Clinical trial results:
A Phase III, Open-Label Multicenter, Randomized Study to Investigate the Efficacy and Safety of Atezolizumab (AntiPD-L1 Antibody) Compared With Docetaxel in Patients With NonSmall Cell Lung Cancer After Failure With Platinum-Containing Chemotherapy (OAK)

Summary

EudraCT number	2013-003331-30
Trial protocol	AT SE FI IT DE PT HU NL ES PL GR FR
Global end of trial date	09 January 2019

Results information

Result version number	v3 (current)
This version publication date	22 December 2019
First version publication date	26 May 2017
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	GO28915

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT02008227
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche AG
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, CH-4070
Public contact	F.Hoffmann-La Roche Ltd., Roche Trial Information Hotline, 41 61 6878333, global.trial_information@roche.com
Scientific contact	F.Hoffmann-La Roche Ltd., Roche Trial Information Hotline, 41 61 6878333, 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	20 June 2019
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	09 January 2019
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

This was a Phase III, open-label, multicenter, randomized study to investigate the efficacy (an improved overall survival [OS] as primary objective) and safety of atezolizumab (an anti-programmed death−ligand 1 [anti-PD-L1] antibody) compared with docetaxel in participants with non−small cell lung cancer (NSCLC) after failure with platinum-containing chemotherapy.

Protection of trial subjects:

This study was conducted in accordance with the International Conference on Harmonisation (ICH)-E6 guideline for Good Clinical Practice, or the laws and regulations of the country in which the research was conducted, whichever affords the greater protection to the individual. The investigators were trained according to applicable sponsor standard operating procedures.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 March 2014
Long term follow-up planned	Yes
Long term follow-up rationale	Efficacy
Long term follow-up duration	27 Months
Independent data monitoring committee (IDMC) involvement?	Yes

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	United States: 330
Country: Number of subjects enrolled	France: 114
Country: Number of subjects enrolled	Spain: 112
Country: Number of subjects enrolled	Japan: 101
Country: Number of subjects enrolled	Germany: 92
Country: Number of subjects enrolled	Korea, Democratic People's Republic of: 85
Country: Number of subjects enrolled	Italy: 79
Country: Number of subjects enrolled	Poland: 54
Country: Number of subjects enrolled	United Kingdom: 31
Country: Number of subjects enrolled	Turkey: 26
Country: Number of subjects enrolled	Hungary: 20
Country: Number of subjects enrolled	Chile: 19
Country: Number of subjects enrolled	New Zealand: 17
Country: Number of subjects enrolled	Thailand: 16
Country: Number of subjects enrolled	Norway: 16
Country: Number of subjects enrolled	Canada: 15

Country: Number of subjects enrolled	Taiwan: 14
Country: Number of subjects enrolled	Switzerland: 13
Country: Number of subjects enrolled	Portugal: 12
Country: Number of subjects enrolled	Finland: 9
Country: Number of subjects enrolled	Netherlands: 8
Country: Number of subjects enrolled	Ukraine: 8
Country: Number of subjects enrolled	Greece: 8
Country: Number of subjects enrolled	Austria: 5
Country: Number of subjects enrolled	Russian Federation: 5
Country: Number of subjects enrolled	Serbia: 5
Country: Number of subjects enrolled	Brazil: 4
Country: Number of subjects enrolled	Guatemala: 4
Country: Number of subjects enrolled	Argentina: 1
Country: Number of subjects enrolled	Panama: 1
Country: Number of subjects enrolled	Sweden: 1
Worldwide total number of subjects	1225
EEA total number of subjects	561

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)	661
From 65 to 84 years	562
85 years and over	2

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

Twelve hundred and twenty-five participants were randomized in the study and were considered the Secondary Population (SP), out of which first 850 randomized participants were considered the Primary Population (PP).

Period 1

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

Arms

Are arms mutually exclusive?	Yes
Arm title	Docetaxel

Arm description:

Docetaxel 75 milligrams per square meter (mg/m^2) was administered intravenously (IV) on Day 1 of each 21-day cycle until disease progression, death, unacceptable toxicity, withdrawal of consent, or study termination by sponsor, whichever occurred first.

Arm type	Active comparator
Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Concentrate and solvent for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Docetaxel was administered IV on Day 1 of each 21-day cycle until disease progression, death, unacceptable toxicity, withdrawal of consent, or study termination by sponsor, whichever occurred first.

Arm title	Atezolizumab

Arm description:

Atezolizumab 1200 milligrams (mg) was administered IV on Day 1 of each 21-day cycle until disease progression or loss of clinical benefit, death, unacceptable toxicity, withdrawal of consent, or study termination by sponsor, whichever occurred first.

Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	
Other name	MPDL3280A
Pharmaceutical forms	Concentrate and solvent for concentrate for solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Atezolizumab was administered IV on Day 1 of each 21-day cycle until disease progression or loss of clinical benefit, death, unacceptable toxicity, withdrawal of consent, or study termination by sponsor, whichever occurred first.

Number of subjects in period 1	Docetaxel	Atezolizumab
Started	612	613
Completed	0	0
Not completed	612	613
Consent withdrawn by subject	67	36
Study Terminated By Sponsor	44	83
Death	494	485
Lost to follow-up	7	9

Baseline characteristics

Reporting groups	
Reporting group title	Docetaxel
Reporting group description:	
Docetaxel 75 milligrams per square meter (mg/m^2) was administered intravenously (IV) on Day 1 of each 21-day cycle until disease progression, death, unacceptable toxicity, withdrawal of consent, or study termination by sponsor, whichever occurred first.	
Reporting group title	Atezolizumab
Reporting group description:	
Atezolizumab 1200 milligrams (mg) was administered IV on Day 1 of each 21-day cycle until disease progression or loss of clinical benefit, death, unacceptable toxicity, withdrawal of consent, or study termination by sponsor, whichever occurred first.	

Reporting group values	Docetaxel	Atezolizumab	Total
Number of subjects	612	613	1225
Age Categorical Units: Subjects			
Age Continuous Units: years			
arithmetic mean	62.9	62.7	
standard deviation	± 9.2	± 9.8	-
Gender Categorical Units: Subjects			
Female	233	234	467
Male	379	379	758
Race Units: Subjects			
American Indian or Alaska Native	2	1	3
Asian	125	124	249
Black or African American	16	11	27
Native Hawaiian or other Pacific Islander	2	3	5
White	432	438	870
Other	12	11	23
Multiple	1	2	3
Unknown	22	23	45
Ethnicity Units: Subjects			
Hispanic or Latino	42	48	90
Not Hispanic or Latino	541	540	1081
Not reported	21	14	35
Unknown	8	11	19

End points

End points reporting groups

Reporting group title	Docetaxel

Reporting group description:

Docetaxel 75 milligrams per square meter (mg/m^2) was administered intravenously (IV) on Day 1 of each 21-day cycle until disease progression, death, unacceptable toxicity, withdrawal of consent, or study termination by sponsor, whichever occurred first.

Reporting group title	Atezolizumab

Reporting group description:

Atezolizumab 1200 milligrams (mg) was administered IV on Day 1 of each 21-day cycle until disease progression or loss of clinical benefit, death, unacceptable toxicity, withdrawal of consent, or study termination by sponsor, whichever occurred first.

Primary: Percentage of Participants Who Died: Primary Population PP-ITT

End point title	Percentage of Participants Who Died: Primary Population PP-ITT[1]

End point description:

PP-ITT analysis set included the first 850 randomized ITT participants regardless of whether they received any study drug.

End point type	Primary

End point timeframe:

Baseline until death due to any cause (up to approximately 2.25 years)

Notes:

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

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	425	425		
Units: Percentage of Participants				
number (not applicable)	70.1	63.8		

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants Who Died: Tumor Cells (TC)1/2/3 or Tumor-Infiltrating Immune Cells (IC)1/2/3 Subgroup of PP

End point title	Percentage of Participants Who Died: Tumor Cells (TC)1/2/3 or Tumor-Infiltrating Immune Cells (IC)1/2/3 Subgroup of PP[2]

End point description:

TC1=presence of discernible PD-L1 staining of any intensity in >/=1% & <5% TCs;TC2:presence of discernible PD-L1 staining of any intensity in >/=5% & <50% TCs;TC3=presence of discernible PD-L1 staining of any intensity in >/=50% TCs;IC1=presence of discernible PD-L1 staining of any intensity in ICs covering between >/=1% & <5% of tumor area occupied by tumor cells,associated intratumoral & contiguous peri-tumoral desmoplastic stroma;IC2=presence of discernible PD-L1 staining of any intensity in ICs covering between >/=5% & <10% of tumor area occupied by tumor cells,associated intratumoral & contiguous peri-tumoral desmoplastic stroma; IC3=presence of discernible PD-L1

staining of any intensity in ICs covering >/=10% of tumor area occupied by tumor cells,associated intratumoral & contiguous peri-tumoral desmoplastic stroma. TC1/2/3 or IC1/2/3 subgroup within PP included ITT participants with the corresponding PD-L1 expression status.

End point type	Primary

End point timeframe:

Baseline until death due to any cause (up to approximately 2.25 years)

Notes:

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

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	222	241		
Units: Percentage of Participants				
number (not applicable)	67.1	62.7		

Statistical analyses

No statistical analyses for this end point

Primary: Overall Survival (OS): PP-ITT

End point title	Overall Survival (OS): PP-ITT

End point description:

OS duration is defined as the difference in time from the date of randomization to the date of death due to any cause. Data for participants who were not reported as having died at the time of analysis were censored at the date they were last known to be alive. Participants who had no post-baseline information were censored at the date of randomization plus 1 day. OS was estimated using KM methodology. The PP-ITT analysis set.

End point type	Primary

End point timeframe:

Baseline until death due to any cause (up to approximately 2.25 years)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	425	425		
Units: Months				
median (confidence interval 95%)	9.6 (8.6 to 11.2)	13.8 (11.8 to 15.7)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Stratified analysis based on the strata of IC levels per interactive voice/web response system (IxRS), the number of prior chemotherapy regimens per IxRS, and histology per electronic case report form

(eCRF).

Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	850
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0003
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	0.87

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
Unstratified Analysis	
Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	850
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0002
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.73
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.62
upper limit	0.86

Primary: OS: TC1/2/3 or IC1/2/3 Subgroup of PP

End point title	OS: TC1/2/3 or IC1/2/3 Subgroup of PP

End point description:

OS duration is defined as the difference in time from the date of randomization to the date of death due to any cause. Data for participants who were not reported as having died at the time of analysis were censored at the date they were last known to be alive. Participants who had no post-baseline information were censored at the date of randomization plus 1 day. OS was estimated using KM methodology. TC1/2/3 or IC1/2/3 subgroup of PP.

End point type	Primary

End point timeframe:

Baseline until death due to any cause (up to approximately 2.25 years)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	222	241		
Units: Months				
median (confidence interval 95%)	10.3 (8.8 to 12.0)	15.7 (12.6 to 18.0)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Stratified analysis based on the strata of IC levels per IxRS, the number of prior chemotherapy regimens per IxRS, and histology per eCRF.	
Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	463
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0102
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.74
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	0.93

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
Unstratified Analysis	
Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	463
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0052
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.58
upper limit	0.91

Primary: OS: SP-ITT

End point title	OS: SP-ITT

End point description:

OS duration is defined as the difference in time from the date of randomization to the date of death due to any cause. Data for participants who were not reported as having died at the time of analysis were censored at the date they were last known to be alive. Participants who had no post-baseline information were censored at the date of randomization plus 1 day. OS was estimated using KM methodology. Secondary population (SP) ITT analysis set included all 1225 randomized participants regardless of whether they received any study drug.

End point type	Primary

End point timeframe:

Baseline until death due to any cause (up to approximately 2.87 years)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	612	613		
Units: Months				
median (confidence interval 95%)	9.8 (8.8 to 11.3)	13.3 (11.3 to 14.9)		

Statistical analyses

Statistical analysis title	Statistical Analysis SP-ITT

Statistical analysis description:

Stratified analysis based on the strata of IC levels per interactive voice/web response system (IxRS), the number of prior chemotherapy regimens per IxRS, and histology per electronic case report form (eCRF).

Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	1225
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0012
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.8
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.7
upper limit	0.92

Primary: OS: TC1/2/3 or IC1/2/3 Subgroup of SP

End point title	OS: TC1/2/3 or IC1/2/3 Subgroup of SP

End point description:

OS duration is defined as the difference in time from the date of randomization to the date of death due to any cause. Data for participants who were not reported as having died at the time of analysis were

censored at the date they were last known to be alive. Participants who had no post-baseline information were censored at the date of randomization plus 1 day. OS was estimated using KM methodology. TC1/2/3 Or IC1/2/3 Subgroup of SP analysis set.

End point type	Primary

End point timeframe:

Baseline until death from any cause (approximately 2.87 years)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	337	347		
Units: Months				
median (confidence interval 95%)	10.8 (9.3 to 12.0)	14.3 (12.4 to 16.7)		

Statistical analyses

Statistical analysis title	Statistical Analysis

Statistical analysis description:

Stratified analysis based on the strata of IC levels per interactive voice/web response system (IxRS), the number of prior chemotherapy regimens per IxRS, and histology per electronic case report form (eCRF).

Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	684
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0045
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.77
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.64
upper limit	0.92

Primary: OS: TC2/3 or IC2/3 Subgroup of SP

End point title	OS: TC2/3 or IC2/3 Subgroup of SP

End point description:

OS duration is defined as the difference in time from the date of randomization to the date of death due to any cause. Data for participants who were not reported as having died at the time of analysis were censored at the date they were last known to be alive. Participants who had no post-baseline information were censored at the date of randomization plus 1 day. OS was estimated using KM methodology. TC2/3 or IC2/3 Subgroup of SP analysis set.

End point type	Primary

End point timeframe:

Baseline until death due to any cause (up to approximately 2.87 years)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	182	168		
Units: Months				
median (confidence interval 95%)	11.4 (9.3 to 12.9)	16.6 (13.6 to 20.1)		

Statistical analyses

Statistical analysis title	Statistical Analysis

Statistical analysis description:

Stratified analysis based on the strata of IC levels per interactive voice/web response system (IxRS), the number of prior chemotherapy regimens per IxRS, and histology per electronic case report form (eCRF).

Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	350
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0012
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.49
upper limit	0.84

Primary: OS: TC3 or IC3 Subgroup of SP

End point title	OS: TC3 or IC3 Subgroup of SP

End point description:

OS duration is defined as the difference in time from the date of randomization to the date of death due to any cause. Data for participants who were not reported as having died at the time of analysis were censored at the date they were last known to be alive. Participants who had no post-baseline information were censored at the date of randomization plus 1 day. OS was estimated using KM methodology. TC3 or IC3 Subgroup of SP analysis set.

End point type	Primary

End point timeframe:

Baseline until death due to any cause (up to approximately 2.87 years)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	85	89		
Units: Months				
median (confidence interval 95%)	9.7 (7.9 to 11.6)	20.5 (16.8 to 30.2)		

Statistical analyses

Statistical analysis title	Statistical Analysis

Statistical analysis description:

Stratified analysis based on the strata of IC levels per interactive voice/web response system (IxRS), the number of prior chemotherapy regimens per IxRS, and histology per electronic case report form (eCRF).

Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	174
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.45
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.3
upper limit	0.68

Secondary: Percentage of Participants With Disease Progression (PD) as Determined by Investigator Using Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1) or Death: PP-ITT

End point title	Percentage of Participants With Disease Progression (PD) as Determined by Investigator Using Response Evaluation Criteria in Solid Tumors Version 1.1 (RECIST v1.1) or Death: PP-ITT

End point description:

PD: at least 20% increase in the sum of diameters of target lesions compared to the smallest sum of diameters on-study and absolute increase of at least 5 millimeters (mm), or presence of new lesions. The PP-ITT analysis set.

End point type	Secondary

End point timeframe:

Baseline up to PD or Death (up to approximately 2.25 years)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	425	425		
Units: Percentage of Participants				
number (not applicable)	88.2	89.4		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With PD as Determined by Investigator Using RECIST v1.1 or Death: TC1/2/3 or IC1/2/3 Subgroup of PP

End point title	Percentage of Participants With PD as Determined by Investigator Using RECIST v1.1 or Death: TC1/2/3 or IC1/2/3 Subgroup of PP

End point description:

PD: at least 20% increase in the sum of diameters of target lesions compared to the smallest sum of diameters on-study and absolute increase of at least 5 mm, or presence of new lesions. TC1/2/3 or IC1/2/3 subgroup of PP.

End point type	Secondary

End point timeframe:

Baseline up to PD or Death (up to approximately 2.25 years)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	222	241		
Units: Percentage of Participants				
number (not applicable)	86.9	89.6		

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-Free Survival (PFS) as Determined by Investigator Using RECIST v1.1: PP-ITT

End point title	Progression-Free Survival (PFS) as Determined by Investigator Using RECIST v1.1: PP-ITT

End point description:

PFS is defined as the time between the date of randomization and the date of first documented PD or death, whichever occurs first. Participants who are alive and have not experienced PD at the time of analysis were censored at the time of the last tumor assessment. Participants with no post-baseline tumor assessment were censored at the randomization date plus 1 day. PD: at least 20% increase in the sum of diameters of target lesions compared to the smallest sum of diameters on-study and absolute increase of at least 5 mm, or presence of new lesions. The PP-ITT analysis set.

End point type	Secondary

End point timeframe:

Baseline up to PD or death due to any cause, whichever occurred first (up to approximately 2.25 years)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	425	425		
Units: Months				
median (confidence interval 95%)	4.0 (3.3 to 4.2)	2.8 (2.6 to 3.0)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Stratified analysis based on the strata of IC levels per IxRS, the number of prior chemotherapy regimens per IxRS, and histology per eCRF.	
Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	850
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.4928
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.95
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.82
upper limit	1.1

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
Unstratified Analysis	
Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	850
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3596
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.93

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.08

Secondary: PFS as Determined by Investigator Using RECIST v1.1: TC1/2/3 or IC1/2/3 Subgroup of PP

End point title	PFS as Determined by Investigator Using RECIST v1.1: TC1/2/3 or IC1/2/3 Subgroup of PP

End point description:

PFS is defined as the time between the date of randomization and the date of first documented PD or death, whichever occurs first. Participants who are alive and have not experienced PD at the time of analysis were censored at the time of the last tumor assessment. Participants with no post-baseline tumor assessment were censored at the randomization date plus 1 day. PD: at least 20% increase in the sum of diameters of target lesions compared to the smallest sum of diameters on-study and absolute increase of at least 5 mm, or presence of new lesions. The TC1/2/3 or IC1/2/3 subgroup of PP.

End point type	Secondary

End point timeframe:

Baseline up to PD or death due to any cause, whichever occurred first (up to approximately 2.25 years)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	222	241		
Units: Months				
median (confidence interval 95%)	4.1 (2.9 to 4.3)	2.8 (2.6 to 4.0)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Stratified analysis based on the strata of IC levels per IxRS, the number of prior chemotherapy regimens per IxRS, and histology per eCRF.

Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	463
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3806
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.12

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: Unstratified Analysis	
Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	463
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.3249
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.91
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.74
upper limit	1.1

Secondary: Percentage of Participants With Objective Response as Determined Using RECIST v1.1: PP-ITT

End point title	Percentage of Participants With Objective Response as Determined Using RECIST v1.1: PP-ITT

End point description:

Objective response is defined as a complete response (CR) or partial response (PR) as determined by the Investigator using RECIST v1.1 on 2 consecutive occasions at least 6 weeks apart. CR was defined as complete disappearance of all target lesions and non-target disease, with the exception of nodal disease. All nodes, both target and non-target, must decrease to normal (short axis less than [<] 10 mm). No new lesions. At least a 30% decrease in the sum of the diameters of all target and all new measurable lesions, taking as reference the baseline sum of diameters, in the absence of CR. No new lesions. The PP-ITT analysis set.

End point type	Secondary

End point timeframe:

Baseline up to PD or death due to any cause, whichever occurred first (up to approximately 2.25 years)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	425	425		
Units: Percentage of Participants				
number (confidence interval 95%)	13.4 (10.32 to 17.02)	13.6 (10.53 to 17.28)		

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With Objective Response as Determined Using RECIST v1.1: TC1/2/3 or IC1/2/3 Subgroup of PP

End point title	Percentage of Participants With Objective Response as Determined Using RECIST v1.1: TC1/2/3 or IC1/2/3 Subgroup of PP

End point description:

Objective response (OR) is defined as a CR or PR as determined by the Investigator using RECIST v1.1 on 2 consecutive occasions at least 6 weeks apart. CR was defined as complete disappearance of all target lesions and non-target disease, with the exception of nodal disease. All nodes, both target and non-target, must decrease to normal (short axis <10 mm). No new lesions. At least a 30% decrease in the sum of the diameters of all target and all new measurable lesions, taking as reference the baseline sum of diameters, in the absence of CR. No new lesions. The TC1/2/3 or IC1/2/3 subgroup of PP.

End point type	Secondary

End point timeframe:

Baseline up to PD or death due to any cause, whichever occurred first (up to approximately 2.25 years)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	222	241		
Units: Percentage of Participants				
number (confidence interval 95%)	16.2 (11.62 to 21.74)	17.8 (13.22 to 23.27)		

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of Response (DOR) as Determined by Investigator Using RECIST v1.1: PP-ITT

End point title	Duration of Response (DOR) as Determined by Investigator Using RECIST v1.1: PP-ITT

End point description:

DOR:Duration from first tumor assessment that supports the participant's OR to PD or death due to any cause.CR:complete disappearance of all target lesions&non-target disease.All nodes,both target&non-target,must decrease to normal.No new lesions.PR:At least 30% decrease in sum of the diameters of all target&all new measurable lesions,taking as reference the baseline sum of diameters,in absence of CR.Participants without PD at time of analysis were censored at the time of the last tumor assessment.Participants with no post-baseline tumor assessment were censored at randomization date plus 1 day.PD:at least 20% increase in sum of diameters of target lesions compared to the smallest sum of diameters on-study&absolute increase of at least 5 mm,progression of existing non-target lesions,or presence of new lesions.DOR was estimated using KM methodology.'99999':due to higher number of censored participants data not estimable. PP-ITT analysis set.

End point type	Secondary

End point timeframe:

From first objective response of CR or PR to PD or death due to any cause, whichever occurred first (up to approximately 2.25 years)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	57	58		
Units: Months				
median (confidence interval 95%)	6.2 (4.9 to 7.6)	16.3 (10.0 to 99999)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description:	
Stratified analysis based on the strata of IC levels per IxRS, the number of prior chemotherapy regimens per IxRS, and histology per eCRF.	
Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.18
upper limit	0.55

Statistical analysis title	Statistical Analysis 2
Statistical analysis description:	
Unstratified Analysis	
Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	115
Analysis specification	Pre-specified
Analysis type	superiority
P-value	< 0.0001
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.34
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.21
upper limit	0.55

Secondary: DOR as Determined by Investigator Using RECIST v1.1: TC1/2/3 or IC1/2/3 Subgroup of PP

End point title	DOR as Determined by Investigator Using RECIST v1.1: TC1/2/3 or IC1/2/3 Subgroup of PP

End point description:

DOR:Duration from first tumor assessment that supports the participant's OR to PD or death due to any cause.CR:complete disappearance of all target lesions&non-target disease.All nodes,both target&non-target,must decrease to normal.No new lesions.PR:At least 30% decrease in sum of the diameters of all target&all new measurable lesions,taking as reference the baseline sum of diameters,in absence of CR.Participants without PD at time of analysis were censored at the time of the last tumor assessment.Participants with no post-baseline tumor assessment were censored at randomization date plus 1 day.PD:at least 20% increase in sum of diameters of target lesions compared to the smallest sum of diameters on-study&absolute increase of at least 5 mm,progression of existing non-target lesions,or presence of new lesions.DOR was estimated using KM methodology.'99999':due to higher number of censored participants data not estimable. TC1/2/3 or IC1/2/3 Subgroup of PP.

End point type	Secondary

End point timeframe:

From first objective response of CR or PR to PD or death due to any cause, whichever occurred first (up to approximately 2.25 years)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	36	43		
Units: Months				
median (confidence interval 95%)	6.2 (4.9 to 9.2)	16.0 (9.7 to 99999)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1

Statistical analysis description:

Stratified analysis based on the strata of IC levels per IxRS, the number of prior chemotherapy regimens per IxRS, and histology per eCRF.

Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	79
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0006
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.31
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.15
upper limit	0.62

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: Unstratified Analysis	
Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	79
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0003
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.38
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.22
upper limit	0.65

Secondary: Percentage of Participants With Anti-Therapeutic Antibodies (ATAs) Against Atezolizumab

End point title	Percentage of Participants With Anti-Therapeutic Antibodies (ATAs) Against Atezolizumab[3]

End point description:

ATA evaluable population included all participants who received atezolizumab treatment and had at least one post treatment ATA result.

End point type	Secondary

End point timeframe:

Baseline up to approximately 2.25 years (assessed at predose [Hour {Hr} 0] on Day 1 of Cycles 1, 2, 3, 4, 8, 16, then every 8 cycles up to end of treatment (EOT) [approximately 2.25 years]; 120 days after EOT [approximately 2.25 years] [1 Cycle=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 analyses for this end point

End point values	Atezolizumab			
Subject group type	Reporting group			
Number of subjects analysed	565			
Units: Percentage of Participants				
number (not applicable)	30.4			

Statistical analyses

No statistical analyses for this end point

Secondary: Maximum Observed Serum Atezolizumab Concentration (Cmax)

End point title	Maximum Observed Serum Atezolizumab Concentration

End point description:

Pharmacokinetic (PK) evaluable population included participants who received atezolizumab treatment and had at least one measurable PK concentration.

End point type	Secondary

End point timeframe:

Predose (Hr 0), 30 minutes (min) post-infusion (infusion duration: 60 min) on Cycle 1 Day 1 (1 Cycle=21 days)

Notes:

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

End point values	Atezolizumab			
Subject group type	Reporting group			
Number of subjects analysed	606			
Units: Micrograms per milliliter (mcg/mL)				
arithmetic mean (standard deviation)	400 (± 127)			

Statistical analyses

No statistical analyses for this end point

Secondary: Minimum Observed Serum Atezolizumab Concentration (Cmin)

End point title	Minimum Observed Serum Atezolizumab Concentration

End point description:

PK evaluable participants. Here, 'n' signifies those participants evaluated for this measure at specific time point. All 606 participants contributed to the endpoint but not all completed evaluation of every timepoint. Convention 'CxDx' refers to cycle number and day number.

End point type	Secondary

End point timeframe:

Predose (Hr 0) on Day 1 of Cycles 1, 2, 3, 4, 8, 16, 24, 32, EOT (approximately 2.25 years); 120 days after EOT (approximately 2.25 years) (1 Cycle=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 analyses for this end point

End point values	Atezolizumab			
Subject group type	Reporting group			
Number of subjects analysed	606			
Units: mcg/mL				
arithmetic mean (standard deviation)				
C1D1 (n= 593)	2.59 (± 30.9)			
C2D1 (n= 534)	83.2 (± 31.0)			
C3D1 (n= 445)	130 (± 55.8)			
C4D1 (n= 405)	158 (± 66.4)			
C8D1 (n= 222)	205 (± 99.4)			

C16D1 (n= 132)	226 (± 105)			
C24D1 (n= 63)	250 (± 99.8)			
C32D1 (n= 11)	277 (± 117)			
EOT (n= 347)	144 (± 101)			
120 days after EOT (n= 124)	10.4 (± 20.0)			

Statistical analyses

No statistical analyses for this end point

Secondary: Time to Deterioration (TTD) in Patient-Reported Lung Cancer Symptoms, Using the European Organization for Research and Treatment of Cancer (EORTC) Quality-of-Life Questionnaire (QLQ) Lung Cancer Supplemental Module 13 (LC13)

End point title	Time to Deterioration (TTD) in Patient-Reported Lung Cancer Symptoms, Using the European Organization for Research and Treatment of Cancer (EORTC) Quality-of-Life Questionnaire (QLQ) Lung Cancer Supplemental Module 13 (LC13)

End point description:

TTD in patient-reported lung cancer symptoms (pain in chest or in arm/shoulder, dyspnea, or cough) was a composite endpoint defined as the time from randomization to the earliest time the participant's scale scores showed a 10 point or greater increase after baseline in any of the symptoms. A >/=10-point change in the score perceived by participants was considered as clinically significant. The QLQ-LC13 consisted of 1 multi-item scale and 9 single items that assessed the specific symptoms (dyspnea, cough, hemoptysis, and site specific pain), side effects (sore mouth, dysphagia, neuropathy, and alopecia), and pain medication use of lung cancer participants receiving chemotherapy. Scale score range: 0 to 100. Higher symptom score = greater degree of symptom severity. The PP-ITT analysis set. 99999 denotes the data not reported because upper limit of CI was not estimable due to higher number of censored participants.

End point type	Secondary

End point timeframe:

Day 1 of each treatment Cycle up to EOT (up to approximately 2.25 years) (1 Cycle = 21 days)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	425	425		
Units: Months				
median (confidence interval 95%)				
Pain in Chest	8.3 (4.6 to 12.5)	18.0 (11.0 to 99999)		
Cough	5.6 (4.0 to 12.8)	5.5 (4.2 to 7.9)		
Dyspnoea	2.1 (1.6 to 2.3)	1.8 (1.5 to 2.3)		
Arm/Shoulder Pain	6.2 (4.9 to 14.7)	8.3 (5.8 to 12.8)		

Statistical analyses

Statistical analysis title	Statistical Analysis 1
Statistical analysis description: Pain in Chest: Stratified analysis based on the strata of IC levels per IxRS, the number of prior chemotherapy regimens per IxRS, and histology per eCRF.	
Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	850
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0111
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.72
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.55
upper limit	0.93

Statistical analysis title	Statistical Analysis 2
Statistical analysis description: Cough: Unstratified Analysis	
Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	850
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.6305
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	1.06
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.84
upper limit	1.33

Statistical analysis title	Statistical Analysis 3
Statistical analysis description: Dyspnoea: Unstratified Analysis	
Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	850
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.7406
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.97

Confidence interval	
level	95 %
sides	2-sided
lower limit	0.81
upper limit	1.16

Statistical analysis title	Statistical Analysis 4
Statistical analysis description:	
Arm/Shoulder Pain: Unstratified Analysis	
Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	850
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5221
Method	Logrank
Parameter estimate	Hazard ratio (HR)
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.73
upper limit	1.17

Secondary: EORTC QLQ Core 30 (C30) Questionnaire Score: Single Items

End point title	EORTC QLQ Core 30 (C30) Questionnaire Score: Single Items

End point description:

EORTC QLQ-C30 included global health status (GHS)/quality of life (QOL), functional (Fx) scales (physical, role, cognitive, emotional, social), symptom (Sx) scales (fatigue, pain, nausea/vomiting), and single items (dyspnea, appetite loss, insomnia, constipation, diarrhea, financial difficulties). Most questions on 4-point scale (1/Not at All to 4/Very Much), except Items 29-30, which comprise GHS scale and were 7-point scale (1/Very Poor to 7/Excellent). For instrument, GHS/QOL and Fx scales linearly transformed so each score 0-100; lower scores=poorer Fx (worsening), higher scores=better Fx (improvement). Sx scales/items also linearly transformed so each score 0-100; higher scores=worse Sx (more severe/worsened), lower scores=less Sx (less severe/improvement). PP-ITT analysis set. ‘n’=subjects evaluated at specific timepoint for each group. '99999'=standard deviation (SD) non-estimable due to 1 participant evaluated. '00000'=data not reported due to no participant evaluated.

End point type	Secondary

End point timeframe:

Day 1 of each treatment Cycle up to EOT (up to approximately 2.25 years); 6 week following PD (Pro Week 6 Pd); survival follow-up-1 (up to approximately 2.25 years) (1 Cycle= 21 days)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	425	425		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Appetite Loss: Baseline (n= 390, 413)	26.58 (± 31.57)	22.92 (± 29.41)		
Appetite Loss: C2D1(n= 342, 368)	27.49 (± 30.39)	26.99 (± 31.16)		
Appetite Loss: C3D1(n= 256, 304)	21.35 (± 28.84)	21.16 (± 28.94)		
Appetite Loss: C4D1(n= 224, 279)	18.75 (± 25.36)	18.40 (± 26.60)		
Appetite Loss: C5D1(n= 166, 238)	18.88 (± 23.89)	16.67 (± 27.52)		
Appetite Loss: C6D1(n= 151, 224)	18.98 (± 25.68)	14.88 (± 25.39)		
Appetite Loss: C7D1(n= 88, 190)	15.91 (± 24.75)	12.46 (± 23.06)		
Appetite Loss: C8D1(n= 72, 170)	13.89 (± 22.20)	12.94 (± 23.27)		
Appetite Loss: C9D1(n= 50, 153)	8.00 (± 18.52)	11.33 (± 22.35)		
Appetite Loss: C10D1(n= 47, 146)	7.80 (± 15.87)	12.33 (± 21.45)		
Appetite Loss: C11D1(n= 37, 134)	11.71 (± 23.85)	11.44 (± 22.43)		
Appetite Loss: C12D1(n= 30, 132)	11.11 (± 20.22)	8.84 (± 18.81)		
Appetite Loss: C13D1(n= 19, 123)	10.53 (± 15.92)	8.40 (± 15.74)		
Appetite Loss: C14D1(n= 18, 120)	7.41 (± 14.26)	10.00 (± 17.61)		
Appetite Loss: C15D1(n= 16, 113)	6.25 (± 13.44)	12.39 (± 22.80)		
Appetite Loss: C16D1(n= 13, 109)	7.69 (± 14.62)	10.09 (± 19.51)		
Appetite Loss: C17D1(n= 11, 98)	6.06 (± 13.48)	7.82 (± 18.41)		
Appetite Loss: C18D1(n= 10, 91)	6.67 (± 14.05)	8.06 (± 18.15)		
Appetite Loss: C19D1(n= 9, 84)	7.41 (± 14.70)	9.13 (± 18.18)		
Appetite Loss: C20D1(n= 9, 80)	11.11 (± 23.57)	9.58 (± 21.34)		
Appetite Loss: C21D1(n= 9, 75)	3.70 (± 11.11)	12.44 (± 26.15)		
Appetite Loss: C22D1(n= 8, 69)	8.33 (± 15.43)	6.76 (± 16.74)		
Appetite Loss: C23D1(n= 8, 66)	8.33 (± 15.43)	7.58 (± 17.34)		
Appetite Loss: C24D1(n= 5, 64)	13.33 (± 18.26)	8.33 (± 15.71)		
Appetite Loss: C25D1(n= 3, 60)	0.00 (± 0.00)	6.11 (± 13.01)		
Appetite Loss: C26D1(n= 3, 55)	22.22 (± 19.24)	5.45 (± 12.45)		
Appetite Loss: C27D1(n= 3, 52)	0.00 (± 0.00)	9.62 (± 19.06)		
Appetite Loss: C28D1(n= 1, 49)	0.00 (± 99999)	7.48 (± 15.61)		
Appetite Loss: C29D1(n= 2, 40)	33.33 (± 47.14)	9.17 (± 16.86)		
Appetite Loss: C30D1(n= 1, 31)	0.00 (± 99999)	1.08 (± 5.99)		
Appetite Loss: C31D1(n= 0, 24)	00000 (± 00000)	6.94 (± 13.83)		

Appetite Loss: C32D1(n= 0, 22)	00000 (± 00000)	7.58 (± 22.84)		
Appetite Loss: C33D1(n= 0,16)	00000 (± 00000)	8.33 (± 25.82)		
Appetite Loss: C34D1(n= 0, 14)	00000 (± 00000)	4.76 (± 17.82)		
Appetite Loss: C35D1(n= 0, 12)	00000 (± 00000)	8.33 (± 20.72)		
Appetite Loss: C36D1(n= 0, 8)	00000 (± 00000)	4.17 (± 11.78)		
Appetite Loss: C37D1(n= 0, 5)	00000 (± 00000)	6.67 (± 14.91)		
Appetite Loss: C38D1(n= 0, 2)	00000 (± 00000)	0.00 (± 0.00)		
Appetite Loss: End of treatment (EOT)(n= 265, 246)	29.81 (± 31.85)	31.98 (± 33.51)		
Appetite Loss: Pro Week 6 Pd(n= 0,1)	00000 (± 00000)	33.33 (± 99999)		
Appetite Loss: Survival Follow-up (FU) 1 (n= 2, 1)	50.00 (± 70.71)	66.67 (± 99999)		
Constipation: Baseline (n= 388, 410)	19.93 (± 27.39)	16.50 (± 26.81)		
Constipation: C2D1(n= 339, 363)	19.47 (± 26.42)	18.09 (± 26.92)		
Constipation: C3D1(n= 255, 304)	19.74 (± 26.91)	15.13 (± 23.71)		
Constipation: C4D1(n= 224, 277)	17.86 (± 23.38)	14.56 (± 23.58)		
Constipation: C5D1(n= 166, 236)	13.05 (± 21.33)	12.15 (± 21.16)		
Constipation: C6D1(n= 151, 225)	14.35 (± 23.89)	12.89 (± 22.42)		
Constipation: C7D1(n= 87, 188)	13.41 (± 20.62)	11.52 (± 21.04)		
Constipation: C8D1(n= 72, 171)	8.33 (± 15.57)	12.28 (± 21.36)		
Constipation: C9D1(n= 50, 153)	9.33 (± 19.10)	10.68 (± 17.79)		
Constipation: C10D1(n= 47, 146)	9.22 (± 17.99)	9.82 (± 17.58)		
Constipation: C11D1(n= 37, 134)	5.41 (± 12.46)	9.95 (± 17.83)		
Constipation: C12D1(n= 30, 132)	11.11 (± 20.22)	10.86 (± 18.65)		
Constipation: C13D1(n= 19, 124)	5.26 (± 12.49)	8.60 (± 15.83)		
Constipation: C14D1(n= 17, 121)	15.69 (± 23.91)	9.09 (± 16.67)		
Constipation: C15D1(n= 15, 113)	2.22 (± 8.61)	10.03 (± 17.75)		
Constipation: C16D1(n= 13, 109)	20.51 (± 32.03)	9.79 (± 18.87)		
Constipation: C17D1(n= 11, 98)	12.12 (± 22.47)	9.86 (± 19.27)		
Constipation: C18D1(n= 10, 92)	6.67 (± 14.05)	9.06 (± 17.89)		
Constipation: C19D1(n= 9, 83)	7.41 (± 14.70)	9.64 (± 18.43)		
Constipation: C20D1(n=9, 80)	14.81 (± 33.79)	12.50 (± 23.35)		
Constipation: C21D1(n= 9, 75)	7.41 (± 14.70)	14.22 (± 25.22)		
Constipation: C22D1(n= 8, 69)	12.50 (± 24.80)	11.59 (± 21.26)		
Constipation: C23D1(n= 8, 66)	4.17 (± 11.78)	10.10 (± 20.23)		

Constipation: C24D1(n=5, 65)	20.00 (± 29.81)	9.74 (± 17.40)		
Constipation: C25D1(n= 3, 60)	0.00 (± 0.00)	11.11 (± 19.08)		
Constipation: C26D1(n= 2, 55)	0.00 (± 0.00)	12.12 (± 20.65)		
Constipation: C27D1(n= 3, 52)	0.00 (± 0.00)	13.46 (± 20.09)		
Constipation: C28D1(n= 1, 48)	0.00 (± 99999)	11.81 (± 22.27)		
Constipation: C29D1(n= 2, 40)	50.00 (± 70.71)	15.83 (± 23.86)		
Constipation: C30D1(n= 1, 31)	0.00 (± 99999)	8.60 (± 19.18)		
Constipation: C31D1(n= 0, 24)	00000 (± 00000)	9.72 (± 20.80)		
Constipation: C32D1(n= 0, 22)	00000 (± 00000)	6.06 (± 13.16)		
Constipation: C33D1(n= 0, 16)	00000 (± 00000)	4.17 (± 11.39)		
Constipation: C34D1(n= 0, 14)	00000 (± 00000)	7.14 (± 14.19)		
Constipation: C35D1(n= 0, 12)	00000 (± 00000)	5.56 (± 12.97)		
Constipation: C36D1(n= 0, 8)	00000 (± 00000)	4.17 (± 11.78)		
Constipation: C37D1(n= 0, 5)	00000 (± 00000)	0.00 (± 0.00)		
Constipation: C38D1(n= 0, 2)	00000 (± 00000)	0.00 (± 0.00)		
Constipation: EOT (n= 265, 246)	19.12 (± 27.28)	19.78 (± 28.36)		
Constipation: Pro Week 6 Pd(n= 0,1)	00000 (± 00000)	66.67 (± 99999)		
Constipation: Survival FU-1 (n= 2,1)	33.33 (± 47.14)	66.67 (± 99999)		
Diarrhea: Baseline (n= 388, 411)	5.84 (± 13.77)	7.22 (± 17.86)		
Diarrhea: C2D1(n= 339, 361)	11.21 (± 20.65)	7.29 (± 17.72)		
Diarrhea: C3D1(n= 255, 304)	10.07 (± 18.68)	6.14 (± 15.75)		
Diarrhea: C4D1(n= 223, 280)	8.22 (± 16.35)	6.67 (± 17.71)		
Diarrhea: C5D1(n= 166, 238)	8.43 (± 17.48)	6.58 (± 16.16)		
Diarrhea: C6D1(n= 151, 222)	7.51 (± 14.99)	6.31 (± 14.88)		
Diarrhea: C7D1(n= 87, 189)	10.34 (± 17.10)	7.94 (± 17.24)		
Diarrhea: C8D1(n= 72, 171)	7.41 (± 15.03)	8.77 (± 17.56)		
Diarrhea: C9D1(n= 50, 153)	11.33 (± 17.31)	7.63 (± 16.44)		
Diarrhea: C10D1(n= 47, 146)	7.80 (± 14.27)	5.48 (± 15.67)		
Diarrhea: C11D1(n= 36, 134)	8.33 (± 14.64)	4.98 (± 14.46)		
Diarrhea: C12D1(n= 30, 132)	10.00 (± 17.83)	6.31 (± 16.54)		
Diarrhea: C13D1(n= 18, 124)	11.11 (± 16.17)	5.65 (± 14.55)		
Diarrhea: C14D1(n= 17, 121)	3.92 (± 11.07)	9.92 (± 19.07)		
Diarrhea: C15D1(n= 15, 113)	8.89 (± 15.26)	7.96 (± 17.97)		
Diarrhea: C16D1(n= 12, 108)	13.89 (± 17.16)	6.48 (± 14.02)		
Diarrhea: C17D1(n= 11, 98)	9.09 (± 15.57)	7.82 (± 16.44)		

Diarrhea: C18D1(n= 10, 92)	13.33 (± 17.21)	8.70 (± 17.73)		
Diarrhea: C19D1(n= 9, 84)	14.81 (± 17.57)	7.94 (± 18.38)		
Diarrhea: C20D1(n= 9, 80)	7.41 (± 14.70)	6.67 (± 14.43)		
Diarrhea: C21D1(n= 9, 75)	18.52 (± 17.57)	11.11 (± 18.45)		
Diarrhea: C22D1(n= 8, 68)	16.67 (± 25.20)	7.84 (± 16.41)		
Diarrhea: C23D1(n= 8, 66)	8.33 (± 15.43)	6.06 (± 16.44)		
Diarrhea: C24D1(n= 5, 64)	6.67 (± 14.91)	6.25 (± 16.67)		
Diarrhea: C25D1(n= 3, 60)	0.00 (± 0.00)	6.11 (± 14.38)		
Diarrhea: C26D1(n= 3, 55)	11.11 (± 19.24)	10.30 (± 21.15)		
Diarrhea: C27D1(n= 3, 52)	11.11 (± 19.24)	5.77 (± 15.79)		
Diarrhea: C28D1(n= 1, 48)	0.00 (± 99999)	4.86 (± 13.73)		
Diarrhea: C29D1(n= 2, 40)	50.00 (± 70.71)	9.17 (± 18.47)		
Diarrhea: C30D1(n= 1, 31)	0.00 (± 99999)	7.53 (± 16.58)		
Diarrhea: C31D1(n= 0, 24)	00000 (± 00000)	6.94 (± 16.97)		
Diarrhea: C32D1(n= 0, 22)	00000 (± 00000)	12.12 (± 16.41)		
Diarrhea: C33D1(n= 0, 16)	00000 (± 00000)	8.33 (± 14.91)		
Diarrhea: C34D1(n= 0, 14)	00000 (± 00000)	4.76 (± 12.10)		
Diarrhea: C35D1(n= 0, 12)	00000 (± 00000)	5.56 (± 12.97)		
Diarrhea: C36D1(n= 0, 8)	00000 (± 00000)	4.17 (± 11.78)		
Diarrhea: C37D1(n= 0, 5)	00000 (± 00000)	6.67 (± 14.91)		
Diarrhea: C38D1(n= 0, 2)	00000 (± 00000)	0.00 (± 0.00)		
Diarrhea: EOT(n= 265, 246)	10.57 (± 19.18)	9.35 (± 20.39)		
Diarrhea: Pro Week 6 Pd(n= 0, 1)	00000 (± 00000)	0.00 (± 99999)		
Diarrhea: Survival FU-1 (n= 2, 1)	33.33 (± 47.14)	33.33 (± 99999)		
Financial Difficulties: Baseline (n=390, 413)	20.76 (± 27.61)	18.09 (± 28.32)		
Financial Difficulties: C2D1 (n=343, 369)	18.45 (± 26.20)	15.93 (± 26.28)		
Financial Difficulties: C3D1 (n=256, 304)	16.86 (± 24.24)	15.63 (± 25.79)		
Financial Difficulties: C4D1 (n=224, 278)	16.74 (± 23.97)	15.12 (± 24.72)		
Financial Difficulties: C5D1 (n=167, 238)	16.57 (± 24.03)	15.13 (± 25.71)		
Financial Difficulties: C6D1 (n=151, 225)	15.66 (± 24.06)	16.67 (± 26.41)		
Financial Difficulties: C7D1 (n=88, 190)	16.28 (± 24.92)	17.46 (± 27.41)		
Financial Difficulties: C8D1 (n=72, 170)	13.15 (± 21.44)	18.82 (± 27.59)		
Financial Difficulties: C9D1 (n=50, 153)	16.33 (± 28.16)	17.54 (± 27.38)		

Financial Difficulties: C10D1 (n=47, 145)	14.49 (± 23.99)	17.81 (± 29.08)		
Financial Difficulties: C11D1 (n=37, 134)	9.26 (± 21.98)	19.65 (± 30.10)		
Financial Difficulties: C12D1 (n=30, 132)	12.22 (± 23.95)	18.43 (± 28.92)		
Financial Difficulties: C13D1 (n=19, 124)	12.96 (± 25.92)	18.31 (± 29.10)		
Financial Difficulties: C14D1 (n=18, 121)	15.69 (± 26.66)	18.46 (± 29.17)		
Financial Difficulties: C15D1 (n=16, 113)	6.67 (± 18.69)	18.29 (± 28.86)		
Financial Difficulties: C16D1 (n=13, 109)	13.89 (± 30.01)	18.65 (± 29.20)		
Financial Difficulties: C17D1 (n=11, 98)	15.15 (± 22.92)	18.37 (± 27.55)		
Financial Difficulties: C18D1 (n=10, 92)	10.00 (± 22.50)	19.57 (± 28.45)		
Financial Difficulties: C19D1 (n=9, 84)	3.70 (± 11.11)	19.05 (± 28.94)		
Financial Difficulties: C20D1 (n=9, 80)	11.11 (± 33.33)	18.75 (± 27.99)		
Financial Difficulties: C21D1 (n=9, 75)	11.11 (± 33.33)	23.11 (± 30.99)		
Financial Difficulties: C22D1 (n=8, 68)	12.50 (± 35.36)	18.63 (± 28.44)		
Financial Difficulties: C23D1 (n=8, 66)	9.52 (± 25.20)	21.72 (± 30.66)		
Financial Difficulties: C24D1 (n=5, 64)	13.33 (± 29.81)	20.83 (± 29.99)		
Financial Difficulties: C25D1 (n=3, 60)	0.00 (± 0.00)	21.67 (± 31.19)		
Financial Difficulties: C26D1 (n=3, 55)	0.00 (± 0.00)	20.00 (± 30.50)		
Financial Difficulties: C27D1 (n=3, 52)	0.00 (± 0.00)	17.31 (± 28.38)		
Financial Difficulties: C28D1 (n=1, 48)	0.00 (± 99999)	18.06 (± 26.59)		
Financial Difficulties: C29D1 (n=2, 40)	50.00 (± 70.71)	19.17 (± 28.13)		
Financial Difficulties: C30D1 (n=1, 31)	0.00 (± 99999)	17.20 (± 25.63)		
Financial Difficulties: C31D1(n=0, 24)	00000 (± 00000)	20.83 (± 25.66)		
Financial Difficulties: C32D1(n=0, 22)	00000 (± 00000)	21.21 (± 26.32)		
Financial Difficulties: C33D1(n=0, 16)	00000 (± 00000)	22.92 (± 29.11)		
Financial Difficulties: C34D1(n=0, 14)	00000 (± 00000)	26.19 (± 35.03)		
Financial Difficulties: C35D1(n=0, 12)	00000 (± 00000)	27.78 (± 37.15)		
Financial Difficulties: C36D1(n=0, 8)	00000 (± 00000)	8.33 (± 15.43)		
Financial Difficulties: C37D1(n=0, 5)	00000 (± 00000)	26.67 (± 43.46)		
Financial Difficulties: C38D1(n=0, 2)	00000 (± 00000)	16.67 (± 23.57)		
Financial Difficulties: EOT(n=267, 245)	21.80 (± 29.23)	19.46 (± 28.75)		
Financial Difficulties: Pro Week 6 Pd (n=0, 1)	00000 (± 00000)	33.33 (± 99999)		

Financial Difficulties:Survival FU-1 (n=2,24)	83.33 (± 23.57)	66.67 (± 99999)		
Insomnia: Baseline (n= 388, 413)	28.87 (± 30.55)	26.15 (± 28.72)		
Insomnia: C2D1(n= 340, 367)	27.55 (± 30.87)	26.52 (± 28.61)		
Insomnia: C3D1(n= 253, 304)	25.69 (± 29.15)	24.89 (± 27.32)		
Insomnia: C4D1(n= 222, 279)	21.32 (± 26.07)	23.66 (± 26.48)		
Insomnia: C5D1(n= 166, 237)	21.49 (± 25.43)	25.88 (± 29.84)		
Insomnia: C6D1(n= 150, 225)	22.00 (± 26.71)	23.41 (± 27.73)		
Insomnia: C7D1(n= 87, 189)	21.07 (± 25.47)	23.99 (± 26.65)		
Insomnia: C8D1(n= 70, 169)	15.24 (± 23.87)	23.87 (± 26.27)		
Insomnia: C9D1(n= 49, 153)	16.33 (± 26.46)	22.88 (± 27.16)		
Insomnia: C10D1(n= 46, 144)	13.77 (± 19.34)	21.53 (± 26.87)		
Insomnia: C11D1(n= 36, 133)	9.26 (± 18.87)	20.55 (± 27.44)		
Insomnia: C12D1(n= 29, 132)	16.09 (± 30.37)	21.46 (± 24.41)		
Insomnia: C13D1(n= 17, 124)	17.65 (± 29.15)	23.39 (± 28.51)		
Insomnia: C14D1(n= 17, 121)	25.49 (± 27.71)	23.69 (± 26.33)		
Insomnia: C15D1(n= 15, 113)	22.22 (± 29.99)	21.53 (± 28.84)		
Insomnia: C16D1(n= 13, 108)	20.51 (± 25.60)	21.60 (± 31.01)		
Insomnia: C17D1(n= 11, 98)	21.21 (± 26.97)	20.07 (± 28.21)		
Insomnia: C18D1(n= 10, 92)	20.00 (± 32.20)	21.38 (± 27.77)		
Insomnia: C19D1(n= 9, 83)	18.52 (± 24.22)	22.49 (± 28.09)		
Insomnia: C20D1(n= 9, 80)	18.52 (± 33.79)	20.83 (± 29.71)		
Insomnia: C21D1(n= 9, 75)	22.22 (± 33.33)	20.89 (± 29.90)		
Insomnia: C22D1(n= 8, 69)	16.67 (± 35.63)	18.84 (± 26.49)		
Insomnia: C23D1(n= 8, 66)	20.83 (± 35.36)	19.70 (± 28.03)		
Insomnia: C24D1(n= 5, 64)	26.67 (± 27.89)	19.79 (± 25.00)		
Insomnia: C25D1(n= 3, 60)	11.11 (± 19.24)	18.89 (± 23.26)		
Insomnia: C26D1(n= 3, 55)	11.11 (± 19.24)	21.21 (± 27.49)		
Insomnia: C27D1(n= 3, 52)	11.11 (± 19.24)	19.23 (± 28.27)		
Insomnia: C28D1(n= 1, 49)	0.00 (± 99999)	21.09 (± 27.80)		
Insomnia: C29D1(n= 2, 40)	33.33 (± 47.14)	21.67 (± 26.74)		
Insomnia: C30D1(n= 1, 31)	0.00 (± 99999)	20.43 (± 28.12)		

Insomnia: C31D1(n= 0, 24)	00000 (± 00000)	20.83 (± 27.47)		
Insomnia: C32D1(n= 0, 22)	00000 (± 00000)	19.70 (± 26.55)		
Insomnia: C33D1(n= 0, 16)	00000 (± 00000)	20.83 (± 34.16)		
Insomnia: C34D1(n= 0, 14)	00000 (± 00000)	23.81 (± 24.21)		
Insomnia: C35D1(n= 0, 12)	00000 (± 00000)	25.00 (± 28.87)		
Insomnia: C36D1(n= 0, 8)	00000 (± 00000)	25.00 (± 23.57)		
Insomnia: C37D1(n= 0, 5)	00000 (± 00000)	33.33 (± 23.57)		
Insomnia: C38D1(n= 0, 2)	00000 (± 00000)	16.67 (± 23.57)		
Insomnia: Pro Week Pd(n= 0, 1)	00000 (± 00000)	66.67 (± 99999)		
Insomnia: Survival FU-1 (n= 2, 1)	50.00 (± 70.71)	100.00 (± 99999)		
Dyspnea: C1D1 (n= 389, 412)	33.50 (± 31.11)	32.04 (± 28.73)		
Dyspnea: C2D1 (n= 341, 368)	32.55 (± 29.03)	31.88 (± 29.70)		
Dyspnea: C3D1 (n= 255, 302)	29.93 (± 27.54)	27.15 (± 26.73)		
Dyspnea: C4D1 (n= 389, 277)	28.38 (± 24.37)	28.28 (± 27.48)		
Dyspnea: C5D1 (n= 222, 236)	29.52 (± 24.46)	27.82 (± 27.03)		
Dyspnea: C6D1 (n= 166, 222)	30.02 (± 26.32)	26.88 (± 25.63)		
Dyspnea: C7D1 (n= 151, 188)	27.13 (± 25.31)	25.53 (± 25.99)		
Dyspnea: C8D1 (n= 86, 169)	28.70 (± 29.76)	26.43 (± 26.70)		
Dyspnea: C9D1 (n= 72, 152)	26.67 (± 28.57)	24.12 (± 24.92)		
Dyspnea: C10D1 (n= 50, 146)	27.66 (± 28.93)	23.52 (± 23.54)		
Dyspnea: C11D1 (n= 47, 134)	25.23 (± 30.84)	22.89 (± 25.00)		
Dyspnea: C12D1 (n= 37, 132)	26.67 (± 26.84)	22.73 (± 25.83)		
Dyspnea: C13D1 (n= 30, 123)	19.30 (± 23.08)	25.47 (± 26.68)		
Dyspnea: C14D1 (n= 19, 119)	20.37 (± 25.92)	21.85 (± 25.47)		
Dyspnea: C15D1 (n= 16, 113)	16.67 (± 17.21)	22.71 (± 24.51)		
Dyspnea: C16D1 (n= 13, 109)	20.51 (± 16.88)	21.71 (± 25.00)		
Dyspnea: C17D1 (n= 11, 98)	15.15 (± 17.41)	21.43 (± 23.57)		
Dyspnea: C18D1 (n= 10, 92)	20.00 (± 17.21)	22.83 (± 25.64)		
Dyspnea: C19D1 (n= 9, 84)	11.11 (± 16.67)	23.41 (± 23.59)		
Dyspnea: C20D1 (n= 9, 80)	18.52 (± 17.57)	21.67 (± 24.36)		
Dyspnea: C21D1 (n= 9, 75)	18.52 (± 17.57)	19.11 (± 20.63)		

Dyspnea: C22D1 (n= 8, 68)	20.83 (± 35.36)	20.59 (± 23.06)		
Dyspnea: C23D1 (n= 8, 65)	12.50 (± 17.25)	18.46 (± 21.27)		
Dyspnea: C24D1 (n= 5, 64)	6.67 (± 14.91)	19.79 (± 24.28)		
Dyspnea: C25D1 (n= 3, 60)	11.11 (± 19.24)	20.00 (± 22.30)		
Dyspnea: C26D1 (n= 3, 55)	0.00 (± 0.00)	20.00 (± 24.51)		
Dyspnea: C27D1 (n= 3, 52)	0.00 (± 0.00)	16.03 (± 19.23)		
Dyspnea: C28D1 (n= 1, 49)	0.00 (± 99999)	17.01 (± 20.55)		
Dyspnea: C29D1 (n= 2, 40)	33.33 (± 47.14)	15.00 (± 21.28)		
Dyspnea: C30D1 (n= 1, 31)	0.00 (± 99999)	16.13 (± 18.99)		
Dyspnea: C31D1 (n= 0, 24)	00000 (± 00000)	22.22 (± 23.40)		
Dyspnea: C32D1 (n= 0, 22)	00000 (± 00000)	22.73 (± 21.54)		
Dyspnea: C33D1 (n= 0, 16)	00000 (± 00000)	25.00 (± 31.03)		
Dyspnea: C34D1 (n= 0, 14)	00000 (± 00000)	26.19 (± 26.73)		
Dyspnea: C35D1 (n= 0, 12)	00000 (± 00000)	25.00 (± 25.13)		
Dyspnea: C36D1 (n= 0, 8)	00000 (± 00000)	20.83 (± 17.25)		
Dyspnea: C37D1 (n= 0, 5)	00000 (± 00000)	26.67 (± 14.91)		
Dyspnea: C38D1 (n= 0, 2)	00000 (± 00000)	33.33 (± 0.00)		
Dyspnea: EOT(n= 266, 247)	38.72 (± 30.51)	39.41 (± 32.57)		
Dyspnea: Pro Week 6 Pd (n= 0, 1)	00000 (± 00000)	33.33 (± 99999)		
Dyspnea: Survival Follow-Up 1 (n= 2, 1)	33.33 (± 47.14)	33.33 (± 99999)		
Insomnia: EOT(n= 264, 246)	28.91 (± 30.65)	29.95 (± 30.30)		

Statistical analyses

No statistical analyses for this end point

Secondary: EORTC QLQ-C30 Questionnaire Score: Functional Subscales

End point title	EORTC QLQ-C30 Questionnaire Score: Functional Subscales

End point description:

EORTC QLQ-C30 included GHS/QOL, Fx scales (physical, role, cognitive, emotional, social), Sx scales (fatigue, pain, nausea/vomiting), and single items (dyspnea, appetite loss, insomnia, constipation, diarrhea, financial difficulties). Most questions on 4-point scale (1/Not at All to 4/Very Much), except Items 29-30, which comprise GHS scale and were 7-point scale (1/Very Poor to 7/Excellent). For instrument, GHS/QOL and Fx scales linearly transformed so each score 0-100; lower scores=poorer Fx (worsening), higher scores=better Fx (improvement). Sx scales/items also linearly transformed so each score 0-100; higher scores=worse Sx (more severe/worsened), lower scores=less Sx (less severe/improvement). PP-ITT analysis set. 'n'=subjects evaluated at specific timepoint for each group.

'99999'=SD non-estimable due to 1 participant evaluated. '00000'=data not reported due to no participant evaluated.

End point type	Secondary

End point timeframe:

Day 1 of each treatment Cycle up to EOT (up to approximately 2.25 years); 6 week following PD (Pro Week 6 Pd) (up to approximately 2.25 years); survival follow-up-1 (up to approximately 2.25 years) (1 Cycle= 21 days)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	425	425		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Cognitive: Baseline (n= 390, 411)	83.38 (± 20.68)	85.16 (± 19.16)		
Cognitive: C2D1(n= 341, 363)	83.38 (± 21.64)	84.94 (± 19.30)		
Cognitive: C3D1(n= 256, 305)	84.05 (± 19.82)	86.28 (± 17.32)		
Cognitive: C4D1(n= 224, 281)	84.82 (± 19.27)	85.35 (± 19.87)		
Cognitive: C5D1(n= 166, 238)	86.04 (± 17.24)	84.38 (± 19.73)		
Cognitive: C6D1(n= 151, 224)	86.09 (± 18.20)	84.45 (± 20.27)		
Cognitive: C7D1(n= 87, 189)	87.55 (± 16.32)	84.74 (± 18.93)		
Cognitive: C8D1(n= 72, 171)	89.58 (± 13.83)	85.58 (± 18.87)		
Cognitive: C9D1(n= 50, 153)	90.00 (± 14.29)	85.95 (± 18.65)		
Cognitive: C10D1(n= 47, 146)	91.13 (± 11.96)	86.53 (± 19.31)		
Cognitive: C11D1(n= 36, 134)	92.59 (± 10.87)	85.95 (± 19.91)		
Cognitive: C12D1(n= 30, 132)	91.11 (± 12.17)	84.22 (± 20.52)		
Cognitive: C13D1(n= 18, 124)	90.74 (± 11.75)	84.27 (± 21.50)		
Cognitive: C14D1(n= 17, 121)	92.16 (± 11.96)	85.67 (± 18.30)		
Cognitive: C15D1(n= 15, 113)	93.33 (± 10.54)	85.10 (± 19.08)		
Cognitive: C16D1(n= 12, 109)	97.22 (± 6.49)	85.32 (± 21.12)		
Cognitive: C17D1(n= 11, 98)	96.97 (± 6.74)	85.37 (± 20.48)		
Cognitive: C18D1(n= 10, 92)	91.67 (± 11.79)	82.97 (± 20.52)		
Cognitive: C19D1(n= 9, 84)	92.59 (± 12.11)	83.53 (± 20.12)		
Cognitive: C20D1(n= 9, 80)	90.74 (± 14.70)	82.29 (± 22.87)		
Cognitive: C21D1(n= 9, 75)	87.04 (± 23.24)	83.78 (± 20.32)		
Cognitive: C22D1(n= 8, 68)	89.58 (± 12.40)	84.56 (± 21.03)		

Cognitive: C23D1(n= 8, 66)	95.83 (± 7.72)	84.09 (± 20.55)		
Cognitive: C24D1(n= 5, 64)	83.33 (± 23.57)	83.85 (± 23.56)		
Cognitive: C25D1(n= 3, 60)	72.22 (± 25.46)	83.61 (± 21.59)		
Cognitive: C26D1(n= 3, 55)	77.78 (± 19.24)	82.73 (± 21.51)		
Cognitive: C27D1(n= 3, 52)	88.89 (± 19.24)	85.26 (± 20.25)		
Cognitive: C28D1(n= 1, 48)	100.00 (± 99999)	85.07 (± 20.98)		
Cognitive: C29D1(n= 2, 40)	50.00 (± 70.71)	83.75 (± 20.84)		
Cognitive: C30D1(n= 1, 31)	100.00 (± 99999)	86.02 (± 20.68)		
Cognitive: C31D1(n= 0, 24)	00000 (± 00000)	80.56 (± 21.23)		
Cognitive: C32D1(n= 0, 22)	00000 (± 00000)	82.58 (± 22.11)		
Cognitive: C33D1(n= 0,16)	00000 (± 00000)	77.08 (± 25.73)		
Cognitive: C34D1(n= 0, 14)	00000 (± 00000)	80.95 (± 24.33)		
Cognitive: C35D1(n= 0, 12)	00000 (± 00000)	76.39 (± 21.86)		
Cognitive: C36D1(n= 0, 8)	00000 (± 00000)	83.33 (± 15.43)		
Cognitive: C37D1(n= 0, 5)	00000 (± 00000)	83.33 (± 16.67)		
Cognitive: C38D1(n= 0, 2)	00000 (± 00000)	91.67 (± 11.79)		
Cognitive: EOT(n= 265, 246)	78.82 (± 24.54)	78.52 (± 22.50)		
Cognitive: Pro Week 6 Pd(n= 0,1)	00000 (± 00000)	83.33 (± 99999)		
Cognitive: Survival FU 1 (n= 2, 1)	50.00 (± 47.14)	0.00 (± 99999)		
Emotional: Baseline (n= 390, 411)	75.83 (± 22.59)	76.55 (± 21.77)		
Emotional: C2D1(n= 341, 363)	78.06 (± 22.63)	79.47 (± 20.72)		
Emotional: C3D1(n= 256, 305)	79.70 (± 22.24)	82.71 (± 17.45)		
Emotional: C4D1(n= 224, 280)	81.67 (± 20.36)	83.69 (± 17.70)		
Emotional: C5D1(n= 166, 238)	80.52 (± 20.24)	81.99 (± 19.22)		
Emotional: C6D1(n= 151, 224)	81.73 (± 20.50)	82.70 (± 19.91)		
Emotional: C7D1(n= 87, 189)	81.42 (± 22.00)	83.77 (± 17.71)		
Emotional: C8D1(n= 72, 171)	84.38 (± 18.66)	83.63 (± 19.40)		
Emotional: C9D1(n= 50, 153)	86.00 (± 17.93)	85.62 (± 18.72)		
Emotional: C10D1(n= 47, 146)	84.93 (± 17.69)	84.13 (± 19.74)		
Emotional: C11D1(n= 36, 134)	89.12 (± 15.15)	84.16 (± 18.14)		
Emotional: C12D1(n= 30, 132)	86.94 (± 14.79)	84.34 (± 20.10)		

Emotional: C13D1(n= 18, 123)	89.35 (± 14.52)	84.35 (± 19.75)		
Emotional: C14D1(n= 17, 121)	86.27 (± 15.57)	84.25 (± 19.11)		
Emotional: C15D1(n= 15, 113)	90.00 (± 14.16)	83.87 (± 20.04)		
Emotional: C16D1(n= 12, 109)	88.89 (± 16.02)	82.11 (± 22.59)		
Emotional: C17D1(n= 11, 98)	88.64 (± 17.59)	83.25 (± 19.50)		
Emotional: C18D1(n= 10, 92)	87.50 (± 19.35)	82.52 (± 21.11)		
Emotional: C19D1(n= 9, 84)	87.96 (± 19.14)	81.42 (± 20.55)		
Emotional: C20D1(n=9, 80)	76.85 (± 34.30)	83.19 (± 18.90)		
Emotional: C21D1(n= 9, 75)	83.33 (± 26.68)	84.19 (± 17.58)		
Emotional: C22D1(n= 8, 68)	76.74 (± 32.60)	86.03 (± 16.44)		
Emotional: C23D1(n= 8, 66)	89.58 (± 15.91)	87.00 (± 17.55)		
Emotional: C24D1(n=5, 65)	78.33 (± 33.12)	83.72 (± 19.18)		
Emotional: C25D1(n= 3, 60)	100.00 (± 0.00)	83.66 (± 18.77)		
Emotional: C26D1(n= 3, 55)	86.11 (± 12.73)	85.15 (± 19.69)		
Emotional: C27D1(n= 3, 52)	100.00 (± 0.00)	86.38 (± 18.38)		
Emotional: C28D1(n= 1, 48)	100.00 (± 99999)	86.92 (± 17.51)		
Emotional: C29D1(n= 2, 40)	50.00 (± 70.71)	87.50 (± 16.45)		
Emotional: C30D1(n= 1, 31)	100.00 (± 99999)	89.79 (± 15.62)		
Emotional: C31D1(n= 0, 24)	00000 (± 00000)	85.76 (± 18.30)		
Emotional: C32D1(n= 0, 22)	00000 (± 00000)	82.95 (± 20.81)		
Emotional: C33D1(n= 0, 16)	00000 (± 00000)	81.25 (± 25.37)		
Emotional: C34D1(n= 0, 14)	00000 (± 00000)	82.14 (± 25.29)		
Emotional: C35D1(n= 0, 12)	00000 (± 00000)	83.33 (± 21.61)		
Emotional: C36D1(n= 0, 8)	00000 (± 00000)	95.83 (± 11.78)		
Emotional: C37D1(n= 0, 5)	00000 (± 00000)	90.00 (± 14.91)		
Emotional: C38D1(n= 0, 2)	00000 (± 00000)	83.33 (± 23.57)		
Emotional: EOT (n= 265, 246)	73.78 (± 26.29)	73.92 (± 23.74)		
Emotional: Pro Week 6 Pd(n= 0,1)	00000 (± 00000)	66.67 (± 99999)		
Emotional: Survival FU-1 (n= 2,1)	25.00 (± 35.36)	33.33 (± 99999)		
Physical: Baseline (n= 390, 413)	73.27 (± 22.58)	74.46 (± 20.66)		
Physical: C2D1(n= 343, 369)	72.64 (± 22.00)	71.70 (± 22.49)		

Physical: C3D1(n= 255, 304)	74.98 (± 21.60)	76.19 (± 19.48)		
Physical: C4D1(n= 224, 277)	75.72 (± 19.05)	76.79 (± 19.95)		
Physical: C5D1(n= 167, 238)	77.30 (± 19.00)	77.79 (± 19.89)		
Physical: C6D1(n= 151, 225)	74.77 (± 19.26)	78.93 (± 18.76)		
Physical: C7D1(n= 88, 189)	77.61 (± 18.08)	79.20 (± 18.42)		
Physical: C8D1(n= 71, 170)	78.45 (± 17.72)	78.87 (± 18.91)		
Physical: C9D1(n= 50, 153)	79.07 (± 20.43)	79.46 (± 18.75)		
Physical: C10D1(n= 47, 146)	79.29 (± 19.96)	79.41 (± 18.85)		
Physical: C11D1(n= 37, 134)	81.44 (± 20.85)	79.09 (± 20.50)		
Physical: C12D1(n= 30, 132)	82.22 (± 15.69)	79.72 (± 18.84)		
Physical: C13D1(n= 19, 124)	87.37 (± 9.66)	80.48 (± 19.33)		
Physical: C14D1(n= 18, 121)	85.56 (± 9.50)	80.33 (± 17.55)		
Physical: C15D1(n= 16, 113)	86.25 (± 8.24)	79.88 (± 18.64)		
Physical: C16D1(n= 13, 109)	85.13 (± 9.49)	78.82 (± 21.32)		
Physical: C17D1(n= 11, 98)	84.24 (± 12.03)	78.57 (± 20.89)		
Physical: C18D1(n= 10, 92)	82.67 (± 13.03)	79.64 (± 19.92)		
Physical: C19D1(n= 9, 84)	87.41 (± 10.77)	78.97 (± 20.48)		
Physical: C20D1(n= 9, 80)	81.48 (± 18.19)	79.19 (± 20.26)		
Physical: C21D1(n= 9, 75)	87.41 (± 11.28)	78.67 (± 20.68)		
Physical: C22D1(n= 8, 69)	82.50 (± 19.82)	82.51 (± 16.92)		
Physical: C23D1(n= 8, 66)	85.00 (± 13.21)	80.81 (± 17.56)		
Physical: C24D1(n= 5, 64)	80.00 (± 18.26)	81.41 (± 17.69)		
Physical: C25D1(n= 3, 60)	82.22 (± 16.78)	83.22 (± 16.67)		
Physical: C26D1(n= 3, 55)	75.56 (± 3.85)	80.12 (± 17.43)		
Physical: C27D1(n= 2, 52)	76.67 (± 4.71)	81.89 (± 16.90)		
Physical: C28D1(n= 2, 49)	65.00 (± 21.21)	84.15 (± 14.41)		
Physical: C29D1(n= 2, 40)	56.67 (± 33.00)	83.00 (± 14.87)		
Physical: C30D1(n= 1, 31)	80.00 (± 99999)	83.01 (± 15.67)		
Physical: C31D1(n= 0, 24)	00000 (± 00000)	78.61 (± 17.25)		
Physical: C32D1(n= 0, 22)	00000 (± 00000)	75.15 (± 18.42)		
Physical: C33D1(n= 0, 16)	00000 (± 00000)	77.92 (± 17.84)		

Physical: C34D1(n= 0, 14)	00000 (± 00000)	75.24 (± 19.47)		
Physical: C35D1(n= 0, 12)	00000 (± 00000)	73.89 (± 20.78)		
Physical: C36D1(n= 0, 8)	00000 (± 00000)	83.33 (± 17.46)		
Physical: C37D1(n= 0, 5)	00000 (± 00000)	74.67 (± 14.45)		
Physical: C38D1(n= 0, 2)	00000 (± 00000)	86.67 (± 0.00)		
Physical: EOT(n= 267, 246)	63.59 (± 24.57)	64.78 (± 26.47)		
Physical: Pro Week 6 Pd(n= 0, 1)	00000 (± 00000)	46.67 (± 99999)		
Physical: Survival FU-1 (n= 2, 1)	36.67 (± 51.85)	46.67 (± 99999)		
Role: Baseline (n=388, 413)	70.92 (± 30.68)	73.61 (± 29.13)		
Role: C2D1 (n=339, 369)	69.91 (± 29.89)	68.29 (± 31.50)		
Role: C3D1 (n=256, 304)	74.61 (± 27.21)	75.27 (± 27.28)		
Role: C4D1 (n=224, 279)	73.36 (± 26.22)	76.70 (± 25.27)		
Role: C5D1 (n=167, 238)	74.35 (± 25.00)	76.05 (± 26.97)		
Role: C6D1 (n=151, 225)	73.62 (± 26.62)	77.70 (± 26.78)		
Role: C7D1 (n=88, 190)	77.27 (± 23.19)	79.04 (± 24.97)		
Role: C8D1 (n=72, 170)	73.61 (± 26.50)	77.35 (± 25.22)		
Role: C9D1 (n=50, 153)	77.67 (± 24.42)	79.30 (± 25.36)		
Role: C10D1 (n=47, 145)	78.72 (± 27.74)	81.38 (± 24.34)		
Role: C11D1 (n=37, 134)	80.63 (± 24.69)	78.61 (± 27.01)		
Role: C12D1 (n=30, 132)	81.11 (± 22.20)	79.80 (± 25.97)		
Role: C13D1 (n=19, 124)	84.21 (± 18.82)	79.44 (± 26.55)		
Role: C14D1 (n=18, 121)	78.70 (± 21.24)	79.48 (± 24.98)		
Role: C15D1 (n=16, 113)	83.33 (± 14.91)	79.20 (± 25.05)		
Role: C16D1 (n=13, 109)	85.90 (± 19.06)	76.45 (± 27.89)		
Role: C17D1 (n=11, 98)	80.30 (± 20.84)	76.02 (± 29.22)		
Role: C18D1 (n=10, 92)	80.00 (± 26.99)	77.17 (± 27.59)		
Role: C19D1 (n=9, 84)	85.19 (± 22.74)	78.17 (± 28.46)		
Role: C20D1 (n=9, 80)	79.63 (± 29.79)	78.54 (± 26.01)		
Role: C21D1 (n=9, 75)	85.19 (± 15.47)	77.33 (± 28.29)		
Role: C22D1 (n=8, 69)	79.17 (± 35.36)	81.64 (± 26.68)		
Role: C23D1 (n=8, 66)	85.42 (± 20.77)	80.30 (± 26.13)		

Role: C24D1 (n=5, 65)	70.00 (± 34.16)	78.72 (± 26.92)		
Role: C25D1 (n=3, 60)	77.78 (± 38.49)	79.44 (± 27.34)		
Role: C26D1 (n=3, 55)	83.33 (± 28.87)	76.97 (± 27.31)		
Role: C27D1 (n=3, 52)	88.89 (± 19.24)	80.77 (± 26.89)		
Role: C28D1 (n=1, 49)	100.00 (± 99999)	82.99 (± 22.69)		
Role: C29D1 (n=2, 40)	66.67 (± 47.14)	83.33 (± 24.75)		
Role: C30D1 (n=1, 31)	100.00 (± 99999)	81.72 (± 24.10)		
Role: C31D1(n=0, 24)	00000 (± 00000)	79.86 (± 25.53)		
Role: C32D1(n=0, 22)	00000 (± 00000)	75.00 (± 27.58)		
Role: C33D1(n=0, 16)	00000 (± 00000)	66.67 (± 34.43)		
Role: C34D1(n=0, 14)	00000 (± 00000)	69.05 (± 33.88)		
Role: C35D1(n=0, 12)	00000 (± 00000)	69.44 (± 32.44)		
Role: C36D1(n=0, 8)	00000 (± 00000)	87.50 (± 17.25)		
Role: C37D1(n=0, 5)	00000 (± 00000)	76.67 (± 22.36)		
Role: C38D1(n=0, 2)	00000 (± 00000)	100.00 (± 0.00)		
Role: EOT(n=266, 246)	58.52 (± 32.99)	60.03 (± 33.25)		
Role: Pro Week 6 Pd (n=0, 1)	00000 (± 00000)	66.67 (± 99999)		
Role: Survival FU-1 (n=2,1)	33.33 (± 47.14)	33.33 (± 99999)		
Social: Baseline (n= 389, 411)	74.16 (± 26.92)	77.41 (± 26.13)		
Social: C2D1(n= 340, 363)	74.51 (± 26.50)	76.86 (± 26.25)		
Social: C3D1(n= 255, 305)	78.37 (± 25.30)	81.15 (± 23.70)		
Social: C4D1(n= 223, 280)	79.60 (± 23.00)	81.31 (± 24.15)		
Social: C5D1(n= 166, 238)	79.32 (± 22.26)	82.00 (± 24.39)		
Social: C6D1(n= 151, 224)	78.15 (± 24.05)	81.99 (± 23.80)		
Social: C7D1(n= 87, 189)	80.65 (± 22.57)	82.80 (± 22.54)		
Social: C8D1(n= 72, 171)	81.94 (± 22.16)	81.19 (± 23.95)		
Social: C9D1(n= 50, 153)	82.00 (± 22.80)	83.77 (± 22.29)		
Social: C10D1(n= 47, 146)	81.21 (± 24.97)	83.79 (± 22.99)		
Social: C11D1(n= 36, 134)	82.41 (± 26.11)	81.47 (± 25.42)		
Social: C12D1(n= 30, 132)	86.67 (± 18.77)	82.95 (± 24.58)		
Social: C13D1(n= 18, 124)	89.81 (± 15.27)	84.27 (± 22.82)		

Social: C14D1(n= 17, 121)	86.27 (± 19.75)	84.16 (± 22.55)		
Social: C15D1(n= 15, 113)	93.33 (± 13.80)	83.92 (± 22.26)		
Social: C16D1(n= 12, 109)	84.72 (± 16.60)	82.72 (± 24.73)		
Social: C17D1(n= 11, 98)	87.88 (± 16.82)	82.99 (± 23.57)		
Social: C18D1(n= 10, 92)	86.67 (± 17.21)	81.34 (± 24.06)		
Social: C19D1(n= 9, 84)	88.89 (± 16.67)	81.94 (± 25.90)		
Social: C20D1(n= 9, 80)	81.48 (± 33.79)	81.46 (± 24.73)		
Social: C21D1(n= 9, 75)	85.19 (± 24.22)	78.67 (± 27.88)		
Social: C22D1(n= 8, 68)	85.42 (± 30.13)	84.31 (± 25.41)		
Social: C23D1(n= 8, 66)	91.67 (± 15.43)	80.56 (± 26.24)		
Social: C24D1(n= 5, 65)	80.00 (± 27.39)	80.77 (± 25.38)		
Social: C25D1(n= 3, 60)	77.78 (± 38.49)	81.39 (± 27.80)		
Social: C26D1(n= 3, 55)	77.78 (± 19.24)	79.70 (± 27.53)		
Social: C27D1(n= 3, 52)	88.89 (± 19.24)	82.05 (± 25.32)		
Social: C28D1(n= 1, 48)	100.00 (± 99999)	84.03 (± 24.30)		
Social: C29D1(n= 2, 40)	50.00 (± 70.71)	82.92 (± 24.60)		
Social: C30D1(n= 1, 31)	100.00 (± 99999)	79.57 (± 27.79)		
Social: C31D1(n= 0, 24)	00000 (± 00000)	79.17 (± 26.12)		
Social: C32D1(n= 0, 22)	00000 (± 00000)	73.48 (± 30.71)		
Social: C33D1(n= 0, 16)	00000 (± 00000)	73.96 (± 32.19)		
Social: C34D1(n= 0, 14)	00000 (± 00000)	67.86 (± 34.88)		
Social: C35D1(n= 0, 12)	00000 (± 00000)	70.83 (± 31.88)		
Social: C36D1(n= 0, 8)	00000 (± 00000)	87.50 (± 17.25)		
Social: C37D1(n= 0, 5)	00000 (± 00000)	80.00 (± 18.26)		
Social: C38D1(n= 0, 2)	00000 (± 00000)	100.00 (± 0.00)		
Social: EOT(n= 264, 245)	69.51 (± 30.65)	70.00 (± 30.05)		
Social: Pro Week Pd(n= 0, 1)	00000 (± 00000)	66.67 (± 99999)		
Social: Survival FU-1 (n= 2, 1)	83.33 (± 23.57)	16.67 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: EORTC QLQ-C30 Questionnaire Score: GHS Scale

End point title	EORTC QLQ-C30 Questionnaire Score: GHS Scale

End point description:

EORTC QLQ-C30 included GHS/QOL, Fx scales (physical, role, cognitive, emotional, social), Sx scales (fatigue, pain, nausea/vomiting), and single items (dyspnea, appetite loss, insomnia, constipation, diarrhea, financial difficulties). Most questions on 4-point scale (1/Not at All to 4/Very Much), except Items 29-30, which comprise GHS scale and were 7-point scale (1/Very Poor to 7/Excellent). For instrument, GHS/QOL and Fx scales linearly transformed so each score 0-100; lower scores=poorer Fx (worsening), higher scores=better Fx (improvement). Sx scales/items also linearly transformed so each score 0-100; higher scores=worse Sx (more severe/worsened), lower scores=less Sx (less severe/improvement). PP-ITT analysis set. 'n'=subjects evaluated at specific timepoint for each group. '99999'=SD non-estimable due to 1 participant evaluated. '00000'=data not reported due to no participant evaluated.

End point type	Secondary

End point timeframe:

Day 1 of each treatment Cycle up to EOT (up to approximately 2.25 years); 6 week following PD (Pro Week 6 Pd) (up to approximately 2.25 years); survival follow-up-1 (up to approximately 2.25 years) (1 Cycle= 21 days)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	425	425		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Global Health: Baseline (n= 387, 410)	60.55 (± 22.25)	61.24 (± 22.31)		
Global Health: C2D1(n= 339, 361)	59.56 (± 22.15)	58.93 (± 23.57)		
Global Health: C3D1(n= 255, 304)	64.64 (± 18.66)	64.61 (± 20.74)		
Global Health: C4D1(n= 222, 279)	63.51 (± 20.67)	65.11 (± 21.36)		
Global Health: C5D1(n= 166, 235)	64.01 (± 18.37)	66.35 (± 19.84)		
Global Health: C6D1(n= 151, 223)	64.51 (± 19.59)	65.73 (± 21.42)		
Global Health: C7D1(n= 87, 187)	64.85 (± 18.13)	66.93 (± 19.61)		
Global Health: C8D1(n= 72, 169)	62.73 (± 20.22)	67.36 (± 19.45)		
Global Health: C9D1(n= 50, 152)	67.17 (± 18.93)	68.09 (± 19.46)		
Global Health: C10D1(n= 47, 145)	66.84 (± 18.67)	69.37 (± 20.90)		
Global Health: C11D1(n= 36, 133)	69.68 (± 17.15)	68.17 (± 21.24)		
Global Health: C12D1(n= 30, 131)	66.67 (± 18.05)	68.32 (± 20.42)		
Global Health: C13D1(n= 18, 124)	69.91 (± 14.33)	67.74 (± 22.52)		
Global Health: C14D1(n= 17, 120)	69.61 (± 14.71)	67.01 (± 20.62)		
Global Health: C15D1(n= 15, 113)	69.44 (± 17.16)	68.66 (± 20.21)		

Global Health: C16D1(n= 12, 109)	62.50 (± 15.69)	67.97 (± 21.67)		
Global Health: C17D1(n= 10, 98)	61.67 (± 19.72)	68.62 (± 19.84)		
Global Health: C18D1(n= 10, 92)	61.67 (± 21.23)	68.57 (± 18.86)		
Global Health: C19D1(n= 9, 84)	65.74 (± 21.43)	68.25 (± 20.10)		
Global Health: C20D1(n= 9, 80)	62.04 (± 26.72)	68.12 (± 20.10)		
Global Health: C21D1(n= 9, 75)	60.19 (± 29.98)	66.56 (± 21.55)		
Global Health: C22D1(n= 8, 68)	54.17 (± 24.80)	73.28 (± 17.13)		
Global Health: C23D1(n= 8, 66)	62.50 (± 19.42)	70.45 (± 18.09)		
Global Health: C24D1(n= 5, 65)	70.00 (± 27.39)	69.36 (± 19.27)		
Global Health: C25D1(n= 3, 60)	66.67 (± 28.87)	69.03 (± 19.23)		
Global Health: C26D1(n= 3, 55)	66.67 (± 28.87)	68.64 (± 20.60)		
Global Health: C27D1(n= 3, 52)	66.67 (± 28.87)	68.91 (± 21.84)		
Global Health: C28D1(n= 2, 48)	87.50 (± 17.68)	71.87 (± 20.60)		
Global Health: C29D1(n= 2, 40)	91.67 (± 11.79)	72.71 (± 20.06)		
Global Health: C30D1(n= 1, 30)	83.33 (± 99999)	75.28 (± 18.63)		
Global Health: C31D1(n= 0, 24)	00000 (± 00000)	71.53 (± 21.13)		
Global Health: C32D1(n= 0, 22)	00000 (± 00000)	70.45 (± 20.21)		
Global Health: C33D1(n= 0,16)	00000 (± 00000)	67.19 (± 27.30)		
Global Health: C34D1(n= 0, 14)	00000 (± 00000)	68.45 (± 26.19)		
Global Health: C35D1(n= 0, 12)	00000 (± 00000)	69.44 (± 26.43)		
Global Health: C36D1(n= 0, 8)	00000 (± 00000)	80.21 (± 16.63)		
Global Health: C37D1(n= 0, 5)	00000 (± 00000)	76.67 (± 19.00)		
Global Health: C38D1(n= 0, 2)	00000 (± 00000)	91.67 (± 11.79)		
Global Health: EOT(n= 262, 245)	51.69 (± 24.02)	52.82 (± 24.48)		
Global Health: Pro Week 6 Pd(n= 0,1)	00000 (± 00000)	50.00 (± 99999)		
Global Health: Survival FU 1 (n= 2, 1)	58.33 (± 35.36)	33.33 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: EORTC QLQ-C30 Questionnaire Score: Symptom Subscale

End point title	EORTC QLQ-C30 Questionnaire Score: Symptom Subscale

End point description:

EORTC QLQ-C30 included GHS/QOL, Fx scales (physical, role, cognitive, emotional, social), Sx scales (fatigue, pain, nausea/vomiting), and single items (dyspnea, appetite loss, insomnia, constipation, diarrhea, financial difficulties). Most questions on 4-point scale (1/Not at All to 4/Very Much), except Items 29-30, which comprise GHS scale and were 7-point scale (1/Very Poor to 7/Excellent). For instrument, GHS/QOL and Fx scales linearly transformed so each score 0-100; lower scores=poorer Fx (worsening), higher scores=better Fx (improvement). Sx scales/items also linearly transformed so each score 0-100; higher scores=worse Sx (more severe/worsened), lower scores=less Sx (less severe/improvement). PP-ITT analysis set. 'n'=subjects evaluated at specific timepoint for each group. '99999'=SD non-estimable due to 1 participant evaluated. '00000'=data not reported due to no participant evaluated.

End point type	Secondary

End point timeframe:

Day 1 of each treatment Cycle up to EOT (up to approximately 2.25 years); 6 week following PD (Pro Week 6 Pd) (up to approximately 2.25 years); survival follow-up-1 (up to approximately 2.25 years) (1 Cycle= 21 days)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	425	425		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Nausea/Vomiting: Baseline (n= 389, 413)	8.01 (± 16.34)	7.59 (± 16.35)		
Nausea/Vomiting: C2D1(n= 342, 369)	11.50 (± 19.30)	9.53 (± 17.25)		
Nausea/Vomiting: C3D1(n= 253, 305)	7.05 (± 15.06)	7.27 (± 15.32)		
Nausea/Vomiting: C4D1(n= 223, 279)	7.40 (± 14.37)	7.17 (± 15.50)		
Nausea/Vomiting: C5D1(n= 167, 238)	6.29 (± 12.49)	6.44 (± 14.54)		
Nausea/Vomiting: C6D1(n= 151, 225)	6.40 (± 13.17)	6.44 (± 15.16)		
Nausea/Vomiting: C7D1(n= 88, 190)	6.82 (± 13.28)	5.61 (± 13.74)		
Nausea/Vomiting: C8D1(n= 72, 170)	6.02 (± 12.91)	4.61 (± 10.57)		
Nausea/Vomiting: C9D1(n= 50, 153)	3.33 (± 8.91)	2.83 (± 8.06)		
Nausea/Vomiting: C10D1(n= 47, 146)	2.48 (± 6.93)	3.54 (± 10.02)		
Nausea/Vomiting: C11D1(n= 37, 134)	3.15 (± 6.62)	3.23 (± 8.54)		
Nausea/Vomiting: C12D1(n= 30, 132)	3.89 (± 8.40)	3.03 (± 7.66)		
Nausea/Vomiting: C13D1(n= 19, 124)	4.39 (± 9.37)	3.36 (± 10.19)		
Nausea/Vomiting: C14D1(n= 18, 121)	4.63 (± 9.58)	3.31 (± 9.03)		
Nausea/Vomiting: C15D1(n= 16, 113)	1.04 (± 4.17)	3.83 (± 11.14)		
Nausea/Vomiting: C16D1(n= 13, 109)	5.13 (± 10.51)	2.75 (± 8.64)		
Nausea/Vomiting: C17D1(n= 11, 98)	9.09 (± 13.67)	2.55 (± 8.06)		
Nausea/Vomiting: C18D1(n= 10, 92)	6.67 (± 11.65)	3.08 (± 8.88)		
Nausea/Vomiting: C19D1(n= 9, 84)	3.70 (± 7.35)	4.17 (± 11.53)		
Nausea/Vomiting: C20D1(n= 9, 80)	5.56 (± 8.33)	3.13 (± 11.28)		
Nausea/Vomiting: C21D1(n= 9, 75)	1.85 (± 5.56)	4.89 (± 13.08)		
Nausea/Vomiting: C22D1(n= 8, 69)	6.25 (± 8.63)	1.93 (± 7.31)		
Nausea/Vomiting: C23D1(n= 8, 66)	6.25 (± 12.40)	2.53 (± 6.69)		
Nausea/Vomiting: C24D1(n= 5, 64)	0.00 (± 0.00)	2.34 (± 7.19)		
Nausea/Vomiting: C25D1(n= 3, 60)	0.00 (± 0.00)	1.94 (± 6.21)		
Nausea/Vomiting: C26D1(n= 3, 55)	0.00 (± 0.00)	2.73 (± 8.34)		
Nausea/Vomiting: C27D1(n= 3, 52)	0.00 (± 0.00)	2.24 (± 6.62)		

Nausea/Vomiting: C28D1(n= 1, 49)	0.00 (± 99999)	1.02 (± 4.04)		
Nausea/Vomiting: C29D1(n= 2, 40)	33.33 (± 47.14)	1.67 (± 5.06)		
Nausea/Vomiting: C30D1(n= 1, 31)	0.00 (± 99999)	1.61 (± 5.01)		
Nausea/Vomiting: C31D1(n= 0, 24)	00000 (± 00000)	2.08 (± 5.63)		
Nausea/Vomiting: C32D1(n= 0, 22)	00000 (± 00000)	1.52 (± 4.90)		
Nausea/Vomiting: C33D1(n= 0,16)	00000 (± 00000)	1.04 (± 4.17)		
Nausea/Vomiting: C34D1(n= 0, 14)	00000 (± 00000)	2.38 (± 8.91)		
Nausea/Vomiting: C35D1(n= 0, 12)	00000 (± 00000)	1.39 (± 4.81)		
Nausea/Vomiting: C36D1(n= 0, 8)	00000 (± 00000)	4.17 (± 11.78)		
Nausea/Vomiting: C37D1(n= 0, 5)	00000 (± 00000)	6.67 (± 9.13)		
Nausea/Vomiting: C38D1(n= 0, 2)	00000 (± 00000)	0.00 (± 0.00)		
Nausea/Vomiting: EOT(n= 266, 245)	11.65 (± 20.11)	10.61 (± 17.62)		
Nausea/Vomiting: Pro Week 6 Pd(n= 0,1)	00000 (± 00000)	16.67 (± 99999)		
Nausea/Vomiting: Survival FU 1 (n= 2, 1)	50.00 (± 70.71)	66.67 (± 99999)		
Fatigue: Baseline (n= 390, 413)	37.59 (± 25.69)	36.21 (± 23.92)		
Fatigue: C2D1(n= 343, 369)	40.52 (± 25.68)	39.78 (± 26.17)		
Fatigue: C3D1(n= 256, 304)	35.29 (± 23.97)	33.90 (± 23.75)		
Fatigue: C4D1(n= 224, 278)	35.59 (± 23.10)	30.72 (± 22.57)		
Fatigue: C5D1(n= 167, 238)	36.03 (± 22.40)	30.95 (± 24.13)		
Fatigue: C6D1(n= 151, 225)	36.28 (± 23.40)	28.89 (± 22.66)		
Fatigue: C7D1(n= 88, 190)	34.34 (± 23.02)	28.33 (± 22.15)		
Fatigue: C8D1(n= 72, 170)	30.86 (± 24.12)	27.97 (± 21.56)		
Fatigue: C9D1(n= 50, 153)	28.67 (± 23.45)	25.78 (± 21.39)		
Fatigue: C10D1(n= 47, 145)	29.31 (± 25.21)	26.32 (± 22.27)		
Fatigue: C11D1(n= 37, 134)	27.63 (± 25.07)	25.62 (± 23.05)		
Fatigue: C12D1(n= 30, 132)	28.89 (± 23.99)	26.60 (± 23.37)		
Fatigue: C13D1(n= 19, 124)	22.22 (± 20.29)	27.51 (± 22.73)		
Fatigue: C14D1(n= 18, 121)	21.60 (± 16.82)	26.31 (± 23.13)		
Fatigue: C15D1(n= 16, 112)	20.14 (± 18.24)	27.73 (± 22.56)		
Fatigue: C16D1(n= 13, 109)	21.79 (± 17.64)	27.22 (± 23.35)		
Fatigue: C17D1(n= 11, 98)	22.22 (± 12.17)	27.21 (± 23.56)		
Fatigue: C18D1(n= 10, 92)	26.67 (± 17.53)	27.29 (± 24.18)		

Fatigue: C19D1(n= 9, 84)	22.22 (± 14.70)	27.65 (± 22.85)		
Fatigue: C20D1(n= 9, 80)	32.10 (± 30.15)	25.21 (± 23.47)		
Fatigue: C21D1(n= 9, 75)	28.39 (± 18.52)	26.44 (± 23.66)		
Fatigue: C22D1(n= 8, 69)	33.33 (± 29.10)	22.38 (± 21.77)		
Fatigue: C23D1(n= 8, 66)	25.00 (± 24.31)	24.16 (± 20.59)		
Fatigue: C24D1(n= 5, 64)	31.11 (± 40.37)	23.78 (± 18.87)		
Fatigue: C25D1(n= 3, 60)	11.11 (± 19.24)	23.89 (± 20.94)		
Fatigue: C26D1(n= 3, 55)	18.52 (± 16.97)	28.69 (± 24.54)		
Fatigue: C27D1(n= 3, 52)	11.11 (± 19.24)	22.65 (± 19.80)		
Fatigue: C28D1(n= 1, 49)	0.00 (± 99999)	22.34 (± 18.23)		
Fatigue: C29D1(n= 2, 40)	44.44 (± 47.14)	21.11 (± 18.63)		
Fatigue: C30D1(n= 1, 31)	22.22 (± 99999)	23.66 (± 20.23)		
Fatigue: C31D1(n= 0, 24)	00000 (± 00000)	23.15 (± 20.96)		
Fatigue: C32D1(n= 0, 22)	00000 (± 00000)	25.25 (± 20.63)		
Fatigue: C33D1(n= 0, 16)	00000 (± 00000)	29.86 (± 26.52)		
Fatigue: C34D1(n= 0, 14)	00000 (± 00000)	31.75 (± 24.21)		
Fatigue: C35D1(n= 0, 12)	00000 (± 00000)	25.00 (± 21.25)		
Fatigue: C36D1(n= 0, 8)	00000 (± 00000)	16.67 (± 15.71)		
Fatigue: C37D1(n= 0, 5)	00000 (± 00000)	24.44 (± 16.48)		
Fatigue: C38D1(n= 0, 2)	00000 (± 00000)	16.67 (± 7.86)		
Fatigue: EOT(n= 267, 246)	47.50 (± 26.72)	43.07 (± 28.15)		
Fatigue: Pro Week 6 Pd(n= 0, 1)	00000 (± 00000)	44.44 (± 99999)		
Fatigue: Survival FU-1 (n= 2, 1)	83.33 (± 23.57)	88.89 (± 99999)		
Pain: Baseline (n= 390, 413)	29.70 (± 29.45)	29.98 (± 29.72)		
Pain: C2D1(n= 343, 368)	28.43 (± 27.24)	29.30 (± 29.03)		
Pain: C3D1(n= 256, 305)	22.59 (± 24.93)	24.15 (± 27.50)		
Pain: C4D1(n= 224, 280)	21.65 (± 24.48)	23.75 (± 25.84)		
Pain: C5D1(n= 167, 239)	20.96 (± 22.55)	23.22 (± 25.41)		
Pain: C6D1(n= 151, 225)	22.41 (± 21.95)	21.63 (± 24.68)		
Pain: C7D1(n= 88, 190)	21.59 (± 22.34)	21.58 (± 25.30)		
Pain: C8D1(n= 72, 171)	23.38 (± 22.49)	22.03 (± 24.36)		

Pain: C9D1(n= 50, 153)	16.33 (± 20.89)	19.28 (± 23.50)		
Pain: C10D1(n= 47, 146)	14.54 (± 17.93)	21.00 (± 24.61)		
Pain: C11D1(n= 37, 134)	13.96 (± 22.05)	21.27 (± 26.60)		
Pain: C12D1(n= 30, 132)	13.33 (± 21.17)	18.69 (± 24.71)		
Pain: C13D1(n= 19, 124)	16.67 (± 25.46)	17.74 (± 21.23)		
Pain: C14D1(n= 18, 120)	12.04 (± 15.97)	17.64 (± 22.17)		
Pain: C15D1(n= 16, 113)	10.42 (± 17.08)	17.40 (± 22.86)		
Pain: C16D1(n= 13, 109)	21.79 (± 21.93)	20.64 (± 25.25)		
Pain: C17D1(n= 11, 98)	16.67 (± 19.72)	20.41 (± 25.39)		
Pain: C18D1(n= 10, 92)	11.67 (± 22.29)	20.83 (± 24.54)		
Pain: C19D1(n= 9, 84)	14.81 (± 22.74)	22.42 (± 28.16)		
Pain: C20D1(n=9, 80)	27.78 (± 31.18)	20.00 (± 23.78)		
Pain: C21D1(n= 9, 75)	14.81 (± 17.57)	19.78 (± 25.95)		
Pain: C22D1(n= 8, 69)	18.75 (± 20.77)	15.22 (± 19.75)		
Pain: C23D1(n= 8, 66)	14.58 (± 27.37)	16.92 (± 23.11)		
Pain: C24D1(n=5, 64)	30.00 (± 36.13)	20.05 (± 25.05)		
Pain: C25D1(n= 3, 60)	16.67 (± 28.87)	18.33 (± 22.90)		
Pain: C26D1(n= 3, 55)	22.22 (± 19.24)	16.36 (± 21.87)		
Pain: C27D1(n= 3, 52)	11.11 (± 19.24)	15.06 (± 20.41)		
Pain: C28D1(n= 1, 49)	0.00 (± 99999)	14.29 (± 18.63)		
Pain: C29D1(n= 2, 40)	41.67 (± 58.93)	13.75 (± 18.06)		
Pain: C30D1(n= 1, 31)	0.00 (± 99999)	15.05 (± 21.24)		
Pain: C31D1(n= 0, 24)	00000 (± 00000)	14.58 (± 21.03)		
Pain: C32D1(n= 0, 22)	00000 (± 00000)	16.67 (± 24.67)		
Pain: C33D1(n= 0, 16)	00000 (± 00000)	20.83 (± 27.55)		
Pain: C34D1(n= 0, 14)	00000 (± 00000)	26.19 (± 27.51)		
Pain: C35D1(n= 0, 12)	00000 (± 00000)	22.22 (± 25.95)		
Pain: C36D1(n= 0, 8)	00000 (± 00000)	22.92 (± 34.43)		
Pain: C37D1(n= 0, 5)	00000 (± 00000)	30.00 (± 34.16)		
Pain: C38D1(n= 0, 2)	00000 (± 00000)	0.00 (± 0.00)		
Pain: EOT (n= 267, 247)	00000 (± 00000)	35.43 (± 31.22)		

Pain: Pro Week 6 Pd(n= 0,1)	32.21 (± 30.36)	16.67 (± 99999)		
Pain: Survival FU-1 (n= 2,1)	66.67 (± 47.14)	83.33 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: EORTC QLQ-LC13 Questionnaire Score: Alopecia

End point title	EORTC QLQ-LC13 Questionnaire Score: Alopecia

End point description:

QLQ-LC13 consisted of 13 questions relating to disease symptoms specific to lung cancer and treatment side effects typical of treatment with chemotherapy and radiotherapy experienced during past 1 week. The 13 questions comprised 1 multi-item scale for dyspnea and 10 single-item symptoms and side effects (coughing, hemoptysis, sore mouth, dysphagia, peripheral neuropathy, alopecia, pain in chest, pain in arm or shoulder, pain in other parts. Response range: (1) not at all to (4) very much. Scores for each item were transformed to 0 to 100, where higher symptom score = greater degree of symptoms. Results have been reported for alopecia. The PP-ITT analysis set. Here, 'n' signifies those participants evaluated for this measure at specific time point for each group respectively. '99999' denotes data not reported because SD was non-estimable since only 1 participant was evaluated for this category. '00000' denotes data not reported because no participant was evaluated for this category.

End point type	Secondary

End point timeframe:

Day 1 of each treatment Cycle up to EOT (up to approximately 2.25 years); 6 week following PD (Pro Week 6 Pd) (up to approximately 2.25 years); survival follow-up-1 (up to approximately 2.25 years) (1 Cycle= 21 days)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	425	425		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Alopecia: Baseline (n= 384, 405)	13.89 (± 27.95)	14.32 (± 29.07)		
Alopecia: C2D1(n= 332, 357)	60.44 (± 36.66)	6.63 (± 16.84)		
Alopecia: C3D1(n= 248, 300)	56.72 (± 35.86)	7.44 (± 18.89)		
Alopecia: C4D1(n= 219, 270)	52.36 (± 35.24)	7.41 (± 19.14)		
Alopecia: C5D1(n= 163, 234)	56.65 (± 37.25)	6.41 (± 16.68)		
Alopecia: C6D1(n= 147, 220)	54.42 (± 37.64)	7.88 (± 19.34)		
Alopecia: C7D1(n= 87, 186)	52.11 (± 39.28)	5.91 (± 16.10)		
Alopecia: C8D1(n= 70, 166)	48.57 (± 37.94)	6.63 (± 17.68)		
Alopecia: C9D1(n= 47, 150)	48.23 (± 39.81)	5.11 (± 14.83)		
Alopecia: C10D1(n= 45, 142)	49.63 (± 39.96)	3.76 (± 13.23)		

Alopecia: C11D1(n= 36, 130)	47.22 (± 45.34)	3.08 (± 11.33)		
Alopecia: C12D1(n= 29, 129)	36.78 (± 43.04)	4.91 (± 13.88)		
Alopecia: C13D1(n= 19, 121)	42.11 (± 41.34)	6.06 (± 15.52)		
Alopecia: C14D1(n= 18, 119)	29.63 (± 35.95)	5.60 (± 14.60)		
Alopecia: C15D1(n= 16, 110)	33.33 (± 34.43)	7.27 (± 17.12)		
Alopecia: C16D1(n= 12, 105)	27.78 (± 31.25)	7.30 (± 17.89)		
Alopecia: C17D1(n= 11, 95)	21.21 (± 30.81)	9.47 (± 19.85)		
Alopecia: C18D1(n= 9, 90)	22.22 (± 33.33)	8.89 (± 17.16)		
Alopecia: C19D1(n= 8, 81)	25.00 (± 34.50)	10.29 (± 18.74)		
Alopecia: C20D1(n= 9, 78)	44.44 (± 44.10)	8.55 (± 15.60)		
Alopecia: C21D1(n= 9, 73)	22.22 (± 33.33)	9.59 (± 16.18)		
Alopecia: C22D1(n= 7, 67)	9.52 (± 16.26)	9.45 (± 16.21)		
Alopecia: C23D1(n= 8, 64)	29.17 (± 37.53)	11.46 (± 18.99)		
Alopecia: C24D1(n= 5, 62)	13.33 (± 18.26)	8.06 (± 15.61)		
Alopecia: C25D1(n= 2, 58)	0.00 (± 0.00)	9.77 (± 16.53)		
Alopecia: C26D1(n= 2, 53)	0.00 (± 0.00)	9.43 (± 16.51)		
Alopecia: C27D1(n= 3, 50)	33.33 (± 57.74)	9.33 (± 16.55)		
Alopecia: C28D1(n= 2, 46)	0.00 (± 0.00)	6.52 (± 15.10)		
Alopecia: C29D1(n= 2, 38)	0.00 (± 0.00)	8.77 (± 20.04)		
Alopecia: C30D1(n= 1, 31)	0.00 (± 99999)	10.75 (± 19.98)		
Alopecia: C31D1(n= 0, 24)	00000 (± 00000)	9.72 (± 20.80)		
Alopecia: C32D1(n= 0, 23)	00000 (± 00000)	7.25 (± 19.99)		
Alopecia: C33D1(n= 0,16)	00000 (± 00000)	8.33 (± 22.77)		
Alopecia: C34D1(n= 0, 14)	00000 (± 00000)	9.52 (± 20.38)		
Alopecia: C35D1(n= 0, 11)	00000 (± 00000)	6.06 (± 13.48)		
Alopecia: C36D1(n= 0, 8)	00000 (± 00000)	4.17 (± 11.78)		
Alopecia: C37D1(n= 0, 5)	00000 (± 00000)	6.67 (± 14.91)		
Alopecia: C38D1(n= 0, 2)	00000 (± 00000)	0.00 (± 0.00)		
Alopecia: EOT(n= 261, 243)	53.51 (± 38.91)	6.58 (± 17.48)		
Alopecia: Pro Week 6 Pd(n= 0,1)	00000 (± 00000)	100.00 (± 99999)		
Alopecia: Survival FU 1 (n= 2, 1)	100.00 (± 0.00)	66.67 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: EORTC QLQ-LC13 Questionnaire Score: Coughing

End point title	EORTC QLQ-LC13 Questionnaire Score: Coughing

End point description:

QLQ-LC13 consisted of 13 questions relating to disease symptoms specific to lung cancer and treatment side effects typical of treatment with chemotherapy and radiotherapy experienced during past 1 week. The 13 questions comprised 1 multi-item scale for dyspnea and 10 single-item symptoms and side effects (coughing, hemoptysis, sore mouth, dysphagia, peripheral neuropathy, alopecia, pain in chest, pain in arm or shoulder, pain in other parts. Response range: (1) not at all to (4) very much. Scores for each item were transformed to 0 to 100, where higher symptom score = greater degree of symptoms. Results have been reported for coughing. The PP-ITT analysis set. Here, 'n' signifies those participants evaluated for this measure at specific time point for each group respectively. '99999' denotes data not reported because SD was non-estimable since only 1 participant was evaluated for this category. '00000' denotes data not reported because no participant was evaluated for this category.

End point type	Secondary

End point timeframe:

Day 1 of each treatment Cycle up to EOT (up to approximately 2.25 years); 6 week following PD (Pro Week 6 Pd) (up to approximately 2.25 years); survival follow-up-1 (up to approximately 2.25 years) (1 Cycle= 21 days)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	425	425		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Coughing: Baseline (n= 383, 406)	38.73 (± 29.64)	37.27 (± 27.23)		
Coughing: C2D1(n= 333, 360)	36.54 (± 28.04)	37.50 (± 28.33)		
Coughing: C3D1(n= 250, 298)	33.73 (± 27.46)	33.89 (± 24.99)		
Coughing: C4D1(n= 219, 272)	31.35 (± 24.13)	32.48 (± 25.52)		
Coughing: C5D1(n= 164, 235)	32.72 (± 23.49)	31.35 (± 25.52)		
Coughing: C6D1(n= 147, 219)	31.75 (± 24.78)	31.05 (± 24.73)		
Coughing: C7D1(n= 87, 185)	32.95 (± 24.64)	30.99 (± 25.07)		
Coughing: C8D1(n= 69, 166)	30.43 (± 28.43)	29.12 (± 25.73)		
Coughing: C9D1(n= 50, 150)	24.67 (± 17.57)	29.11 (± 24.52)		
Coughing: C10D1(n= 47, 140)	23.40 (± 19.55)	27.86 (± 22.83)		
Coughing: C11D1(n= 37, 129)	21.62 (± 19.59)	27.39 (± 23.37)		
Coughing: C12D1(n= 30, 129)	20.00 (± 18.77)	25.06 (± 23.95)		
Coughing: C13D1(n= 19, 121)	15.79 (± 17.10)	24.79 (± 23.78)		
Coughing: C14D1(n= 18, 119)	16.67 (± 17.15)	24.37 (± 22.42)		

Coughing: C15D1(n= 16, 110)	12.50 (± 16.67)	25.76 (± 23.31)		
Coughing: C16D1(n= 13, 106)	20.51 (± 21.68)	24.53 (± 22.21)		
Coughing: C17D1(n= 11, 94)	21.21 (± 16.82)	24.82 (± 23.92)		
Coughing: C18D1(n= 10, 90)	26.67 (± 21.08)	26.30 (± 24.22)		
Coughing: C19D1(n= 9, 82)	22.22 (± 16.67)	25.61 (± 26.86)		
Coughing: C20D1(n= 9, 78)	25.93 (± 14.70)	28.21 (± 26.36)		
Coughing: C21D1(n= 9, 73)	22.22 (± 16.67)	28.77 (± 27.95)		
Coughing: C22D1(n= 8, 67)	25.00 (± 38.83)	22.89 (± 23.36)		
Coughing: C23D1(n= 8, 64)	20.83 (± 17.25)	23.44 (± 26.35)		
Coughing: C24D1(n= 5, 62)	26.67 (± 14.91)	24.73 (± 23.33)		
Coughing: C25D1(n= 3, 58)	33.33 (± 0.00)	25.86 (± 23.40)		
Coughing: C26D1(n= 3, 53)	44.44 (± 19.25)	26.41 (± 24.77)		
Coughing: C27D1(n= 3, 50)	11.11 (± 19.24)	24.67 (± 22.14)		
Coughing: C28D1(n= 2, 46)	16.67 (± 23.57)	20.29 (± 20.46)		
Coughing: C29D1(n= 2, 38)	16.67 (± 23.57)	19.30 (± 22.77)		
Coughing: C30D1(n= 1, 31)	0.00 (± 99999)	18.28 (± 20.80)		
Coughing: C31D1(n= 0, 24)	00000 (± 00000)	23.61 (± 25.02)		
Coughing: C32D1(n= 0, 23)	00000 (± 00000)	26.09 (± 19.99)		
Coughing: C33D1(n= 0,16)	00000 (± 00000)	27.08 (± 32.70)		
Coughing: C34D1(n= 0, 14)	00000 (± 00000)	26.19 (± 29.75)		
Coughing: C35D1(n= 0, 11)	00000 (± 00000)	21.21 (± 22.47)		
Coughing: C36D1(n= 0, 8)	00000 (± 00000)	25.00 (± 15.43)		
Coughing: C37D1(n= 0, 5)	00000 (± 00000)	26.67 (± 14.91)		
Coughing: C38D1(n= 0, 2)	00000 (± 00000)	33.33 (± 0.00)		
Coughing: EOT(n= 262, 246)	35.75 (± 27.03)	38.48 (± 26.95)		
Coughing: Pro Week 6 Pd(n= 0,1)	00000 (± 00000)	33.33 (± 99999)		
Coughing: Survival FU 1 (n= 2, 1)	50.00 (± 23.57)	33.33 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: EORTC QLQ-LC13 Questionnaire Score: Dysphagia

End point title	EORTC QLQ-LC13 Questionnaire Score: Dysphagia

End point description:

QLQ-LC13:13 questions relating to disease symptoms specific to lung cancer and treatment side effects typical of treatment with chemotherapy and radiotherapy experienced during past 1 week. The 13 questions comprised 1 multi-item scale for dyspnea and 10 single-item symptoms and side effects (coughing, hemoptysis, sore mouth, dysphagia, peripheral neuropathy, alopecia, pain in chest, pain in arm or shoulder, pain in other parts. Response range: (1) not at all to (4) very much. Scores for each item were transformed to 0 to 100, where higher symptom score = greater degree of symptoms. Results have been reported for dysphagia. The PP-ITT analysis set. Here, 'n' signifies those participants evaluated for this measure at specific time point for each group respectively. '99999' denotes data not reported because SD was non-estimable since only 1 participant was evaluated for this category. '00000' denotes data not reported because no participant was evaluated for this category.

End point type	Secondary

End point timeframe:

Day 1 of each treatment Cycle up to EOT (up to approximately 2.25 years); 6 week following PD (Pro Week 6 Pd) (up to approximately 2.25 years); survival follow-up-1 (up to approximately 2.25 years) (1 Cycle= 21 days)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	425	425		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Dysphagia: Baseline (n= 387, 406)	6.20 (± 17.52)	5.09 (± 15.05)		
Dysphagia: C2D1(n= 336, 358)	10.22 (± 21.50)	6.42 (± 15.75)		
Dysphagia: C3D1(n= 251, 301)	9.16 (± 20.87)	5.43 (± 14.53)		
Dysphagia: C4D1(n= 217, 272)	8.60 (± 19.45)	5.88 (± 16.39)		
Dysphagia: C5D1(n= 163, 236)	6.75 (± 16.63)	6.64 (± 16.79)		
Dysphagia: C6D1(n= 147, 219)	6.80 (± 15.58)	4.72 (± 13.28)		
Dysphagia: C7D1(n= 87, 187)	4.21 (± 11.14)	5.70 (± 15.17)		
Dysphagia: C8D1(n=70, 167)	5.71 (± 12.65)	4.79 (± 12.82)		
Dysphagia: C9D1(n= 50, 151)	1.33 (± 6.60)	4.64 (± 14.42)		
Dysphagia: C10D1(n= 47, 143)	1.42 (± 6.80)	5.36 (± 15.14)		
Dysphagia: C11D1(n= 37, 130)	1.80 (± 7.64)	2.82 (± 11.01)		
Dysphagia: C12D1(n= 29, 129)	2.30 (± 8.60)	3.88 (± 12.93)		
Dysphagia: C13D1(n= 19, 121)	0.00 (± 0.00)	3.86 (± 11.54)		
Dysphagia: C14D1(n= 18, 119)	5.56 (± 12.78)	5.04 (± 13.47)		
Dysphagia: C15D1(n= 16, 110)	0.00 (± 0.00)	3.33 (± 11.01)		
Dysphagia: C16D1(n= 13, 106)	0.00 (± 0.00)	3.77 (± 12.45)		
Dysphagia: C17D1(n= 11, 95)	3.03 (± 10.05)	3.86 (± 13.63)		
Dysphagia: C18D1(n= 10, 90)	0.00 (± 0.00)	4.44 (± 15.96)		
Dysphagia: C19D1(n= 9, 82)	3.70 (± 11.11)	5.28 (± 15.24)		
Dysphagia: C20D1(n= 9, 78)	0.00 (± 0.00)	4.70 (± 12.85)		
Dysphagia: C21D1(n= 9, 73)	0.00 (± 0.00)	5.02 (± 15.39)		
Dysphagia: C22D1(n= 8, 67)	0.00 (± 0.00)	2.99 (± 11.21)		
Dysphagia: C23D1(n= 8, 64)	0.00 (± 0.00)	3.65 (± 12.05)		
Dysphagia: C24D1(n= 5, 62)	0.00 (± 0.00)	4.84 (± 15.79)		

Dysphagia: C25D1(n= 3, 58)	0.00 (± 0.00)	4.02 (± 15.39)		
Dysphagia: C26D1(n= 3, 53)	0.00 (± 0.00)	4.40 (± 13.14)		
Dysphagia: C27D1(n= 3, 50)	0.00 (± 0.00)	2.67 (± 11.35)		
Dysphagia: C28D1(n= 2, 46)	0.00 (± 0.00)	4.35 (± 15.09)		
Dysphagia: C29D1(n= 2, 38)	0.00 (± 0.00)	4.39 (± 13.80)		
Dysphagia: C30D1(n= 1, 31)	0.00 (± 99999)	5.38 (± 15.15)		
Dysphagia: C31D1(n= 0, 24)	00000 (± 00000)	5.56 (± 21.23)		
Dysphagia: C32D1(n= 0, 23)	00000 (± 00000)	7.25 (± 17.28)		
Dysphagia: C33D1(n= 0,16)	00000 (± 00000)	6.25 (± 13.44)		
Dysphagia: C34D1(n= 0, 14)	00000 (± 00000)	9.52 (± 20.38)		
Dysphagia: C35D1(n= 0, 11)	00000 (± 00000)	3.03 (± 10.05)		
Dysphagia: C36D1(n= 0, 8)	00000 (± 00000)	4.17 (± 11.78)		
Dysphagia: C37D1(n= 0, 5)	00000 (± 00000)	6.67 (± 14.91)		
Dysphagia: C38D1(n= 0, 2)	00000 (± 00000)	0.00 (± 0.00)		
Dysphagia: EOT(n= 264, 245)	10.23 (± 20.77)	8.98 (± 18.87)		
Dysphagia: Pro Week 6 Pd(n= 0,1)	00000 (± 00000)	0.00 (± 99999)		
Dysphagia: Survival FU 1 (n= 2, 1)	0.00 (± 0.00)	0.00 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: EORTC QLQ-LC13 Questionnaire Score: Dyspnea

End point title	EORTC QLQ-LC13 Questionnaire Score: Dyspnea

End point description:

QLQ-LC13 consisted of 13 questions relating to disease symptoms specific to lung cancer and treatment side effects typical of treatment with chemotherapy and radiotherapy experienced during past 1 week. The 13 questions comprised 1 multi-item scale for dyspnea and 10 single-item symptoms and side effects (coughing, hemoptysis, sore mouth, dysphagia, peripheral neuropathy, alopecia, pain in chest, pain in arm or shoulder, pain in other parts. Response range: (1) not at all to (4) very much. Scores for each item were transformed to 0 to 100, where higher symptom score = greater degree of symptoms. Results have been reported for dyspnea. The PP-ITT analysis set. Here, 'n' signifies those participants evaluated for this measure at specific time point for each group respectively. '99999' denotes data not reported because SD was non-estimable since only 1 participant was evaluated for this category. '00000' denotes data not reported because no participant was evaluated for this category.

End point type	Secondary

End point timeframe:

Day 1 of each treatment Cycle up to EOT (up to approximately 2.25 years); 6 week following PD (Pro Week 6 Pd) (up to approximately 2.25 years); survival follow-up-1 (up to approximately 2.25 years) (1 Cycle= 21 days)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	425	425		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Dyspnea: Baseline (n= 386, 407)	28.55 (± 23.21)	26.78 (± 22.43)		
Dyspnea: C2D1(n= 335, 361)	28.14 (± 23.48)	28.79 (± 23.67)		
Dyspnea: C3D1(n= 252, 301)	28.13 (± 22.45)	25.40 (± 20.60)		
Dyspnea: C4D1(n= 220, 273)	27.75 (± 19.85)	25.17 (± 21.14)		
Dyspnea: C5D1(n= 165, 236)	26.57 (± 19.61)	24.72 (± 19.90)		
Dyspnea: C6D1(n= 148, 221)	29.69 (± 21.94)	24.01 (± 21.09)		
Dyspnea: C7D1(n= 87, 187)	25.35 (± 21.07)	24.42 (± 21.23)		
Dyspnea: C8D1(n=70, 167)	28.02 (± 24.12)	24.42 (± 22.33)		
Dyspnea: C9D1(n= 50, 151)	26.00 (± 21.49)	22.44 (± 21.87)		
Dyspnea: C10D1(n= 47, 143)	27.42 (± 22.56)	22.18 (± 21.35)		
Dyspnea: C11D1(n= 37, 130)	22.67 (± 19.79)	20.43 (± 21.44)		
Dyspnea: C12D1(n= 30, 129)	22.41 (± 18.94)	22.27 (± 20.47)		
Dyspnea: C13D1(n= 19, 121)	16.37 (± 15.87)	22.22 (± 21.52)		
Dyspnea: C14D1(n= 18, 119)	17.90 (± 12.13)	22.41 (± 20.66)		
Dyspnea: C15D1(n= 16, 110)	15.28 (± 12.75)	22.12 (± 18.71)		
Dyspnea: C16D1(n= 13, 106)	14.53 (± 13.13)	21.91 (± 20.71)		
Dyspnea: C17D1(n= 10, 95)	18.89 (± 14.86)	23.51 (± 21.84)		
Dyspnea: C18D1(n= 10, 90)	20.00 (± 12.61)	22.65 (± 21.97)		
Dyspnea: C19D1(n= 9, 82)	18.52 (± 13.61)	22.09 (± 20.91)		
Dyspnea: C20D1(n= 9, 78)	20.37 (± 15.21)	22.65 (± 21.37)		
Dyspnea: C21D1(n= 9, 73)	19.75 (± 15.49)	20.40 (± 19.69)		
Dyspnea: C22D1(n= 8, 67)	18.06 (± 20.52)	19.90 (± 17.68)		
Dyspnea: C23D1(n= 8, 64)	16.67 (± 13.28)	21.2 (± 19.13)		
Dyspnea: C24D1(n= 5, 62)	20.00 (± 14.49)	21.33 (± 20.94)		
Dyspnea: C25D1(n= 3, 58)	29.63 (± 25.66)	19.73 (± 18.39)		
Dyspnea: C26D1(n= 3, 53)	22.22 (± 11.11)	21.80 (± 19.97)		
Dyspnea: C27D1(n= 3, 50)	18.52 (± 6.41)	20.33 (± 20.87)		
Dyspnea: C28D1(n= 2, 46)	5.56 (± 7.86)	18.36 (± 17.87)		

Dyspnea: C29D1(n= 2, 38)	5.56 (± 7.86)	19.30 (± 16.48)		
Dyspnea: C30D1(n= 1, 31)	11.11 (± 99999)	17.92 (± 17.14)		
Dyspnea: C31D1(n= 0, 24)	00000 (± 00000)	24.07 (± 18.73)		
Dyspnea: C32D1(n= 0, 23)	00000 (± 00000)	24.15 (± 20.00)		
Dyspnea: C33D1(n= 0,16)	00000 (± 00000)	25.69 (± 27.13)		
Dyspnea: C34D1(n= 0, 14)	00000 (± 00000)	27.78 (± 22.96)		
Dyspnea: C35D1(n= 0, 11)	00000 (± 00000)	26.26 (± 19.42)		
Dyspnea: C36D1(n= 0, 8)	00000 (± 00000)	18.06 (± 13.20)		
Dyspnea: C37D1(n= 0, 5)	00000 (± 00000)	24.44 (± 4.97)		
Dyspnea: C38D1(n= 0, 2)	00000 (± 00000)	16.67 (± 7.86)		
Dyspnea: EOT(n= 263, 246)	36.12 (± 24.82)	34.51 (± 26.36)		
Dyspnea: Pro Week 6 Pd(n= 0,1)	00000 (± 00000)	22.22 (± 99999)		
Dyspnea: Survival FU 1 (n= 2, 1)	66.67 (± 15.71)	44.44 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: EORTC QLQ-LC13 Questionnaire Score: Hemoptysis

End point title	EORTC QLQ-LC13 Questionnaire Score: Hemoptysis

End point description:

QLQ-LC13:13 questions relating to disease symptoms specific to lung cancer and treatment side effects typical of treatment with chemotherapy and radiotherapy experienced during past 1 week. The 13 questions comprised 1 multi-item scale for dyspnea and 10 single-item symptoms and side effects (coughing, hemoptysis, sore mouth, dysphagia, peripheral neuropathy, alopecia, pain in chest, pain in arm or shoulder, pain in other parts. Response range: (1) not at all to (4) very much. Scores for each item were transformed to 0 to 100, where higher symptom score = greater degree of symptoms. Results have been reported for hemoptysis. The PP-ITT analysis set. Here, 'n' signifies those participants evaluated for this measure at specific time point for each group respectively. '99999' denotes data not reported because SD was non-estimable since only 1 participant was evaluated for this category. '00000' denotes data not reported because no participant was evaluated for this category.

End point type	Secondary

End point timeframe:

Day 1 of each treatment Cycle up to EOT (up to approximately 2.25 years); 6 week following PD (Pro Week 6 Pd) (up to approximately 2.25 years); survival follow-up-1 (up to approximately 2.25 years) (1 Cycle= 21 days)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	425	425		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Hemoptysis: Baseline (n= 386, 406)	4.32 (± 13.32)	3.86 (± 12.12)		
Hemoptysis: C2D1(n= 336, 359)	4.76 (± 14.24)	3.16 (± 10.97)		
Hemoptysis: C3D1(n= 251, 301)	4.38 (± 13.11)	3.10 (± 11.12)		
Hemoptysis: C4D1(n= 220, 270)	2.88 (± 10.89)	2.10 (± 9.94)		
Hemoptysis: C5D1(n= 163, 234)	1.43 (± 7.72)	1.42 (± 6.76)		
Hemoptysis: C6D1(n= 148, 219)	1.80 (± 7.56)	1.22 (± 6.27)		
Hemoptysis: C7D1(n= 87, 187)	1.15 (± 6.12)	1.43 (± 6.76)		
Hemoptysis: C8D1(n=70, 166)	1.90 (± 9.64)	2.41 (± 10.09)		
Hemoptysis: C9D1(n= 50, 151)	2.00 (± 8.00)	1.77 (± 7.49)		
Hemoptysis: C10D1(n= 47, 143)	2.84 (± 9.40)	0.70 (± 4.79)		
Hemoptysis: C11D1(n= 37, 130)	1.80 (± 7.64)	1.03 (± 5.78)		
Hemoptysis: C12D1(n= 30, 129)	0.00 (± 0.00)	1.03 (± 5.80)		
Hemoptysis: C13D1(n= 19, 121)	3.51 (± 10.51)	1.10 (± 5.98)		
Hemoptysis: C14D1(n= 18, 119)	1.85 (± 7.86)	1.68 (± 7.32)		
Hemoptysis: C15D1(n= 16, 110)	0.00 (± 0.00)	1.82 (± 10.91)		
Hemoptysis: C16D1(n= 13, 106)	0.00 (± 0.00)	2.83 (± 10.41)		
Hemoptysis: C17D1(n= 11, 94)	0.00 (± 0.00)	2.84 (± 12.61)		
Hemoptysis: C18D1(n= 10, 90)	0.00 (± 0.00)	2.96 (± 12.88)		
Hemoptysis: C19D1(n= 9, 82)	0.00 (± 0.00)	2.03 (± 12.11)		
Hemoptysis: C20D1(n= 9, 78)	0.00 (± 0.00)	2.56 (± 12.90)		
Hemoptysis: C21D1(n= 8, 73)	0.00 (± 0.00)	1.83 (± 7.64)		
Hemoptysis: C22D1(n= 8, 67)	0.00 (± 0.00)	1.99 (± 9.85)		
Hemoptysis: C23D1(n= 8, 64)	0.00 (± 0.00)	1.04 (± 5.85)		
Hemoptysis: C24D1(n= 5, 61)	0.00 (± 0.00)	2.73 (± 11.05)		
Hemoptysis: C25D1(n= 3, 58)	0.00 (± 0.00)	3.45 (± 13.52)		
Hemoptysis: C26D1(n= 3, 53)	0.00 (± 0.00)	3.77 (± 14.11)		
Hemoptysis: C27D1(n= 3, 50)	0.00 (± 0.00)	2.00 (± 8.00)		
Hemoptysis: C28D1(n= 2, 46)	33.33 (± 47.14)	1.45 (± 6.87)		
Hemoptysis: C29D1(n= 2, 38)	0.00 (± 0.00)	0.88 (± 5.41)		
Hemoptysis: C30D1(n= 1, 31)	0.00 (± 99999)	1.08 (± 5.99)		
Hemoptysis: C31D1(n= 0, 24)	00000 (± 00000)	2.78 (± 9.41)		
Hemoptysis: C32D1(n= 0, 23)	00000 (± 00000)	2.90 (± 9.60)		
Hemoptysis: C33D1(n= 0,16)	00000 (± 00000)	0.00 (± 0.00)		
Hemoptysis: C34D1(n= 0, 14)	00000 (± 00000)	0.00 (± 0.00)		
Hemoptysis: C35D1(n= 0, 11)	00000 (± 00000)	0.00 (± 0.00)		
Hemoptysis: C36D1(n= 0, 8)	00000 (± 00000)	4.17 (± 11.78)		
Hemoptysis: C37D1(n= 0, 5)	00000 (± 00000)	0.00 (± 0.00)		
Hemoptysis: C38D1(n= 0, 2)	00000 (± 00000)	0.00 (± 0.00)		
Hemoptysis: EOT(n= 264, 243)	5.18 (± 14.33)	6.04 (± 16.60)		
Hemoptysis: Pro Week 6 Pd(n= 0,1)	00000 (± 00000)	0.00 (± 99999)		

Hemoptysis: Survival FU 1 (n= 2, 1)	33.33 (± 47.14)	0.00 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: EORTC QLQ-LC13 Questionnaire Score: Pain in Arm Or Shoulder

End point title	EORTC QLQ-LC13 Questionnaire Score: Pain in Arm Or Shoulder

End point description:

QLQ-LC13 consisted of 13 questions relating to disease symptoms specific to lung cancer and treatment side effects typical of treatment with chemotherapy and radiotherapy experienced during past 1 week. The 13 questions comprised 1 multi-item scale for dyspnea and 10 single-item symptoms and side effects (coughing, hemoptysis, sore mouth, dysphagia, peripheral neuropathy, alopecia, pain in chest, pain in arm or shoulder, pain in other parts. Response range: (1) not at all to (4) very much. Scores for each item were transformed to 0 to 100, where higher symptom score = greater degree of symptoms. Results have been reported for pain in arm or shoulder. The PP-ITT analysis set. 'n'=participants evaluated for this measure at specific time point for each group respectively. '99999' denotes data not reported because SD was non-estimable since only 1 participant was evaluated for this category. '00000' denotes data not reported because no participant was evaluated for this category.

End point type	Secondary

End point timeframe:

Day 1 of each treatment Cycle up to EOT (up to approximately 2.25 years); 6 week following PD (up to approximately 2.25 years); survival follow-up-1 (up to approximately 2.25 years) (1 Cycle= 21 days)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	425	425		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Pain in Arm or Shoulder: Baseline (n= 384, 405)	20.49 (± 28.85)	20.16 (± 27.09)		
Pain in Arm or Shoulder: C2D1(n= 332, 358)	19.58 (± 27.45)	18.34 (± 26.56)		
Pain in Arm or Shoulder: C3D1(n= 248, 294)	17.20 (± 27.16)	16.44 (± 25.50)		
Pain in Arm or Shoulder: C4D1(n= 217, 270)	14.75 (± 23.74)	18.15 (± 26.57)		
Pain in Arm or Shoulder: C5D1(n= 164, 232)	16.06 (± 24.06)	14.94 (± 23.76)		
Pain in Arm or Shoulder: C6D1(n= 147, 219)	15.42 (± 23.17)	15.68 (± 24.37)		
Pain in Arm or Shoulder: C7D1(n= 86, 184)	14.73 (± 23.77)	16.67 (± 26.31)		
Pain in Arm or Shoulder: C8D1(n=69, 163)	15.94 (± 25.95)	16.77 (± 25.22)		
Pain in Arm or Shoulder: C9D1(n= 50, 149)	14.00 (± 24.36)	16.78 (± 25.89)		
Pain in Arm or Shoulder: C10D1(n= 46, 141)	14.49 (± 20.67)	17.73 (± 27.18)		

Pain in Arm or Shoulder: C11D1(n= 36, 127)	11.11 (± 19.52)	15.49 (± 26.82)		
Pain in Arm or Shoulder: C12D1(n= 30, 126)	12.22 (± 18.54)	16.93 (± 26.91)		
Pain in Arm or Shoulder: C13D1(n= 19, 117)	12.28 (± 19.91)	14.81 (± 22.93)		
Pain in Arm or Shoulder: C14D1(n= 18, 117)	11.11 (± 19.80)	15.67 (± 22.56)		
Pain in Arm or Shoulder: C15D1(n= 16, 108)	12.50 (± 20.64)	15.74 (± 24.31)		
Pain in Arm or Shoulder: C16D1(n= 13, 104)	7.69 (± 14.62)	14.10 (± 23.54)		
Pain in Arm or Shoulder: C17D1(n= 11, 93)	9.09 (± 15.57)	16.49 (± 25.83)		
Pain in Arm or Shoulder: C18D1(n= 10, 88)	13.33 (± 23.31)	18.18 (± 25.73)		
Pain in Arm or Shoulder: C19D1(n= 9, 80)	7.41 (± 14.70)	20.83 (± 29.23)		
Pain in Arm or Shoulder: C20D1(n= 9, 76)	11.11 (± 23.57)	18.42 (± 25.18)		
Pain in Arm or Shoulder: C21D1(n= 9, 71)	11.11 (± 16.67)	12.68 (± 19.81)		
Pain in Arm or Shoulder: C22D1(n= 8, 65)	16.67 (± 25.20)	13.33 (± 21.89)		
Pain in Arm or Shoulder: C23D1(n= 8, 62)	16.67 (± 25.20)	15.05 (± 22.32)		
Pain in Arm or Shoulder: C24D1(n= 5, 59)	20.00 (± 29.81)	18.08 (± 24.23)		
Pain in Arm or Shoulder: C25D1(n= 3, 57)	11.11 (± 19.24)	14.62 (± 21.84)		
Pain in Arm or Shoulder: C26D1(n= 2, 52)	16.67 (± 23.57)	15.38 (± 22.35)		
Pain in Arm or Shoulder: C27D1(n= 3, 49)	11.11 (± 19.24)	14.97 (± 23.63)		
Pain in Arm or Shoulder: C28D1(n= 2, 45)	0.00 (± 0.00)	11.85 (± 19.01)		
Pain in Arm or Shoulder: C29D1(n= 2, 37)	0.00 (± 0.00)	10.81 (± 22.30)		
Pain in Arm or Shoulder: C30D1(n= 1, 30)	0.00 (± 99999)	10.00 (± 21.71)		
Pain in Arm or Shoulder: C31D1(n= 0, 23)	00000 (± 00000)	10.14 (± 21.17)		
Pain in Arm or Shoulder: C32D1(n= 0, 22)	00000 (± 00000)	13.64 (± 26.55)		
Pain in Arm or Shoulder: C33D1(n= 0, 15)	00000 (± 00000)	20.00 (± 27.60)		
Pain in Arm or Shoulder: C34D1(n= 0, 14)	00000 (± 00000)	16.67 (± 28.49)		
Pain in Arm or Shoulder: C35D1(n= 0, 11)	00000 (± 00000)	27.27 (± 32.72)		
Pain in Arm or Shoulder: C36D1(n= 0, 8)	00000 (± 00000)	16.67 (± 35.63)		
Pain in Arm or Shoulder: C37D1(n= 0, 5)	00000 (± 00000)	33.33 (± 47.14)		
Pain in Arm or Shoulder: C38D1(n= 0, 2)	00000 (± 00000)	0.00 (± 0.00)		
Pain in Arm or Shoulder: EOT(n= 264, 242)	21.72 (± 30.48)	23.14 (± 29.55)		
Pain in Arm or Shoulder: Pro Week 6 Pd(n= 0,1)	00000 (± 00000)	66.67 (± 99999)		
Pain in Arm or Shoulder: Survival FU 1 (n= 2, 1)	83.33 (± 23.57)	33.33 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: EORTC QLQ-LC13 Questionnaire Score: Pain in Chest

End point title	EORTC QLQ-LC13 Questionnaire Score: Pain in Chest

End point description:

QLQ-LC13 consisted of 13 questions relating to disease symptoms specific to lung cancer and treatment side effects typical of treatment with chemotherapy and radiotherapy experienced during past 1 week. The 13 questions comprised 1 multi-item scale for dyspnea and 10 single-item symptoms and side effects (coughing, hemoptysis, sore mouth, dysphagia, peripheral neuropathy, alopecia, pain in chest, pain in arm or shoulder, pain in other parts. Response range: (1) not at all to (4) very much. Scores for each item were transformed to 0 to 100, where higher symptom score = greater degree of symptoms. Results have been reported for pain in chest. The PP-ITT analysis set. 'n'=participants evaluated for this measure at specific time point for each group respectively. '99999' denotes data not reported because SD was non-estimable since only 1 participant was evaluated for this category. '00000' denotes data not reported because no participant was evaluated for this category.

End point type	Secondary

End point timeframe:

Day 1 of each treatment Cycle up to EOT (up to approximately 2.25 years); 6 week following PD (up to approximately 2.25 years); survival follow-up-1 (up to approximately 2.25 years) (1 Cycle= 21 days)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	425	425		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Pain in Chest: Baseline (n= 385, 403)	17.92 (± 25.33)	19.52 (± 26.49)		
Pain in Chest: C2D1(n= 332, 356)	16.67 (± 24.65)	15.26 (± 22.68)		
Pain in Chest: C3D1(n= 249, 296)	14.59 (± 21.92)	15.43 (± 23.42)		
Pain in Chest: C4D1(n= 217, 268)	14.44 (± 22.37)	14.43 (± 23.77)		
Pain in Chest: C5D1(n= 164, 233)	11.99 (± 18.42)	12.16 (± 19.82)		
Pain in Chest: C6D1(n= 145, 217)	12.18 (± 19.96)	12.60 (± 21.40)		
Pain in Chest: C7D1(n= 86, 184)	12.40 (± 19.83)	11.78 (± 20.91)		
Pain in Chest: C8D1(n=69, 164)	10.63 (± 20.21)	14.02 (± 21.52)		
Pain in Chest: C9D1(n= 49, 149)	7.48 (± 17.03)	10.74 (± 20.96)		
Pain in Chest: C10D1(n= 46, 142)	5.07 (± 12.11)	8.45 (± 19.62)		
Pain in Chest: C11D1(n= 36, 127)	3.70 (± 10.62)	9.45 (± 22.18)		
Pain in Chest: C12D1(n= 30, 128)	3.33 (± 10.17)	8.85 (± 17.49)		

Pain in Chest: C13D1(n= 19, 120)	3.51 (± 10.51)	7.50 (± 16.99)		
Pain in Chest: C14D1(n= 18, 118)	5.56 (± 12.78)	7.63 (± 15.96)		
Pain in Chest: C15D1(n= 16, 109)	6.25 (± 13.44)	8.56 (± 18.37)		
Pain in Chest: C16D1(n= 13, 105)	5.13 (± 12.52)	8.25 (± 16.53)		
Pain in Chest: C17D1(n= 11, 94)	0.00 (± 0.00)	8.87 (± 20.84)		
Pain in Chest: C18D1(n= 10, 89)	6.67 (± 14.05)	7.49 (± 15.69)		
Pain in Chest: C19D1(n= 9, 80)	7.41 (± 14.70)	7.50 (± 19.10)		
Pain in Chest: C20D1(n= 9, 76)	3.70 (± 11.11)	10.09 (± 20.38)		
Pain in Chest: C21D1(n= 9, 71)	0.00 (± 0.00)	7.98 (± 15.39)		
Pain in Chest: C22D1(n= 8, 66)	4.17 (± 11.78)	7.58 (± 16.33)		
Pain in Chest: C23D1(n= 8, 62)	4.17 (± 11.78)	7.53 (± 17.51)		
Pain in Chest: C24D1(n= 5, 61)	0.00 (± 0.00)	8.20 (± 15.70)		
Pain in Chest: C25D1(n= 3, 57)	0.00 (± 0.00)	8.77 (± 16.09)		
Pain in Chest: C26D1(n= 2, 52)	0.00 (± 0.00)	10.90 (± 19.49)		
Pain in Chest: C27D1(n= 3, 49)	11.11 (± 19.24)	8.84 (± 18.97)		
Pain in Chest: C28D1(n= 2, 45)	0.00 (± 0.00)	8.15 (± 16.14)		
Pain in Chest: C29D1(n= 2, 37)	0.00 (± 0.00)	8.11 (± 16.49)		
Pain in Chest: C30D1(n= 1, 31)	0.00 (± 99999)	5.38 (± 12.46)		
Pain in Chest: C31D1(n= 0, 24)	00000 (± 00000)	4.17 (± 11.26)		
Pain in Chest: C32D1(n= 0, 23)	00000 (± 00000)	13.04 (± 19.43)		
Pain in Chest: C33D1(n= 0, 16)	00000 (± 00000)	14.58 (± 24.25)		
Pain in Chest: C34D1(n= 0, 14)	00000 (± 00000)	14.29 (± 25.20)		
Pain in Chest: C35D1(n= 0, 11)	00000 (± 00000)	6.06 (± 13.48)		
Pain in Chest: C36D1(n= 0, 8)	00000 (± 00000)	4.17 (± 11.78)		
Pain in Chest: C37D1(n= 0, 5)	00000 (± 00000)	6.67 (± 14.91)		
Pain in Chest: C38D1(n= 0, 2)	00000 (± 00000)	0.00 (± 0.00)		
Pain in Chest: EOT(n= 265, 245)	18.99 (± 26.35)	19.46 (± 26.95)		
Pain in Chest: Pro Week 6 Pd(n= 0,1)	00000 (± 00000)	0.00 (± 99999)		
Pain in Chest: Survival FU 1 (n= 2, 1)	50.00 (± 70.71)	33.33 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: EORTC QLQ-LC13 Questionnaire Score: Peripheral Neuropathy

End point title	EORTC QLQ-LC13 Questionnaire Score: Peripheral Neuropathy

End point description:

QLQ-LC13 consisted of 13 questions relating to disease symptoms specific to lung cancer and treatment side effects typical of treatment with chemotherapy and radiotherapy experienced during past 1 week. The 13 questions comprised 1 multi-item scale for dyspnea and 10 single-item symptoms and side effects (coughing, hemoptysis, sore mouth, dysphagia, peripheral neuropathy, alopecia, pain in chest,

pain in arm or shoulder, pain in other parts. Response range: (1) not at all to (4) very much. Scores for each item were transformed to 0 to 100, where higher symptom score = greater degree of symptoms. Results have been reported for peripheral neuropathy. The PP-ITT analysis set. 'n'=participants evaluated for this measure at specific time point for each group respectively. '99999' denotes data not reported because SD was non-estimable since only 1 participant was evaluated for this category. '00000' denotes data not reported because no participant was evaluated for this category.

End point type	Secondary

End point timeframe:

Day 1 of each treatment Cycle up to EOT (up to approximately 2.25 years); 6 week following PD (up to approximately 2.25 years); survival follow-up-1 (up to approximately 2.25 years) (1 Cycle= 21 days)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	425	425		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Peripheral Neuropathy: Baseline (n= 386, 406)	19.26 (± 28.94)	19.21 (± 27.77)		
Peripheral Neuropathy: C2D1(n= 335, 358)	25.57 (± 29.63)	20.02 (± 27.21)		
Peripheral Neuropathy: C3D1(n= 250, 300)	25.60 (± 29.16)	17.78 (± 25.04)		
Peripheral Neuropathy: C4D1(n= 221, 272)	28.05 (± 29.94)	17.77 (± 25.75)		
Peripheral Neuropathy: C5D1(n= 165, 235)	29.29 (± 28.94)	18.44 (± 25.97)		
Peripheral Neuropathy: C6D1(n= 147, 221)	31.97 (± 30.69)	17.50 (± 25.34)		
Peripheral Neuropathy: C7D1(n= 86, 185)	31.01 (± 30.59)	18.02 (± 25.29)		
Peripheral Neuropathy: C8D1(n=70, 167)	35.24 (± 26.55)	17.56 (± 25.30)		
Peripheral Neuropathy: C9D1(n= 50, 150)	36.00 (± 29.23)	15.78 (± 24.02)		
Peripheral Neuropathy: C10D1(n= 47, 143)	36.17 (± 30.16)	18.18 (± 25.86)		
Peripheral Neuropathy: C11D1(n= 37, 129)	27.93 (± 24.23)	17.05 (± 24.69)		
Peripheral Neuropathy: C12D1(n= 30, 129)	30.00 (± 25.30)	17.57 (± 23.96)		
Peripheral Neuropathy: C13D1(n= 19, 121)	26.32 (± 21.02)	17.91 (± 25.83)		
Peripheral Neuropathy: C14D1(n= 18, 119)	25.93 (± 21.56)	17.09 (± 23.72)		
Peripheral Neuropathy: C15D1(n= 15, 110)	24.44 (± 15.26)	17.58 (± 21.99)		
Peripheral Neuropathy: C16D1(n= 13, 105)	20.51 (± 16.88)	17.14 (± 24.07)		
Peripheral Neuropathy: C17D1(n= 11, 95)	21.21 (± 16.82)	19.30 (± 26.44)		
Peripheral Neuropathy: C18D1(n= 10, 90)	23.33 (± 22.50)	18.15 (± 26.52)		
Peripheral Neuropathy: C19D1(n= 9, 82)	14.81 (± 17.57)	20.33 (± 26.06)		
Peripheral Neuropathy: C20D1(n= 9, 78)	22.22 (± 23.57)	17.52 (± 26.17)		

Peripheral Neuropathy: C21D1(n= 9, 73)	29.63 (± 20.03)	18.72 (± 25.45)		
Peripheral Neuropathy: C22D1(n= 7, 66)	23.81 (± 16.26)	15.66 (± 23.55)		
Peripheral Neuropathy: C23D1(n= 8, 64)	16.67 (± 17.82)	20.31 (± 22.71)		
Peripheral Neuropathy: C24D1(n= 5, 62)	13.33 (± 18.26)	20.43 (± 22.87)		
Peripheral Neuropathy: C25D1(n= 3, 58)	11.11 (± 19.24)	18.39 (± 20.87)		
Peripheral Neuropathy: C26D1(n= 2, 53)	16.67 (± 23.57)	20.13 (± 25.60)		
Peripheral Neuropathy: C27D1(n= 3, 50)	11.11 (± 19.24)	19.33 (± 24.36)		
Peripheral Neuropathy: C28D1(n= 2, 46)	0.00 (± 0.00)	19.57 (± 22.85)		
Peripheral Neuropathy: C29D1(n= 2, 38)	0.00 (± 0.00)	19.30 (± 22.77)		
Peripheral Neuropathy: C30D1(n= 1, 31)	0.00 (± 99999)	20.43 (± 28.12)		
Peripheral Neuropathy: C31D1(n= 0, 24)	00000 (± 00000)	23.61 (± 26.88)		
Peripheral Neuropathy: C32D1(n= 0, 23)	00000 (± 00000)	18.84 (± 22.08)		
Peripheral Neuropathy: C33D1(n= 0, 16)	00000 (± 00000)	22.92 (± 20.07)		
Peripheral Neuropathy: C34D1(n= 0, 14)	00000 (± 00000)	19.05 (± 21.54)		
Peripheral Neuropathy: C35D1(n= 0, 11)	00000 (± 00000)	15.15 (± 17.41)		
Peripheral Neuropathy: C36D1(n= 0, 8)	00000 (± 00000)	8.33 (± 15.43)		
Peripheral Neuropathy: C37D1(n= 0, 5)	00000 (± 00000)	26.67 (± 27.89)		
Peripheral Neuropathy: C38D1(n= 0, 2)	00000 (± 00000)	16.67 (± 23.57)		
Peripheral Neuropathy: EOT(n= 262, 244)	31.81 (± 31.53)	19.54 (± 27.32)		
Peripheral Neuropathy: Pro Week 6 Pd(n= 0,1)	00000 (± 00000)	66.67 (± 99999)		
Peripheral Neuropathy: Survival FU 1 (n= 2, 1)	50.00 (± 23.57)	33.33 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: EORTC QLQ-LC13 Questionnaire Score: Pain in Other Parts

End point title	EORTC QLQ-LC13 Questionnaire Score: Pain in Other Parts

End point description:

QLQ-LC13 consisted of 13 questions relating to disease symptoms specific to lung cancer and treatment side effects typical of treatment with chemotherapy and radiotherapy experienced during past 1 week. The 13 questions comprised 1 multi-item scale for dyspnea and 10 single-item symptoms and side effects (coughing, hemoptysis, sore mouth, dysphagia, peripheral neuropathy, alopecia, pain in chest, pain in arm or shoulder, pain in other parts. Response range: (1) not at all to (4) very much. Scores for each item were transformed to 0 to 100, where higher symptom score = greater degree of symptoms. Results have been reported for pain in other parts. The PP-ITT analysis set. 'n'=participants evaluated for this measure at specific time point for each group respectively. '99999' denotes data not reported

because SD was non-estimable since only 1 participant was evaluated for this category. '00000' denotes data not reported because no participant was evaluated for this category.

End point type	Secondary

End point timeframe:

Day 1 of each treatment Cycle up to EOT (up to approximately 2.25 years); 6 week following PD (up to approximately 2.25 years); survival follow-up-1 (up to approximately 2.25 years) (1 Cycle= 21 days)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	425	425		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Pain in Other Parts: Baseline (n= 373, 402)	27.52 (± 30.41)	27.94 (± 31.52)		
Pain in Other Parts: C2D1(n= 320, 347)	29.58 (± 30.44)	27.76 (± 30.53)		
Pain in Other Parts: C3D1(n= 239, 286)	22.87 (± 27.79)	25.87 (± 29.79)		
Pain in Other Parts: C4D1(n= 211, 263)	21.48 (± 26.86)	23.45 (± 26.92)		
Pain in Other Parts: C5D1(n= 154, 230)	21.21 (± 26.63)	22.32 (± 27.24)		
Pain in Other Parts: C6D1(n= 139, 214)	22.78 (± 25.39)	21.50 (± 27.88)		
Pain in Other Parts: C7D1(n= 81, 180)	23.05 (± 28.21)	24.63 (± 29.56)		
Pain in Other Parts: C8D1(n=65, 158)	24.10 (± 28.57)	18.35 (± 24.54)		
Pain in Other Parts: C9D1(n= 44, 135)	18.18 (± 28.26)	21.48 (± 28.35)		
Pain in Other Parts: C10D1(n= 44, 136)	15.15 (± 23.24)	21.57 (± 28.84)		
Pain in Other Parts: C11D1(n= 34, 123)	14.71 (± 23.49)	20.05 (± 27.90)		
Pain in Other Parts: C12D1(n= 26, 122)	8.97 (± 17.78)	16.67 (± 25.80)		
Pain in Other Parts: C13D1(n= 17, 113)	17.65 (± 23.91)	19.76 (± 25.05)		
Pain in Other Parts: C14D1(n= 18, 115)	18.52 (± 23.49)	22.03 (± 29.58)		
Pain in Other Parts: C15D1(n= 15, 106)	6.67 (± 13.80)	19.18 (± 25.18)		
Pain in Other Parts: C16D1(n= 13, 105)	20.51 (± 21.68)	21.90 (± 26.89)		
Pain in Other Parts: C17D1(n= 11, 93)	15.15 (± 22.92)	22.22 (± 27.51)		
Pain in Other Parts: C18D1(n= 10, 89)	13.33 (± 23.31)	22.10 (± 27.50)		
Pain in Other Parts: C19D1(n= 9, 80)	18.52 (± 24.22)	24.58 (± 29.88)		
Pain in Other Parts: C20D1(n= 9, 74)	25.93 (± 36.43)	21.17 (± 27.90)		
Pain in Other Parts: C21D1(n= 8, 69)	12.50 (± 17.25)	21.26 (± 31.30)		
Pain in Other Parts: C22D1(n= 8, 62)	20.83 (± 24.80)	18.82 (± 25.34)		

Pain in Other Parts: C23D1(n= 8, 62)	20.83 (± 30.54)	18.82 (± 23.86)		
Pain in Other Parts: C24D1(n= 5, 61)	26.67 (± 43.46)	19.67 (± 28.14)		
Pain in Other Parts: C25D1(n= 3, 55)	11.11 (± 19.24)	16.97 (± 26.35)		
Pain in Other Parts: C26D1(n= 2, 50)	16.67 (± 23.57)	18.67 (± 26.22)		
Pain in Other Parts: C27D1(n= 3, 49)	11.11 (± 19.24)	14.29 (± 21.52)		
Pain in Other Parts: C28D1(n= 2, 44)	0.00 (± 0.00)	15.15 (± 25.37)		
Pain in Other Parts: C29D1(n= 2, 36)	0.00 (± 0.00)	21.30 (± 26.61)		
Pain in Other Parts: C30D1(n= 1, 30)	0.00 (± 99999)	16.67 (± 30.01)		
Pain in Other Parts: C31D1(n= 0, 23)	00000 (± 00000)	11.59 (± 21.58)		
Pain in Other Parts: C32D1(n= 0, 23)	00000 (± 00000)	20.29 (± 27.96)		
Pain in Other Parts: C33D1(n= 0, 15)	00000 (± 00000)	11.11 (± 27.22)		
Pain in Other Parts: C34D1(n= 0, 14)	00000 (± 00000)	30.95 (± 33.24)		
Pain in Other Parts: C35D1(n= 0, 10)	00000 (± 00000)	26.67 (± 34.43)		
Pain in Other Parts: C36D1(n= 0, 8)	00000 (± 00000)	20.83 (± 35.36)		
Pain in Other Parts: C37D1(n= 0, 5)	00000 (± 00000)	33.33 (± 40.82)		
Pain in Other Parts: C38D1(n= 0, 2)	00000 (± 00000)	0.00 (± 0.00)		
Pain in Other Parts: EOT(n= 250, 226)	30.80 (± 32.97)	32.01 (± 33.89)		
Pain in Other Parts: Pro Week 6 Pd(n= 0,1)	00000 (± 00000)	0.00 (± 99999)		
Pain in Other Parts: Survival FU 1 (n= 2, 1)	83.33 (± 23.57)	66.67 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: EORTC QLQ-LC13 Questionnaire Score: Sore Mouth

End point title	EORTC QLQ-LC13 Questionnaire Score: Sore Mouth

End point description:

QLQ-LC13:13 questions relating to disease symptoms specific to lung cancer and treatment side effects typical of treatment with chemotherapy and radiotherapy experienced during past 1 week. The 13 questions comprised 1 multi-item scale for dyspnea and 10 single-item symptoms and side effects (coughing, hemoptysis, sore mouth, dysphagia, peripheral neuropathy, alopecia, pain in chest, pain in arm or shoulder, pain in other parts. Response range: (1) not at all to (4) very much. Scores for each item were transformed to 0 to 100, where higher symptom score = greater degree of symptoms. Results have been reported for sore mouth. The PP-ITT analysis set. Here, 'n' signifies those participants evaluated for this measure at specific time point for each group respectively. '99999' denotes data not reported because SD was non-estimable since only 1 participant was evaluated for this category. '00000' denotes data not reported because no participant was evaluated for this category.

End point type	Secondary

End point timeframe:

Day 1 of each treatment Cycle up to EOT (up to approximately 2.25 years); 6 week following PD (up to approximately 2.25 years); survival follow-up-1 (up to approximately 2.25 years) (1 Cycle= 21 days)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	425	425		
Units: Units on a scale				
arithmetic mean (standard deviation)				
Sore Mouth: Baseline (n= 387, 404)	5.68 (± 16.34)	4.95 (± 15.32)		
Sore Mouth: C2D1(n= 335, 357)	15.52 (± 25.75)	7.10 (± 18.17)		
Sore Mouth: C3D1(n= 252, 297)	14.29 (± 23.59)	5.61 (± 14.18)		
Sore Mouth: C4D1(n= 219, 270)	14.00 (± 22.95)	4.81 (± 13.99)		
Sore Mouth: C5D1(n= 165, 234)	11.31 (± 19.65)	4.27 (± 13.49)		
Sore Mouth: C6D1(n= 148, 218)	13.29 (± 23.24)	4.13 (± 13.89)		
Sore Mouth: C7D1(n= 87, 185)	9.20 (± 20.77)	5.59 (± 15.50)		
Sore Mouth: C8D1(n=70, 166)	8.57 (± 16.73)	5.02 (± 14.96)		
Sore Mouth: C9D1(n= 50, 151)	6.00 (± 17.42)	3.09 (± 14.06)		
Sore Mouth: C10D1(n= 47, 143)	7.09 (± 15.44)	3.96 (± 14.53)		
Sore Mouth: C11D1(n= 37, 130)	4.50 (± 13.97)	3.33 (± 12.35)		
Sore Mouth: C12D1(n= 30, 129)	2.22 (± 8.46)	4.65 (± 14.87)		
Sore Mouth: C13D1(n= 19, 121)	1.75 (± 7.65)	5.23 (± 15.52)		
Sore Mouth: C14D1(n= 18, 119)	3.70 (± 10.78)	5.32 (± 15.64)		
Sore Mouth: C15D1(n= 15, 110)	0.00 (± 0.00)	4.24 (± 13.63)		
Sore Mouth: C16D1(n= 13, 106)	0.00 (± 0.00)	3.77 (± 16.15)		
Sore Mouth: C17D1(n= 11, 95)	3.03 (± 10.05)	6.32 (± 17.73)		
Sore Mouth: C18D1(n= 10, 90)	3.33 (± 10.54)	3.70 (± 11.66)		
Sore Mouth: C19D1(n= 9, 82)	0.00 (± 0.00)	4.47 (± 12.57)		
Sore Mouth: C20D1(n= 9, 78)	0.00 (± 0.00)	5.56 (± 15.59)		
Sore Mouth: C21D1(n= 9, 73)	0.00 (± 0.00)	7.76 (± 17.14)		
Sore Mouth: C22D1(n= 8, 67)	4.17 (± 11.78)	6.47 (± 17.64)		
Sore Mouth: C23D1(n= 8, 64)	4.17 (± 11.78)	6.25 (± 16.67)		
Sore Mouth: C24D1(n= 5, 62)	0.00 (± 0.00)	5.38 (± 13.75)		
Sore Mouth: C25D1(n= 3, 57)	0.00 (± 0.00)	3.51 (± 10.32)		
Sore Mouth: C26D1(n= 3, 53)	0.00 (± 0.00)	6.92 (± 13.65)		
Sore Mouth: C27D1(n= 3, 50)	0.00 (± 0.00)	4.00 (± 10.94)		
Sore Mouth: C28D1(n= 2, 46)	0.00 (± 0.00)	4.35 (± 11.35)		
Sore Mouth: C29D1(n= 2, 38)	0.00 (± 0.00)	3.51 (± 10.37)		
Sore Mouth: C30D1(n= 1, 31)	0.00 (± 99999)	4.30 (± 11.36)		
Sore Mouth: C31D1(n= 0, 24)	00000 (± 00000)	4.17 (± 11.26)		
Sore Mouth: C32D1(n= 0, 23)	00000 (± 00000)	4.35 (± 11.48)		
Sore Mouth: C33D1(n= 0, 16)	00000 (± 00000)	4.17 (± 11.39)		
Sore Mouth: C34D1(n= 0, 14)	00000 (± 00000)	9.52 (± 15.63)		

Sore Mouth: C35D1(n= 0, 11)	00000 (± 00000)	6.06 (± 13.48)		
Sore Mouth: C36D1(n= 0, 8)	00000 (± 00000)	4.17 (± 11.78)		
Sore Mouth: C37D1(n= 0, 5)	00000 (± 00000)	13.33 (± 29.81)		
Sore Mouth: C38D1(n= 0, 2)	00000 (± 00000)	0.00 (± 0.00)		
Sore Mouth: EOT(n= 265, 243)	11.57 (± 22.85)	7.00 (± 17.18)		
Sore Mouth: Pro Week 6 Pd(n= 0,1)	00000 (± 00000)	66.67 (± 99999)		
Sore Mouth: Survival FU 1 (n= 2, 1)	16.67 (± 23.57)	0.00 (± 99999)		

Statistical analyses

No statistical analyses for this end point

Secondary: PFS as Determined by Investigator Using RECIST v1.1: SP-ITT

End point title	PFS as Determined by Investigator Using RECIST v1.1: SP-ITT

End point description:

PFS is defined as the time between the date of randomization and the date of first documented PD or death, whichever occurs first. Participants who are alive and have not experienced PD at the time of analysis were censored at the time of the last tumor assessment. Participants with no post-baseline tumor assessment were censored at the randomization date plus 1 day. PD: at least 20% increase in the sum of diameters of target lesions compared to the smallest sum of diameters on-study and absolute increase of at least 5 mm, or presence of new lesions. SP-ITT analysis set.

End point type	Secondary

End point timeframe:

Baseline up to PD or death due to any cause, whichever occurred first (up to approximately 2.87 years)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	612	613		
Units: Months				
median (confidence interval 95%)	3.8 (3.3 to 4.1)	2.7 (2.4 to 2.9)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Docetaxel v Atezolizumab

Number of subjects included in analysis	1225
Analysis specification	Pre-specified
Analysis type	other
P-value	= 0.4981
Method	Logrank
Parameter estimate	Stratified Hazard Ratio
Point estimate	0.96
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.85
upper limit	1.08

Secondary: Percentage of Participants With Objective Response as Determined Using RECIST v1.1: SP-ITT

End point title	Percentage of Participants With Objective Response as Determined Using RECIST v1.1: SP-ITT

End point description:

Objective response is defined as a complete response (CR) or partial response (PR) as determined by the Investigator using RECIST v1.1 on 2 consecutive occasions at least 6 weeks apart. CR was defined as complete disappearance of all target lesions and non-target disease, with the exception of nodal disease. All nodes, both target and non-target, must decrease to normal (short axis less than [<] 10 mm). No new lesions. At least a 30% decrease in the sum of the diameters of all target and all new measurable lesions, taking as reference the baseline sum of diameters, in the absence of CR. No new lesions. SP-ITT analysis set.

End point type	Secondary

End point timeframe:

Baseline up to PD or death due to any cause, whichever occurred first (up to approximately 2.87 years)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	612	613		
Units: Percentage of Participants				
number (confidence interval 95%)	11.8 (9.32 to 14.59)	13.7 (11.08 to 16.68)		

Statistical analyses

No statistical analyses for this end point

Secondary: DOR as Determined by Investigator Using RECIST v1.1: SP ITT

End point title	DOR as Determined by Investigator Using RECIST v1.1: SP ITT

End point description:

DOR:Duration from first tumor assessment that supports the participant's OR to PD or death due to any cause.CR:complete disappearance of all target lesions&non-target disease.All nodes,both target&non-target,must decrease to normal.No new lesions.PR:At least 30% decrease in sum of the diameters of all target&all new measurable lesions,taking as reference the baseline sum of diameters,in absence of CR.

Participants without PD at time of analysis were censored at the time of the last tumor assessment.Participants with no post-baseline tumor assessment were censored at randomization date plus 1 day.PD:at least 20% increase in sum of diameters of target lesions compared to the smallest sum of diameters on-study&absolute increase of at least 5 mm,progression of existing non-target lesions,or presence of new lesions.DOR was estimated using KM methodology.'99999':due to higher number of censored participants data not estimable.SP-ITT analysis set.

End point type	Secondary

End point timeframe:

From first objective response of CR or PR to PD or death due to any cause, whichever occurred first (up to approximately 2.87 years)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	72	84		
Units: Months				
median (confidence interval 95%)	6.3 (5.5 to 7.6)	23.9 (12.8 to 999999)		

Statistical analyses

Statistical analysis title	Statistical Analysis
Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	156
Analysis specification	Pre-specified
Analysis type	superiority
Parameter estimate	Unstratified Hazard Ratio
Point estimate	0.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.21
upper limit	0.48

Adverse events

Adverse events information	
Timeframe for reporting adverse events:	
Baseline up to approximate 5.28 years.	
Assessment type	Non-systematic

Dictionary used	
Dictionary name	MedDRA
Dictionary version	22.0

Reporting groups	
Reporting group title	Atezolizumab
Reporting group description:	
Atezolizumab 1200 mg was administered IV on Day 1 of each 21-day cycle until disease progression or loss of clinical benefit, death, unacceptable toxicity, withdrawal of consent, or study termination by sponsor, whichever occurred first.	
Reporting group title	Docetaxel
Reporting group description:	
Docetaxel 75 mg/m^2 was administered IV on Day 1 of each 21-day cycle until disease progression, death, unacceptable toxicity, withdrawal of consent, or study termination by sponsor, whichever occurred first.	

Serious adverse events	Atezolizumab	Docetaxel	
Total subjects affected by serious adverse events			
subjects affected / exposed	200 / 609 (32.84%)	180 / 578 (31.14%)	
number of deaths (all causes)	485	494	
number of deaths resulting from adverse events			
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Cancer pain			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colon cancer			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neoplasm malignant			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Prostate cancer			

subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Basal cell carcinoma			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Deep vein thrombosis			
subjects affected / exposed	1 / 609 (0.16%)	2 / 578 (0.35%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematoma			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypotension			
subjects affected / exposed	3 / 609 (0.49%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Thrombosis			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superior vena cava syndrome			
subjects affected / exposed	3 / 609 (0.49%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	1 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	3 / 609 (0.49%)	3 / 578 (0.52%)	
occurrences causally related to treatment / all	1 / 4	3 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

Chest discomfort			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Chest pain			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Fatigue			
subjects affected / exposed	2 / 609 (0.33%)	4 / 578 (0.69%)	
occurrences causally related to treatment / all	1 / 2	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
General physical health deterioration			
subjects affected / exposed	2 / 609 (0.33%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised oedema			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza like illness			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised oedema			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			

subjects affected / exposed	2 / 609 (0.33%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	9 / 609 (1.48%)	8 / 578 (1.38%)	
occurrences causally related to treatment / all	4 / 11	5 / 8	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sudden death			
subjects affected / exposed	1 / 609 (0.16%)	2 / 578 (0.35%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 2	
Systemic inflammatory response syndrome			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Immune system disorders			
Hypersensitivity			
subjects affected / exposed	3 / 609 (0.49%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Reproductive system and breast disorders			
Benign prostatic hyperplasia			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (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			
Acute respiratory distress syndrome			

subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Acute respiratory failure			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspiration			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atelectasis			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchial obstruction			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchospasm			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (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 / 609 (0.33%)	3 / 578 (0.52%)	
occurrences causally related to treatment / all	0 / 2	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cough			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			

subjects affected / exposed	13 / 609 (2.13%)	7 / 578 (1.21%)	
occurrences causally related to treatment / all	1 / 14	1 / 8	
deaths causally related to treatment / all	0 / 1	0 / 1	
Emphysema			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (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	6 / 609 (0.99%)	5 / 578 (0.87%)	
occurrences causally related to treatment / all	0 / 6	0 / 5	
deaths causally related to treatment / all	0 / 0	0 / 1	
Hypoxia			
subjects affected / exposed	3 / 609 (0.49%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	1 / 4	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Interstitial lung disease			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Organising pneumonia			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	11 / 609 (1.81%)	5 / 578 (0.87%)	
occurrences causally related to treatment / all	1 / 12	4 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural fistula			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleuritic pain			

subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia aspiration			
subjects affected / exposed	2 / 609 (0.33%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	6 / 609 (0.99%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	6 / 6	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	3 / 609 (0.49%)	2 / 578 (0.35%)	
occurrences causally related to treatment / all	1 / 3	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax spontaneous			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary embolism			
subjects affected / exposed	9 / 609 (1.48%)	2 / 578 (0.35%)	
occurrences causally related to treatment / all	0 / 9	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary haemorrhage			
subjects affected / exposed	1 / 609 (0.16%)	2 / 578 (0.35%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 1	0 / 1	
Pulmonary oedema			
subjects affected / exposed	1 / 609 (0.16%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory distress			

subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Respiratory failure			
subjects affected / exposed	3 / 609 (0.49%)	2 / 578 (0.35%)	
occurrences causally related to treatment / all	0 / 3	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachypnoea			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Psychiatric disorders			
Confusional state			
subjects affected / exposed	1 / 609 (0.16%)	2 / 578 (0.35%)	
occurrences causally related to treatment / all	1 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Mental status change			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutrophil count decreased			
subjects affected / exposed	0 / 609 (0.00%)	5 / 578 (0.87%)	
occurrences causally related to treatment / all	0 / 0	6 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	

White blood cell count decreased			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Burns third degree			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hip fracture			
subjects affected / exposed	3 / 609 (0.49%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Humerus fracture			
subjects affected / exposed	1 / 609 (0.16%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infusion related reaction			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lumbar vertebral fracture			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Overdose			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Post procedural haematuria			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Radius fracture			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal compression fracture			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper limb fracture			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fall			
subjects affected / exposed	1 / 609 (0.16%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ankle fracture			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Femoral neck fracture			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fracture displacement			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			
subjects affected / exposed	0 / 609 (0.00%)	2 / 578 (0.35%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Angina pectoris			

subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Arrhythmia			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	1 / 609 (0.16%)	3 / 578 (0.52%)	
occurrences causally related to treatment / all	0 / 1	1 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial flutter			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac arrest			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac tamponade			
subjects affected / exposed	2 / 609 (0.33%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Left ventricular dysfunction			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial infarction			
subjects affected / exposed	2 / 609 (0.33%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myocardial ischaemia			

subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Pericardial effusion			
subjects affected / exposed	3 / 609 (0.49%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	1 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericarditis			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stress cardiomyopathy			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Supraventricular tachycardia			
subjects affected / exposed	0 / 609 (0.00%)	2 / 578 (0.35%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia			
subjects affected / exposed	1 / 609 (0.16%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tachycardia paroxysmal			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure congestive			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 3	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Nervous system disorders			
Aphasia			

subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral artery embolism			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebral thrombosis			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cerebrovascular accident			
subjects affected / exposed	2 / 609 (0.33%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cognitive disorder			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Depressed level of consciousness			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dizziness			
subjects affected / exposed	1 / 609 (0.16%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalopathy			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Generalised tonic-clonic seizure			

subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Guillain-Barre syndrome			
subjects affected / exposed	2 / 609 (0.33%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hemiparesis			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukoencephalopathy			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neuralgia			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral sensory neuropathy			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sciatica			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Seizure			
subjects affected / exposed	3 / 609 (0.49%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Syncope			

subjects affected / exposed	1 / 609 (0.16%)	3 / 578 (0.52%)	
occurrences causally related to treatment / all	0 / 1	2 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhage intracranial			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (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	5 / 609 (0.82%)	7 / 578 (1.21%)	
occurrences causally related to treatment / all	0 / 6	4 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	0 / 609 (0.00%)	37 / 578 (6.40%)	
occurrences causally related to treatment / all	0 / 0	40 / 41	
deaths causally related to treatment / all	0 / 0	0 / 0	
Leukocytosis			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	0 / 609 (0.00%)	3 / 578 (0.52%)	
occurrences causally related to treatment / all	0 / 0	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Eye disorders			
Retinopathy			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 609 (0.16%)	4 / 578 (0.69%)	
occurrences causally related to treatment / all	0 / 1	1 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	

Abdominal pain lower			
subjects affected / exposed	2 / 609 (0.33%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Abdominal pain upper			
subjects affected / exposed	1 / 609 (0.16%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	1 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	2 / 609 (0.33%)	2 / 578 (0.35%)	
occurrences causally related to treatment / all	1 / 2	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	1 / 609 (0.16%)	7 / 578 (1.21%)	
occurrences causally related to treatment / all	0 / 1	6 / 7	
deaths causally related to treatment / all	0 / 0	0 / 0	
Duodenal perforation			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
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 / 609 (0.16%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Faeces discoloured			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastritis erosive			

subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematochezia			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Intestinal obstruction			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower gastrointestinal haemorrhage			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Melaena			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (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	2 / 609 (0.33%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal fistula			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal obstruction			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oesophageal varices haemorrhage			

subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pancreatitis			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	1 / 609 (0.16%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Stomatitis			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Subileus			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vomiting			
subjects affected / exposed	1 / 609 (0.16%)	5 / 578 (0.87%)	
occurrences causally related to treatment / all	0 / 1	3 / 5	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatobiliary disorders			
Acute hepatic failure			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis			

subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cholecystitis acute			
subjects affected / exposed	1 / 609 (0.16%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Drug-induced liver injury			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis			
subjects affected / exposed	2 / 609 (0.33%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hepatitis acute			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Pemphigoid			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pruritus			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pruritus generalised			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			

Acute kidney injury			
subjects affected / exposed	1 / 609 (0.16%)	4 / 578 (0.69%)	
occurrences causally related to treatment / all	0 / 1	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haematuria			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Henoch−Schonlein purpura nephritis			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal failure			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 1	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	2 / 609 (0.33%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	3 / 609 (0.49%)	2 / 578 (0.35%)	
occurrences causally related to treatment / all	0 / 4	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bone pain			
subjects affected / exposed	4 / 609 (0.66%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 4	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal chest pain			
subjects affected / exposed	2 / 609 (0.33%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	

Musculoskeletal pain			
subjects affected / exposed	1 / 609 (0.16%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neck pain			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Rhabdomyolysis			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain in extremity			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Muscular weakness			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (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			
Abdominal sepsis			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Appendicitis			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bacterial sepsis			

subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Bronchitis			
subjects affected / exposed	1 / 609 (0.16%)	2 / 578 (0.35%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cellulitis			
subjects affected / exposed	1 / 609 (0.16%)	2 / 578 (0.35%)	
occurrences causally related to treatment / all	0 / 1	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile colitis			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Clostridium difficile infection			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Device related infection			
subjects affected / exposed	1 / 609 (0.16%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diverticulitis			
subjects affected / exposed	0 / 609 (0.00%)	2 / 578 (0.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Encephalitis			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Enteritis infectious			

subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile infection			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis			
subjects affected / exposed	1 / 609 (0.16%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal fungal infection			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal infection			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infected skin ulcer			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infection			
subjects affected / exposed	0 / 609 (0.00%)	2 / 578 (0.35%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious pleural effusion			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infective exacerbation of chronic obstructive airways disease			

subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza			
subjects affected / exposed	2 / 609 (0.33%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 2	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	3 / 609 (0.49%)	3 / 578 (0.52%)	
occurrences causally related to treatment / all	0 / 7	2 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infection			
subjects affected / exposed	3 / 609 (0.49%)	3 / 578 (0.52%)	
occurrences causally related to treatment / all	0 / 3	4 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Meningitis			
subjects affected / exposed	3 / 609 (0.49%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenic sepsis			
subjects affected / exposed	0 / 609 (0.00%)	2 / 578 (0.35%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paronychia			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Parotitis			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			

subjects affected / exposed	2 / 609 (0.33%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural infection			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumocystis jirovecii pneumonia			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	20 / 609 (3.28%)	34 / 578 (5.88%)	
occurrences causally related to treatment / all	3 / 23	11 / 36	
deaths causally related to treatment / all	0 / 1	0 / 2	
Pneumonia bacterial			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pseudomembranous colitis			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pulmonary sepsis			
subjects affected / exposed	2 / 609 (0.33%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection			
subjects affected / exposed	8 / 609 (1.31%)	4 / 578 (0.69%)	
occurrences causally related to treatment / all	1 / 8	2 / 5	
deaths causally related to treatment / all	0 / 0	1 / 2	
Sepsis			

subjects affected / exposed	5 / 609 (0.82%)	2 / 578 (0.35%)	
occurrences causally related to treatment / all	1 / 5	0 / 2	
deaths causally related to treatment / all	0 / 2	0 / 1	
Septic shock			
subjects affected / exposed	1 / 609 (0.16%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 1	0 / 0	
Skin infection			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tonsillitis			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper respiratory tract infection bacterial			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urinary tract infection			
subjects affected / exposed	0 / 609 (0.00%)	2 / 578 (0.35%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urosepsis			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastroenteritis viral			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Localised infection			

subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyelonephritis			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (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			
Decreased appetite			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dehydration			
subjects affected / exposed	1 / 609 (0.16%)	3 / 578 (0.52%)	
occurrences causally related to treatment / all	0 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Failure to thrive			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypercalcaemia			
subjects affected / exposed	1 / 609 (0.16%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	3 / 609 (0.49%)	0 / 578 (0.00%)	
occurrences causally related to treatment / all	1 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoglycaemia			
subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypokalaemia			

subjects affected / exposed	0 / 609 (0.00%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyponatraemia			
subjects affected / exposed	1 / 609 (0.16%)	1 / 578 (0.17%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

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

Non-serious adverse events	Atezolizumab	Docetaxel	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	541 / 609 (88.83%)	535 / 578 (92.56%)	
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	36 / 609 (5.91%)	14 / 578 (2.42%)	
occurrences (all)	54	16	
Aspartate aminotransferase increased			
subjects affected / exposed	42 / 609 (6.90%)	12 / 578 (2.08%)	
occurrences (all)	53	13	
Neutrophil count decreased			
subjects affected / exposed	3 / 609 (0.49%)	50 / 578 (8.65%)	
occurrences (all)	6	223	
Weight decreased			
subjects affected / exposed	56 / 609 (9.20%)	30 / 578 (5.19%)	
occurrences (all)	71	33	
Nervous system disorders			
Dizziness			
subjects affected / exposed	48 / 609 (7.88%)	32 / 578 (5.54%)	
occurrences (all)	61	37	
Dysgeusia			
subjects affected / exposed	18 / 609 (2.96%)	48 / 578 (8.30%)	
occurrences (all)	20	69	
Headache			

subjects affected / exposed	62 / 609 (10.18%)	46 / 578 (7.96%)	
occurrences (all)	74	47	
Neuropathy peripheral			
subjects affected / exposed	27 / 609 (4.43%)	65 / 578 (11.25%)	
occurrences (all)	29	75	
Paraesthesia			
subjects affected / exposed	23 / 609 (3.78%)	45 / 578 (7.79%)	
occurrences (all)	26	58	
Peripheral sensory neuropathy			
subjects affected / exposed	5 / 609 (0.82%)	43 / 578 (7.44%)	
occurrences (all)	6	59	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	71 / 609 (11.66%)	130 / 578 (22.49%)	
occurrences (all)	98	184	
Neutropenia			
subjects affected / exposed	12 / 609 (1.97%)	88 / 578 (15.22%)	
occurrences (all)	17	118	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	117 / 609 (19.21%)	113 / 578 (19.55%)	
occurrences (all)	173	177	
Chest pain			
subjects affected / exposed	55 / 609 (9.03%)	25 / 578 (4.33%)	
occurrences (all)	64	30	
Fatigue			
subjects affected / exposed	165 / 609 (27.09%)	206 / 578 (35.64%)	
occurrences (all)	223	313	
Influenza like illness			
subjects affected / exposed	35 / 609 (5.75%)	14 / 578 (2.42%)	
occurrences (all)	52	18	
Malaise			
subjