnaire consisted of five items evaluating the number of atezolizumab SC and IV administrations done, convenience, potential time savings, and overall satisfaction with atezolizumab SC and atezolizumab IV, as well as reasons for HCP-reported satisfaction or dissatisfaction. HCPs who administered at least three doses of atezolizumab as an IV infusion and as a SC injection across all participants in Part 2 of this study responded to this questionnaire, of which question 2 is being reported here: Question 2: Which formulation of atezolizumab (SC or IV) do you think is more convenient for you? Responses to this question are reported in the data table. HCPs were allowed to complete the questionnaire until the last participant completed their assessments (duration between the 'first participant in [FPI]' date to 'last participant last visit [LPLV]' for Part 2). Number analyzed included HCPs who completed Question 2 of the questionnaire.

End point type	Secondary

End point timeframe:

After HCP has completed administering at least 3 doses of atezolizumab SC and IV across all participants in Part 2 (Up to approximately 48 months)

End point values	Part 2: Atezolizumab IV/Atezolizumab SC			
Subject group type	Subject analysis set			
Number of subjects analysed	50			
Units: percentage of HCPs				
number (not applicable)				
Atezolizumab SC is much more convenient	24.0			
Atezolizumab SC is a little more convenient	16.0			
Both formulations are equally convenient	26.0			
Atezolizumab IV is a little more convenient	12.0			
Atezolizumab IV is much more convenient	22.0			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of Participants With Ant-Drug Antibodies (ADAs) to Atezolizumab After SC or IV Administration

End point title	Part 2: Percentage of Participants With Ant-Drug Antibodies (ADAs) to Atezolizumab After SC or IV Administration[25]

End point description:

The percentage of ADA-positive participants after atezolizumab administration was reported. Participants who received atezolizumab were considered to be treatment-emergent ADA-positive if they were ADA-negative or had missing data at baseline but developed an ADA response following atezolizumab exposure (treatment-induced ADA response), or if they were ADA-positive at baseline and the titer of one or more post-baseline samples was at least 0.60 titer units (t.u.) greater than the titer of the baseline sample (treatment-enhanced ADA response). Safety-evaluable population included all participants who received at least one dose of atezolizumab (IV or SC), with participants grouped according to treatment received. Number analyzed is the number of participants with data available for analysis. Percentages have been rounded to one decimal place.

End point type	Secondary

End point timeframe:

From Cycle 1 Day 1 (Cycle length = 21 days) up to treatment discontinuation visit (Up to approximately 20 months)

Notes:

[25] - The end point is not reporting statistics for all the arms in the baseline period. It is expected all the baseline period arms will be reported on when providing values for an end point on the baseline period.
Justification: No statistical analysis for this endpoint.

End point values	Part 2: Atezolizumab IV 1200 mg	Part 2: Atezolizumab SC 1875 mg		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	112	228		
Units: percentage of participants				
number (not applicable)	14.3	20.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of Participants With ADAs to rHuPH20 After SC Administration

End point title	Part 2: Percentage of Participants With ADAs to rHuPH20 After SC Administration[26]

End point description:

The percentage of ADA-positive participants after atezolizumab SC formulated with rHuPH20 administration was reported. Participants who received atezolizumab SC formulated with rHuPH20 were considered to be treatment-emergent ADA-positive if they were ADA-negative or had missing data at baseline but developed an ADA response following rHuPH20 exposure (treatment-induced ADA response), or if they were ADA-positive at baseline and the titer of one or more post-baseline samples was at least 0.60 t.u. greater than the titer of the baseline sample (treatment-enhanced ADA response). Safety-evaluable population included all participants who received at least one dose of atezolizumab SC formulated with rHuPH20. Number analyzed is the number of participants with data available for analysis. Percentages have been rounded to one decimal place.

End point type	Secondary

End point timeframe:

From Cycle 1 Day 1 (Cycle length = 21 days) up to treatment discontinuation visit (Up to approximately 20 months)

Notes:

[26] - 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: No statistical analysis for this endpoint.

End point values	Part 2: Atezolizumab SC 1875 mg			
Subject group type	Reporting group			
Number of subjects analysed	228			
Units: percentage of participants				
number (not applicable)	5.7			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of HCPs by Their Response to Question 3 of the HCP SC Versus IV Perspective Questionnaire

End point title	Part 2: Percentage of HCPs by Their Response to Question 3 of the HCP SC Versus IV Perspective Questionnaire

End point description:

The HCP SC versus IV Perspective Questionnaire consisted of five items evaluating the number of atezolizumab SC and IV administrations done, convenience, potential time savings, and overall satisfaction with atezolizumab SC and atezolizumab IV, as well as reasons for HCP-reported satisfaction

or dissatisfaction. HCPs who administered at least three doses of atezolizumab as an IV infusion and as a SC injection across all participants in Part 2 of this study responded to this questionnaire, of which question 3 is being reported here: Question 3: If used in routine practice, do you think administering atezolizumab SC could save staff time compared to atezolizumab IV? The responses to this question could be Yes; No; Unsure. HCPs were allowed to complete the questionnaire until the last participant completed their assessments (duration between the 'FPI in' date to 'LPLV' for Part 2). Number analyzed included HCPs who completed Question 3 of the questionnaire.

End point type	Secondary

End point timeframe:

After HCP has completed administering at least 3 doses of atezolizumab SC and IV across all participants in Part 2 (Up to approximately 44.7 months)

End point values	Part 2: Atezolizumab IV/Atezolizumab SC			
Subject group type	Subject analysis set			
Number of subjects analysed	50			
Units: percentage of HCPs				
number (not applicable)				
Yes	74.0			
Unsure	14.0			
No	12.0			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of HCPs by Their Response to Question 4 of the HCP SC Versus IV Perspective Questionnaire

End point title	Part 2: Percentage of HCPs by Their Response to Question 4 of the HCP SC Versus IV Perspective Questionnaire

End point description:

HCP SC versus IV Perspective Questionnaire consisted of 5 items evaluating number of atezolizumab SC and IV administrations done, convenience, potential time savings, and overall satisfaction with atezolizumab SC and atezolizumab IV, as well as reasons for HCP-reported satisfaction or dissatisfaction. HCPs who administered at least three doses of atezolizumab as an IV infusion and as a SC injection across all participants in Part 2 of this study responded to this questionnaire, of which question 4 is being reported here: Question 4: Overall, were you more satisfied with atezolizumab SC or atezolizumab IV? The responses included: More satisfied with atezolizumab SC; Equally satisfied with both formulations; More satisfied with atezolizumab IV. HCPs were allowed to complete the questionnaire until the last participant completed their assessments (duration between the 'FPI in' date to 'LPLV' for Part 2). Number analyzed included HCPs who completed Question 4 of the questionnaire.

End point type	Secondary

End point timeframe:

After HCP has completed administering at least 3 doses of atezolizumab SC and IV across all participants in Part 2 (Up to approximately 44.7 months)

End point values	Part 2: Atezolizumab IV/Atezolizumab SC			
Subject group type	Subject analysis set			
Number of subjects analysed	50			
Units: percentage of HCPs				
number (not applicable)				
More satisfied with atezolizumab SC	32.0			
Equally satisfied with both formulations	38.0			
More satisfied with atezolizumab IV	30.0			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of HCPs by Their Response to Question 3 of the HCP SC Perspective Questionnaire

End point title	Part 2: Percentage of HCPs by Their Response to Question 3 of the HCP SC Perspective Questionnaire

End point description:

The HCP SC Perspective Questionnaire consisted of five items evaluating the convenience, ease of administration and overall satisfaction with atezolizumab SC, as well as reasons for HCP-reported satisfaction or dissatisfaction. HCPs who administered at least three doses of atezolizumab as a SC injection across all participants in Part 2 of this study responded to this questionnaire, of which question 3 is being reported here: Question 3: Overall, how easy did you find atezolizumab SC administration? The responses to this question could be: Very easy; Fairly easy; Not at all easy. HCPs were allowed to complete the questionnaire until the last participant completed their assessments (duration between the 'FPI in' date to 'LPLV' for Part 2). Percentages have been rounded to one decimal place. Number analyzed included HCPs who completed Question 3 of the questionnaire.

End point type	Secondary

End point timeframe:

After HCP has completed administering at least 3 doses of atezolizumab SC across all participants in Part 2 (Up to approximately 44.7 months)

End point values	Part 2: Atezolizumab IV/Atezolizumab SC			
Subject group type	Subject analysis set			
Number of subjects analysed	84			
Units: percentage of HCPs				
number (not applicable)				
Very easy	54.8			
Fairly easy	34.5			
Not at all easy	10.7			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of HCPs by Their Response to Question 2 of the HCP SC Perspective Questionnaire

End point title	Part 2: Percentage of HCPs by Their Response to Question 2 of the HCP SC Perspective Questionnaire

End point description:

The HCP SC Perspective Questionnaire consisted of five items evaluating the convenience, ease of administration and overall satisfaction with atezolizumab SC, as well as reasons for HCP-reported satisfaction or dissatisfaction. HCPs who administered at least three doses of atezolizumab as a SC injection across all participants in Part 2 of this study responded to this questionnaire, of which question 2 is being reported here: Question 2: Do you think atezolizumab SC is convenient? The responses to this question could be: Yes; No; and Unsure. HCPs were allowed to complete the questionnaire until the last participant completed their assessments (duration between the 'FPI in' date to 'LPLV' for Part 2). Percentages have been rounded to one decimal place. Number analyzed included HCPs who completed Question 2 of the questionnaire.

End point type	Secondary

End point timeframe:

After HCP has completed administering at least 3 doses of atezolizumab SC across all participants in Part 2 (Up to approximately 44.7 months)

End point values	Part 2: Atezolizumab IV/Atezolizumab SC			
Subject group type	Subject analysis set			
Number of subjects analysed	84			
Units: percentage of HCPs				
number (not applicable)				
Yes	78.6			
Unsure	14.3			
No	7.1			

Statistical analyses

No statistical analyses for this end point

Secondary: Part 2: Percentage of HCPs by Their Response to Question 4 of the HCP SC Perspective Questionnaire

End point title	Part 2: Percentage of HCPs by Their Response to Question 4 of the HCP SC Perspective Questionnaire

End point description:

The HCP SC Perspective Questionnaire consisted of five items evaluating the convenience, ease of administration and overall satisfaction with atezolizumab SC, as well as reasons for HCP-reported satisfaction or dissatisfaction. HCPs who administered at least three doses of atezolizumab as a SC injection across all participants in Part 2 of this study responded to this questionnaire, of which question 4 is being reported here: Question 4: Overall, how satisfied were you with atezolizumab SC? The responses to this question could be: Very satisfied; Satisfied; Dissatisfied; Very dissatisfied. HCPs were allowed to complete the questionnaire until the last participant completed their assessments (duration between the 'FPI in' date to 'LPLV' for Part 2). Percentages have been rounded to one decimal place. Number analyzed included HCPs who completed Question 4 of the questionnaire.

End point type	Secondary

End point timeframe:

After HCP has completed administering at least 3 doses of atezolizumab SC across all participants in Part 2 (Up to approximately 44.7 months)

End point values	Part 2: Atezolizumab IV/Atezolizumab SC			
Subject group type	Subject analysis set			
Number of subjects analysed	84			
Units: percentage of HCPs				
number (not applicable)				
Very satisfied	34.5			
Satisfied	50.0			
Dissatisfied	13.1			
Very dissatisfied	2.4			

Statistical analyses

No statistical analyses for this end point

Adverse events information

Timeframe for reporting adverse events:

From initiation of study treatment up to approximately 69 months in Part 1 and up to approximately 44.7 months in Part 2

Adverse event reporting additional description:

Safety-evaluable population included all participants who received at least one dose of atezolizumab (IV or SC), with participants grouped per treatment received. HCPs who administered atezo to participants were not enrolled in the study. No adverse event data were collected for the HCPs in this study.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.1

Reporting groups

Reporting group title	Part 1 Cohort 1: Atezolizumab SC Co-mix 1800 mg

Reporting group description:

Participants received atezolizumab, 1800 mg, co-mixed with rHuPH20, as SC injection on Cycle 1 Day 1 (1 cycle=21 days), followed by atezolizumab, 1200 mg, as an IV infusion, Q3W on Day 1 of subsequent cycles until PD, loss of clinical benefit, unacceptable toxicity, or withdrawal of consent.

Reporting group title	Part 1 Cohort 2: Atezolizumab SC Co-mix 1200 mg

Reporting group description:

Participants received atezolizumab, 1200 mg, co-mixed with rHuPH20, as SC injection, Q2W, on Day 1 of the first 3 cycles (Cycle 1-3=14 days), followed by atezolizumab, 1200 mg, as an IV infusion, Q3W, on Day 1 of subsequent cycles (1 cycle=21 days) until PD, loss of clinical benefit, unacceptable toxicity, or withdrawal of consent.

Reporting group title	Part 2: Atezolizumab SC 1875 mg

Reporting group description:

Participants received atezolizumab, 1875 mg, co-formulated with rHuPH20, as SC injection, on Day 1 of each cycle (1 cycle=21 days) until PD, loss of clinical benefit, or unacceptable toxicity.

Reporting group title	Part 2: Atezolizumab IV 1200 mg

Reporting group description:

Participants received atezolizumab, 1200 mg, as an IV infusion, Q3W, on Day 1 of each cycle (1 cycle=21 days) until PD, loss of clinical benefit, or unacceptable toxicity.

Reporting group title	Part 1 Cohort 3: Atezolizumab SC Co-mix 1800 mg

Reporting group description:

Participants received atezolizumab, 1800 mg, co-mixed with rHuPH20, as SC injection, Q3W, on Day 1 of first 3 cycles, followed by atezolizumab, 1200 mg, as an IV infusion, Q3W on Day 1 for subsequent cycles (1 cycle=21 days) until PD, loss of clinical benefit, unacceptable toxicity, or withdrawal of consent.

Serious adverse events	Part 1 Cohort 1: Atezolizumab SC Co-mix 1800 mg	Part 1 Cohort 2: Atezolizumab SC Co-mix 1200 mg	Part 2: Atezolizumab SC 1875 mg
Total subjects affected by serious adverse events			
subjects affected / exposed	2 / 13 (15.38%)	4 / 15 (26.67%)	50 / 247 (20.24%)
number of deaths (all causes)	4	6	206
number of deaths resulting from adverse events	1	1	17
Vascular disorders			
Aortic aneurysm			

subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Orthostatic hypotension			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
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 arterial occlusive disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
General disorders and administration site conditions			
Death			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pyrexia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chest pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
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			
Dyspnoea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	2 / 247 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumothorax			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	2 / 247 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Pneumonitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
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	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Asthma			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pleural effusion			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	2 / 247 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pulmonary embolism			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 1	0 / 1
Pulmonary haemorrhage			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
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 oedema			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	2 / 247 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Investigations			

Alanine aminotransferase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
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 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
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 sodium decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
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			
Infusion related reaction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hip fracture			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Head injury			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Fall			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
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			
Arrhythmia			

subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Autoimmune myocarditis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Acute coronary syndrome			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
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 arrest			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Cardiac failure congestive			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
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 failure			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
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 / 13 (0.00%)	0 / 15 (0.00%)	4 / 247 (1.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 3
Nervous system disorders			
Epilepsy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
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 / 13 (7.69%)	0 / 15 (0.00%)	0 / 247 (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
Balance disorder			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
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 / 13 (0.00%)	0 / 15 (0.00%)	3 / 247 (1.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Transient ischaemic attack			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 247 (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 and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Splenic infarction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Eye disorders			
Cataract			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Diarrhoea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
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 / 13 (0.00%)	1 / 15 (6.67%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 1	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Nausea			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Constipation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Colitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
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			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
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 pain			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 247 (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
Intestinal perforation			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
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			

subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
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 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hepatobiliary disorders			
Immune-mediated hepatitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Skin and subcutaneous tissue disorders			
Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Rash maculo-papular			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Toxic epidermal necrolysis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 1
Renal and urinary disorders			
Nephropathy			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 247 (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

Renal failure			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	2 / 247 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infections and infestations			
Pneumonia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	8 / 247 (3.24%)
occurrences causally related to treatment / all	0 / 1	0 / 0	0 / 8
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Gastroenteritis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Tracheobronchitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	3 / 247 (1.21%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 3
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pyelonephritis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
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 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Bronchitis			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	2 / 247 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

COVID-19			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
COVID-19 pneumonia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	4 / 247 (1.62%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 4
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 2
Enteritis infectious			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
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 abscess			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 247 (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
Influenza			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia aspiration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	2 / 247 (0.81%)
occurrences causally related to treatment / all	0 / 0	0 / 0	1 / 2
deaths causally related to treatment / all	0 / 0	0 / 0	1 / 2
Pulmonary sepsis			

subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Pneumonia bacterial			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
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 device infection			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 247 (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
Urinary tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Upper respiratory tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Respiratory tract infection			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 1
Pyelonephritis acute			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
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			
Hyponatraemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hypercalcaemia			

subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
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 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Dehydration			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 1
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperglycaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0
Hyperkalaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences causally related to treatment / all	0 / 0	0 / 0	0 / 0
deaths causally related to treatment / all	0 / 0	0 / 0	0 / 0

Serious adverse events	Part 2: Atezolizumab IV 1200 mg	Part 1 Cohort 3: Atezolizumab SC Co-mix 1800 mg	
Total subjects affected by serious adverse events			
subjects affected / exposed	35 / 124 (28.23%)	8 / 39 (20.51%)	
number of deaths (all causes)	97	19	
number of deaths resulting from adverse events	9	2	
Vascular disorders			
Aortic aneurysm			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Orthostatic hypotension			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Peripheral arterial occlusive disease			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (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			
Death			
subjects affected / exposed	0 / 124 (0.00%)	1 / 39 (2.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pyrexia			
subjects affected / exposed	2 / 124 (1.61%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			

subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Asthma			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	2 / 124 (1.61%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	2 / 124 (1.61%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary embolism			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pulmonary haemorrhage			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pulmonary oedema			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	0 / 124 (0.00%)	1 / 39 (2.56%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			

subjects affected / exposed	0 / 124 (0.00%)	1 / 39 (2.56%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood sodium decreased			
subjects affected / exposed	0 / 124 (0.00%)	1 / 39 (2.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Infusion related reaction			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Head injury			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Arrhythmia			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Autoimmune myocarditis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (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 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (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	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Myocardial infarction			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (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			
Epilepsy			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Balance disorder			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ischaemic stroke			

subjects affected / exposed	0 / 124 (0.00%)	1 / 39 (2.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Transient ischaemic attack			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Splenic infarction			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Cataract			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	0 / 124 (0.00%)	1 / 39 (2.56%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Nausea			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal pain			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal perforation			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Enterocolitis			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Oesophageal stenosis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			

Immune-mediated hepatitis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Drug reaction with eosinophilia and systemic symptoms			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rash maculo-papular			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Toxic epidermal necrolysis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Nephropathy			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tubulointerstitial nephritis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (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 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Pneumonia			
subjects affected / exposed	6 / 124 (4.84%)	1 / 39 (2.56%)	
occurrences causally related to treatment / all	0 / 7	0 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Gastroenteritis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tracheobronchitis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (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	4 / 124 (3.23%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
COVID-19 pneumonia			

subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis infectious			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (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	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	0 / 124 (0.00%)	1 / 39 (2.56%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung abscess			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (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 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia bacterial			

subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular device infection			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	3 / 124 (2.42%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Respiratory tract infection			
subjects affected / exposed	1 / 124 (0.81%)	1 / 39 (2.56%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis acute			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (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			
Hyponatraemia			
subjects affected / exposed	0 / 124 (0.00%)	1 / 39 (2.56%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	2 / 124 (1.61%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Hypokalaemia			

subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 0	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (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	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Part 1 Cohort 1: Atezolizumab SC Co-mix 1800 mg	Part 1 Cohort 2: Atezolizumab SC Co-mix 1200 mg	Part 2: Atezolizumab SC 1875 mg
Total subjects affected by non-serious adverse events			
subjects affected / exposed	13 / 13 (100.00%)	12 / 15 (80.00%)	204 / 247 (82.59%)
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hair follicle tumour benign			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences (all)	1	0	0
Melanocytic naevus			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences (all)	1	0	0
Vascular disorders			
Hypertension			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	3 / 247 (1.21%)
occurrences (all)	0	0	5
Venous thrombosis limb			

subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 247 (0.00%)
occurrences (all)	0	1	0
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	1 / 247 (0.40%)
occurrences (all)	0	2	1
Fatigue			
subjects affected / exposed	1 / 13 (7.69%)	3 / 15 (20.00%)	31 / 247 (12.55%)
occurrences (all)	2	3	33
Oedema			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences (all)	1	0	1
Asthenia			
subjects affected / exposed	5 / 13 (38.46%)	3 / 15 (20.00%)	19 / 247 (7.69%)
occurrences (all)	5	3	19
Pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	4 / 247 (1.62%)
occurrences (all)	0	0	4
Pyrexia			
subjects affected / exposed	3 / 13 (23.08%)	1 / 15 (6.67%)	12 / 247 (4.86%)
occurrences (all)	3	1	16
Chest pain			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	11 / 247 (4.45%)
occurrences (all)	0	2	14
Gait disturbance			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	2 / 247 (0.81%)
occurrences (all)	1	0	3
Injection site erythema			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	1 / 247 (0.40%)
occurrences (all)	0	1	1
Injection site inflammation			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences (all)	1	0	0
Injection site reaction			

subjects affected / exposed	3 / 13 (23.08%)	1 / 15 (6.67%)	5 / 247 (2.02%)
occurrences (all)	3	1	15
Mucosal inflammation			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 247 (0.00%)
occurrences (all)	0	1	0
Oedema peripheral			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	5 / 247 (2.02%)
occurrences (all)	0	1	5
Xerosis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	3 / 247 (1.21%)
occurrences (all)	1	0	3
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	1 / 13 (7.69%)	2 / 15 (13.33%)	26 / 247 (10.53%)
occurrences (all)	1	2	27
Haemoptysis			
subjects affected / exposed	0 / 13 (0.00%)	2 / 15 (13.33%)	7 / 247 (2.83%)
occurrences (all)	0	2	9
Dysphonia			
subjects affected / exposed	1 / 13 (7.69%)	1 / 15 (6.67%)	4 / 247 (1.62%)
occurrences (all)	1	1	4
Cough			
subjects affected / exposed	5 / 13 (38.46%)	3 / 15 (20.00%)	33 / 247 (13.36%)
occurrences (all)	6	3	37
Chronic obstructive pulmonary disease			
subjects affected / exposed	0 / 13 (0.00%)	2 / 15 (13.33%)	1 / 247 (0.40%)
occurrences (all)	0	4	1
Dyspnoea exertional			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences (all)	1	0	1
Pleuritic pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences (all)	1	0	1
Productive cough			

subjects affected / exposed	1 / 13 (7.69%)	1 / 15 (6.67%)	5 / 247 (2.02%)
occurrences (all)	1	1	6
Pulmonary embolism			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 247 (0.00%)
occurrences (all)	0	1	0
Psychiatric disorders			
Insomnia			
subjects affected / exposed	2 / 13 (15.38%)	1 / 15 (6.67%)	8 / 247 (3.24%)
occurrences (all)	2	1	8
Anxiety			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	5 / 247 (2.02%)
occurrences (all)	1	0	5
Depression			
subjects affected / exposed	1 / 13 (7.69%)	1 / 15 (6.67%)	1 / 247 (0.40%)
occurrences (all)	1	1	1
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 13 (0.00%)	2 / 15 (13.33%)	23 / 247 (9.31%)
occurrences (all)	0	2	28
Amylase increased			
subjects affected / exposed	0 / 13 (0.00%)	2 / 15 (13.33%)	0 / 247 (0.00%)
occurrences (all)	0	2	0
Alanine aminotransferase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	24 / 247 (9.72%)
occurrences (all)	0	0	25
Blood albumin decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences (all)	0	0	2
Blood alkaline phosphatase increased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	20 / 247 (8.10%)
occurrences (all)	0	1	21
Blood bilirubin increased			
subjects affected / exposed	1 / 13 (7.69%)	1 / 15 (6.67%)	1 / 247 (0.40%)
occurrences (all)	1	1	2
Blood cholesterol increased			

subjects affected / exposed	1 / 13 (7.69%)	3 / 15 (20.00%)	3 / 247 (1.21%)
occurrences (all)	3	3	3
Blood sodium decreased			
subjects affected / exposed	0 / 13 (0.00%)	2 / 15 (13.33%)	1 / 247 (0.40%)
occurrences (all)	0	2	1
Blood lactate dehydrogenase increased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	12 / 247 (4.86%)
occurrences (all)	0	0	16
Blood glucose increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences (all)	1	0	0
Blood creatinine increased			
subjects affected / exposed	1 / 13 (7.69%)	1 / 15 (6.67%)	6 / 247 (2.43%)
occurrences (all)	1	1	8
Blood magnesium decreased			
subjects affected / exposed	1 / 13 (7.69%)	1 / 15 (6.67%)	2 / 247 (0.81%)
occurrences (all)	1	1	3
Haemoglobin decreased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 247 (0.00%)
occurrences (all)	0	1	0
Gamma-glutamyltransferase increased			
subjects affected / exposed	0 / 13 (0.00%)	2 / 15 (13.33%)	7 / 247 (2.83%)
occurrences (all)	0	2	7
Blood triglycerides increased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 247 (0.00%)
occurrences (all)	0	1	0
Blood thyroid stimulating hormone increased			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	7 / 247 (2.83%)
occurrences (all)	1	0	15
Lipase increased			
subjects affected / exposed	1 / 13 (7.69%)	2 / 15 (13.33%)	0 / 247 (0.00%)
occurrences (all)	5	3	0
Weight decreased			

subjects affected / exposed	1 / 13 (7.69%)	2 / 15 (13.33%)	15 / 247 (6.07%)
occurrences (all)	1	2	18
Platelet count decreased			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0	0
Neutrophil count increased			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 247 (0.00%)
occurrences (all)	0	1	0
Injury, poisoning and procedural complications			
Injection related reaction			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	5 / 247 (2.02%)
occurrences (all)	0	0	9
Lack of injection site rotation			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 247 (0.00%)
occurrences (all)	0	1	0
Procedural pain			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences (all)	1	0	0
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	3 / 247 (1.21%)
occurrences (all)	0	1	3
Supraventricular tachycardia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	1 / 247 (0.40%)
occurrences (all)	0	1	1
Nervous system disorders			
Tremor			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences (all)	1	0	0
Dysgeusia			
subjects affected / exposed	2 / 13 (15.38%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences (all)	2	0	1
Headache			
subjects affected / exposed	2 / 13 (15.38%)	0 / 15 (0.00%)	17 / 247 (6.88%)
occurrences (all)	3	0	21
Dizziness			

subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	5 / 247 (2.02%)
occurrences (all)	1	0	6
Trigeminal neuralgia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences (all)	1	0	0
Sensory loss			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 247 (0.00%)
occurrences (all)	0	1	0
Neuropathy peripheral			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	2 / 247 (0.81%)
occurrences (all)	1	0	2
Blood and lymphatic system disorders			
Leukocytosis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	3 / 247 (1.21%)
occurrences (all)	1	0	4
Thrombocytopenia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	9 / 247 (3.64%)
occurrences (all)	0	1	18
Lymphopenia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	8 / 247 (3.24%)
occurrences (all)	0	1	9
Anaemia			
subjects affected / exposed	3 / 13 (23.08%)	5 / 15 (33.33%)	47 / 247 (19.03%)
occurrences (all)	3	8	54
Neutropenia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences (all)	2	0	1
Eye disorders			
Periorbital oedema			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences (all)	1	0	0
Gastrointestinal disorders			
Dyspepsia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	3 / 247 (1.21%)
occurrences (all)	1	0	3
Vomiting			

subjects affected / exposed	2 / 13 (15.38%)	2 / 15 (13.33%)	7 / 247 (2.83%)
occurrences (all)	2	2	7
Diarrhoea			
subjects affected / exposed	4 / 13 (30.77%)	1 / 15 (6.67%)	21 / 247 (8.50%)
occurrences (all)	5	1	27
Nausea			
subjects affected / exposed	1 / 13 (7.69%)	3 / 15 (20.00%)	15 / 247 (6.07%)
occurrences (all)	1	4	16
Constipation			
subjects affected / exposed	2 / 13 (15.38%)	2 / 15 (13.33%)	17 / 247 (6.88%)
occurrences (all)	2	2	17
Flatulence			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	2 / 247 (0.81%)
occurrences (all)	0	1	3
Abdominal pain			
subjects affected / exposed	2 / 13 (15.38%)	0 / 15 (0.00%)	12 / 247 (4.86%)
occurrences (all)	2	0	12
Anal haemorrhage			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences (all)	1	0	0
Dry mouth			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	4 / 247 (1.62%)
occurrences (all)	0	1	7
Gastrooesophageal reflux disease			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	4 / 247 (1.62%)
occurrences (all)	0	0	4
Stomatitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences (all)	2	0	1
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	14 / 247 (5.67%)
occurrences (all)	0	1	14
Alopecia			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	1 / 247 (0.40%)
occurrences (all)	1	0	1

Rash			
subjects affected / exposed	1 / 13 (7.69%)	1 / 15 (6.67%)	13 / 247 (5.26%)
occurrences (all)	1	1	15
Eczema			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences (all)	1	0	0
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences (all)	1	0	0
Rash erythematous			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences (all)	1	0	0
Dry skin			
subjects affected / exposed	2 / 13 (15.38%)	0 / 15 (0.00%)	5 / 247 (2.02%)
occurrences (all)	2	0	5
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 247 (0.00%)
occurrences (all)	0	1	0
Acute kidney injury			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	3 / 247 (1.21%)
occurrences (all)	1	0	3
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 13 (0.00%)	2 / 15 (13.33%)	21 / 247 (8.50%)
occurrences (all)	0	2	25
Hyperthyroidism			
subjects affected / exposed	2 / 13 (15.38%)	2 / 15 (13.33%)	7 / 247 (2.83%)
occurrences (all)	2	2	7
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	11 / 247 (4.45%)
occurrences (all)	0	1	13
Arthralgia			
subjects affected / exposed	2 / 13 (15.38%)	1 / 15 (6.67%)	18 / 247 (7.29%)
occurrences (all)	2	2	21

Joint swelling			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences (all)	1	0	0
Back pain			
subjects affected / exposed	3 / 13 (23.08%)	2 / 15 (13.33%)	21 / 247 (8.50%)
occurrences (all)	3	3	21
Musculoskeletal chest pain			
subjects affected / exposed	1 / 13 (7.69%)	1 / 15 (6.67%)	4 / 247 (1.62%)
occurrences (all)	1	1	4
Musculoskeletal pain			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences (all)	0	0	0
Pain in extremity			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	13 / 247 (5.26%)
occurrences (all)	0	1	17
Muscle spasms			
subjects affected / exposed	1 / 13 (7.69%)	1 / 15 (6.67%)	3 / 247 (1.21%)
occurrences (all)	1	1	4
Infections and infestations			
Folliculitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 247 (0.00%)
occurrences (all)	0	1	0
Bronchitis			
subjects affected / exposed	1 / 13 (7.69%)	1 / 15 (6.67%)	3 / 247 (1.21%)
occurrences (all)	1	1	3
Furuncle			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences (all)	1	0	0
Pneumonia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	13 / 247 (5.26%)
occurrences (all)	0	1	15
Nasopharyngitis			
subjects affected / exposed	1 / 13 (7.69%)	2 / 15 (13.33%)	2 / 247 (0.81%)
occurrences (all)	1	2	4
Laryngitis			

subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences (all)	1	0	0
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 247 (0.00%)
occurrences (all)	0	2	0
COVID-19			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	19 / 247 (7.69%)
occurrences (all)	0	0	19
Conjunctivitis bacterial			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences (all)	1	0	0
Upper respiratory tract infection			
subjects affected / exposed	2 / 13 (15.38%)	0 / 15 (0.00%)	7 / 247 (2.83%)
occurrences (all)	3	0	7
Pharyngitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	5 / 247 (2.02%)
occurrences (all)	1	0	5
Respiratory tract infection			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	4 / 247 (1.62%)
occurrences (all)	5	0	4
Sinusitis			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences (all)	1	0	0
Fungal infection			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	1 / 247 (0.40%)
occurrences (all)	0	1	1
Viral infection			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 247 (0.00%)
occurrences (all)	0	1	0
Vestibular neuronitis			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	0 / 247 (0.00%)
occurrences (all)	0	1	0
Urinary tract infection			
subjects affected / exposed	2 / 13 (15.38%)	1 / 15 (6.67%)	11 / 247 (4.45%)
occurrences (all)	2	2	15
Metabolism and nutrition disorders			

Hypoalbuminaemia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	14 / 247 (5.67%)
occurrences (all)	0	1	15
Hypercreatininaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	3 / 247 (1.21%)
occurrences (all)	0	0	3
Hyponatraemia			
subjects affected / exposed	0 / 13 (0.00%)	2 / 15 (13.33%)	17 / 247 (6.88%)
occurrences (all)	0	2	18
Hypercalcaemia			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	2 / 247 (0.81%)
occurrences (all)	0	1	3
Hypokalaemia			
subjects affected / exposed	1 / 13 (7.69%)	1 / 15 (6.67%)	8 / 247 (3.24%)
occurrences (all)	1	1	9
Hyperglycaemia			
subjects affected / exposed	1 / 13 (7.69%)	1 / 15 (6.67%)	12 / 247 (4.86%)
occurrences (all)	1	1	18
Hypomagnesaemia			
subjects affected / exposed	2 / 13 (15.38%)	0 / 15 (0.00%)	8 / 247 (3.24%)
occurrences (all)	2	0	9
Hyperkalaemia			
subjects affected / exposed	0 / 13 (0.00%)	0 / 15 (0.00%)	9 / 247 (3.64%)
occurrences (all)	0	0	14
Dehydration			
subjects affected / exposed	0 / 13 (0.00%)	1 / 15 (6.67%)	2 / 247 (0.81%)
occurrences (all)	0	2	2
Decreased appetite			
subjects affected / exposed	2 / 13 (15.38%)	3 / 15 (20.00%)	31 / 247 (12.55%)
occurrences (all)	2	3	32
Vitamin D deficiency			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences (all)	1	0	0
Vitamin B12 deficiency			
subjects affected / exposed	1 / 13 (7.69%)	0 / 15 (0.00%)	0 / 247 (0.00%)
occurrences (all)	1	0	0

Non-serious adverse events	Part 2: Atezolizumab IV 1200 mg	Part 1 Cohort 3: Atezolizumab SC Co-mix 1800 mg	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	91 / 124 (73.39%)	31 / 39 (79.49%)	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Hair follicle tumour benign			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Melanocytic naevus			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Vascular disorders			
Hypertension			
subjects affected / exposed	3 / 124 (2.42%)	4 / 39 (10.26%)	
occurrences (all)	10	5	
Venous thrombosis limb			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
General disorders and administration site conditions			
Chills			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Fatigue			
subjects affected / exposed	16 / 124 (12.90%)	11 / 39 (28.21%)	
occurrences (all)	20	14	
Oedema			
subjects affected / exposed	0 / 124 (0.00%)	1 / 39 (2.56%)	
occurrences (all)	0	1	
Asthenia			
subjects affected / exposed	9 / 124 (7.26%)	7 / 39 (17.95%)	
occurrences (all)	11	12	
Pain			
subjects affected / exposed	2 / 124 (1.61%)	3 / 39 (7.69%)	
occurrences (all)	2	3	
Pyrexia			

subjects affected / exposed	6 / 124 (4.84%)	1 / 39 (2.56%)	
occurrences (all)	8	1	
Chest pain			
subjects affected / exposed	9 / 124 (7.26%)	2 / 39 (5.13%)	
occurrences (all)	9	3	
Gait disturbance			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences (all)	1	0	
Injection site erythema			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Injection site inflammation			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Injection site reaction			
subjects affected / exposed	0 / 124 (0.00%)	2 / 39 (5.13%)	
occurrences (all)	0	4	
Mucosal inflammation			
subjects affected / exposed	0 / 124 (0.00%)	1 / 39 (2.56%)	
occurrences (all)	0	1	
Oedema peripheral			
subjects affected / exposed	1 / 124 (0.81%)	3 / 39 (7.69%)	
occurrences (all)	1	3	
Xerosis			
subjects affected / exposed	1 / 124 (0.81%)	2 / 39 (5.13%)	
occurrences (all)	1	2	
Respiratory, thoracic and mediastinal disorders			
Dyspnoea			
subjects affected / exposed	20 / 124 (16.13%)	5 / 39 (12.82%)	
occurrences (all)	21	5	
Haemoptysis			
subjects affected / exposed	3 / 124 (2.42%)	3 / 39 (7.69%)	
occurrences (all)	3	3	
Dysphonia			

subjects affected / exposed	1 / 124 (0.81%)	1 / 39 (2.56%)	
occurrences (all)	1	1	
Cough			
subjects affected / exposed	9 / 124 (7.26%)	7 / 39 (17.95%)	
occurrences (all)	9	10	
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences (all)	2	0	
Dyspnoea exertional			
subjects affected / exposed	0 / 124 (0.00%)	1 / 39 (2.56%)	
occurrences (all)	0	1	
Pleuritic pain			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Productive cough			
subjects affected / exposed	2 / 124 (1.61%)	0 / 39 (0.00%)	
occurrences (all)	2	0	
Pulmonary embolism			
subjects affected / exposed	1 / 124 (0.81%)	1 / 39 (2.56%)	
occurrences (all)	1	1	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	8 / 124 (6.45%)	0 / 39 (0.00%)	
occurrences (all)	8	0	
Anxiety			
subjects affected / exposed	2 / 124 (1.61%)	1 / 39 (2.56%)	
occurrences (all)	2	1	
Depression			
subjects affected / exposed	2 / 124 (1.61%)	0 / 39 (0.00%)	
occurrences (all)	2	0	
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	13 / 124 (10.48%)	4 / 39 (10.26%)	
occurrences (all)	14	5	
Amylase increased			

subjects affected / exposed	0 / 124 (0.00%)	5 / 39 (12.82%)		
occurrences (all)	0	6		
Alanine aminotransferase increased				
subjects affected / exposed	10 / 124 (8.06%)	5 / 39 (12.82%)		
occurrences (all)	12	5		
Blood albumin decreased				
subjects affected / exposed	0 / 124 (0.00%)	3 / 39 (7.69%)		
occurrences (all)	0	3		
Blood alkaline phosphatase increased				
subjects affected / exposed	7 / 124 (5.65%)	4 / 39 (10.26%)		
occurrences (all)	7	4		
Blood bilirubin increased				
subjects affected / exposed	2 / 124 (1.61%)	2 / 39 (5.13%)		
occurrences (all)	9	4		
Blood cholesterol increased				
subjects affected / exposed	1 / 124 (0.81%)	5 / 39 (12.82%)		
occurrences (all)	2	8		
Blood sodium decreased				
subjects affected / exposed	0 / 124 (0.00%)	4 / 39 (10.26%)		
occurrences (all)	0	5		
Blood lactate dehydrogenase increased				
subjects affected / exposed	6 / 124 (4.84%)	2 / 39 (5.13%)		
occurrences (all)	6	2		
Blood glucose increased				
subjects affected / exposed	1 / 124 (0.81%)	1 / 39 (2.56%)		
occurrences (all)	1	1		
Blood creatinine increased				
subjects affected / exposed	7 / 124 (5.65%)	3 / 39 (7.69%)		
occurrences (all)	8	4		
Blood magnesium decreased				
subjects affected / exposed	0 / 124 (0.00%)	1 / 39 (2.56%)		
occurrences (all)	0	1		
Haemoglobin decreased				
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)		
occurrences (all)	0	0		

Gamma-glutamyltransferase increased			
subjects affected / exposed	4 / 124 (3.23%)	0 / 39 (0.00%)	
occurrences (all)	4	0	
Blood triglycerides increased			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Blood thyroid stimulating hormone increased			
subjects affected / exposed	3 / 124 (2.42%)	0 / 39 (0.00%)	
occurrences (all)	3	0	
Lipase increased			
subjects affected / exposed	0 / 124 (0.00%)	5 / 39 (12.82%)	
occurrences (all)	0	6	
Weight decreased			
subjects affected / exposed	6 / 124 (4.84%)	2 / 39 (5.13%)	
occurrences (all)	7	2	
Platelet count decreased			
subjects affected / exposed	1 / 124 (0.81%)	3 / 39 (7.69%)	
occurrences (all)	4	4	
Neutrophil count increased			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Injury, poisoning and procedural complications			
Injection related reaction			
subjects affected / exposed	0 / 124 (0.00%)	2 / 39 (5.13%)	
occurrences (all)	0	3	
Lack of injection site rotation			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Procedural pain			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Cardiac disorders			
Tachycardia			
subjects affected / exposed	0 / 124 (0.00%)	1 / 39 (2.56%)	
occurrences (all)	0	1	

Supraventricular tachycardia			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Nervous system disorders			
Tremor			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Dysgeusia			
subjects affected / exposed	0 / 124 (0.00%)	1 / 39 (2.56%)	
occurrences (all)	0	1	
Headache			
subjects affected / exposed	7 / 124 (5.65%)	0 / 39 (0.00%)	
occurrences (all)	7	0	
Dizziness			
subjects affected / exposed	5 / 124 (4.03%)	3 / 39 (7.69%)	
occurrences (all)	5	3	
Trigeminal neuralgia			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Sensory loss			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Neuropathy peripheral			
subjects affected / exposed	2 / 124 (1.61%)	0 / 39 (0.00%)	
occurrences (all)	2	0	
Blood and lymphatic system disorders			
Leukocytosis			
subjects affected / exposed	3 / 124 (2.42%)	0 / 39 (0.00%)	
occurrences (all)	3	0	
Thrombocytopenia			
subjects affected / exposed	7 / 124 (5.65%)	1 / 39 (2.56%)	
occurrences (all)	7	1	
Lymphopenia			
subjects affected / exposed	3 / 124 (2.42%)	0 / 39 (0.00%)	
occurrences (all)	3	0	
Anaemia			

subjects affected / exposed	21 / 124 (16.94%)	13 / 39 (33.33%)	
occurrences (all)	30	16	
Neutropenia			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Eye disorders			
Periorbital oedema			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Gastrointestinal disorders			
Dyspepsia			
subjects affected / exposed	3 / 124 (2.42%)	0 / 39 (0.00%)	
occurrences (all)	3	0	
Vomiting			
subjects affected / exposed	3 / 124 (2.42%)	3 / 39 (7.69%)	
occurrences (all)	3	3	
Diarrhoea			
subjects affected / exposed	3 / 124 (2.42%)	4 / 39 (10.26%)	
occurrences (all)	4	6	
Nausea			
subjects affected / exposed	4 / 124 (3.23%)	9 / 39 (23.08%)	
occurrences (all)	4	12	
Constipation			
subjects affected / exposed	9 / 124 (7.26%)	1 / 39 (2.56%)	
occurrences (all)	9	1	
Flatulence			
subjects affected / exposed	3 / 124 (2.42%)	1 / 39 (2.56%)	
occurrences (all)	3	1	
Abdominal pain			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences (all)	1	0	
Anal haemorrhage			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Dry mouth			

subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Gastrooesophageal reflux disease			
subjects affected / exposed	1 / 124 (0.81%)	2 / 39 (5.13%)	
occurrences (all)	1	2	
Stomatitis			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences (all)	1	0	
Skin and subcutaneous tissue disorders			
Pruritus			
subjects affected / exposed	12 / 124 (9.68%)	4 / 39 (10.26%)	
occurrences (all)	13	7	
Alopecia			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Rash			
subjects affected / exposed	10 / 124 (8.06%)	3 / 39 (7.69%)	
occurrences (all)	14	3	
Eczema			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences (all)	1	0	
Palmar-plantar erythrodysaesthesia syndrome			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Rash erythematous			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Dry skin			
subjects affected / exposed	0 / 124 (0.00%)	2 / 39 (5.13%)	
occurrences (all)	0	2	
Renal and urinary disorders			
Renal failure			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Acute kidney injury			

subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences (all)	1	0	
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	7 / 124 (5.65%)	1 / 39 (2.56%)	
occurrences (all)	9	1	
Hyperthyroidism			
subjects affected / exposed	2 / 124 (1.61%)	0 / 39 (0.00%)	
occurrences (all)	2	0	
Musculoskeletal and connective tissue disorders			
Myalgia			
subjects affected / exposed	4 / 124 (3.23%)	4 / 39 (10.26%)	
occurrences (all)	6	4	
Arthralgia			
subjects affected / exposed	7 / 124 (5.65%)	7 / 39 (17.95%)	
occurrences (all)	8	10	
Joint swelling			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Back pain			
subjects affected / exposed	9 / 124 (7.26%)	5 / 39 (12.82%)	
occurrences (all)	9	5	
Musculoskeletal chest pain			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences (all)	1	0	
Musculoskeletal pain			
subjects affected / exposed	0 / 124 (0.00%)	2 / 39 (5.13%)	
occurrences (all)	0	2	
Pain in extremity			
subjects affected / exposed	6 / 124 (4.84%)	1 / 39 (2.56%)	
occurrences (all)	7	1	
Muscle spasms			
subjects affected / exposed	1 / 124 (0.81%)	1 / 39 (2.56%)	
occurrences (all)	1	2	
Infections and infestations			

Folliculitis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Bronchitis			
subjects affected / exposed	1 / 124 (0.81%)	2 / 39 (5.13%)	
occurrences (all)	1	4	
Furuncle			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Pneumonia			
subjects affected / exposed	3 / 124 (2.42%)	1 / 39 (2.56%)	
occurrences (all)	3	1	
Nasopharyngitis			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences (all)	1	0	
Laryngitis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Asymptomatic bacteriuria			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
COVID-19			
subjects affected / exposed	10 / 124 (8.06%)	0 / 39 (0.00%)	
occurrences (all)	11	0	
Conjunctivitis bacterial			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Upper respiratory tract infection			
subjects affected / exposed	3 / 124 (2.42%)	3 / 39 (7.69%)	
occurrences (all)	3	3	
Pharyngitis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Respiratory tract infection			
subjects affected / exposed	2 / 124 (1.61%)	1 / 39 (2.56%)	
occurrences (all)	3	2	

Sinusitis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Fungal infection			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Viral infection			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Vestibular neuronitis			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	
Urinary tract infection			
subjects affected / exposed	8 / 124 (6.45%)	1 / 39 (2.56%)	
occurrences (all)	11	1	
Metabolism and nutrition disorders			
Hypoalbuminaemia			
subjects affected / exposed	5 / 124 (4.03%)	2 / 39 (5.13%)	
occurrences (all)	6	2	
Hypercreatininaemia			
subjects affected / exposed	7 / 124 (5.65%)	0 / 39 (0.00%)	
occurrences (all)	10	0	
Hyponatraemia			
subjects affected / exposed	13 / 124 (10.48%)	7 / 39 (17.95%)	
occurrences (all)	17	7	
Hypercalcaemia			
subjects affected / exposed	6 / 124 (4.84%)	0 / 39 (0.00%)	
occurrences (all)	9	0	
Hypokalaemia			
subjects affected / exposed	6 / 124 (4.84%)	1 / 39 (2.56%)	
occurrences (all)	9	1	
Hyperglycaemia			
subjects affected / exposed	13 / 124 (10.48%)	3 / 39 (7.69%)	
occurrences (all)	22	3	
Hypomagnesaemia			

subjects affected / exposed	8 / 124 (6.45%)	4 / 39 (10.26%)	
occurrences (all)	9	4	
Hyperkalaemia			
subjects affected / exposed	11 / 124 (8.87%)	3 / 39 (7.69%)	
occurrences (all)	15	4	
Dehydration			
subjects affected / exposed	1 / 124 (0.81%)	0 / 39 (0.00%)	
occurrences (all)	1	0	
Decreased appetite			
subjects affected / exposed	15 / 124 (12.10%)	8 / 39 (20.51%)	
occurrences (all)	16	8	
Vitamin D deficiency			
subjects affected / exposed	0 / 124 (0.00%)	1 / 39 (2.56%)	
occurrences (all)	0	1	
Vitamin B12 deficiency			
subjects affected / exposed	0 / 124 (0.00%)	0 / 39 (0.00%)	
occurrences (all)	0	0	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
01 June 2019	Amendment v2: 1. Subcutaneous site of first drug administration for Cohort 3 was changed from thigh to abdomen to accommodate participant convenience, increased participant privacy, and possible administration of higher drug volume. 2. Study drug dosage for Cohort 3 was changed from 2400 mg Q4W to 1800 mg Q3W to assess the alternate administration site (abdomen). 3. Enrollment for Cohort 3 was increased to approximately 20-30 participants to provide enough participants who could be assessed for feasibility of abdominal administration.
30 March 2020	Amendment v3: No changes impacted study conduct.
28 August 2020	Amendment v4: 1. A randomized control arm comprising of participants treated with atezolizumab IV as per standard of care was added in Part 2 and enrollment was expanded to include an extension in China. 2. Investigational treatment in Part 2 was modified to atezolizumab monotherapy and inclusion criteria modified to include participants in whom platinum therapy had failed, to allow for assessment of atezolizumab SC without confounding factors associated with use in combination with chemotherapy. 3. Model-predicted area under the atezolizumab AUC at Cycle 1 (AUCcycle 1) was added as a key secondary endpoint. 4. Additional secondary PK objectives for Part 2 were added to evaluate exposure following administration of atezolizumab SC compared with atezolizumab IV. 5. Duration of response was added as an efficacy endpoint in Part 2. 6. Patient- and health care professional-reported experience assessments was added to Part 2 to provide a more comprehensive characterization of the SC formulation.
10 February 2021	Amendment v5: 1. A new co-primary PK endpoint was introduced (model-predicted AUC0-21d at Cycle 1). 2. Number of participants enrolled in Part 2 was increased to 327 to accommodate the new co-primary PK endpoint.
25 February 2022	Amendment v6: 1. Adverse event management guidelines were updated to align with the atezolizumab investigator’s brochure, version 18. 2. References to an extended recruitment in China was removed. 3. Estimand language in Section 6.6.2 was corrected to match the definition of Per Protocol PK analysis population provided in Section 6.2.2. 4. Benefit-risk assessment and guidance on concomitant administration of severe acute respiratory syndrome coronavirus 2 vaccines with atezolizumab was added. 5. Responsibilities of the Principal Investigator and the role of the medical monitor in determining participant eligibility was clarified.
07 February 2023	Amendment v7: 1. The list of identified risks for atezolizumab was revised to include pericardial disorders. 2. The list of identified risks for atezolizumab was revised to include myelitis and facial paresis. 3. Hemophagocytic lymphohistiocytosis was updated from a potential risk to an identified risk associated with atezolizumab and language has been revised accordingly. 4. The list of adverse events of special interest (AESIs) was revised to include myelitis and facial paresis. 5. A description of the technical and organizational security measures taken to protect personal data was added to align with CTR requirements. 6. Appendix 8 was revised to indicate that caution should be used when considering atezolizumab for participants who have previously experienced a pericardial disorder while receiving another immunostimulatory anti-cancer agent.

18 March 2024	Amendment v8: 1. The list of approved indications for atezolizumab was updated to include alveolar soft part sarcoma. 2. The adverse event management guidelines were streamlined by removing standard of care information and restructured for consistency with regulatory guidelines and industry standards.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported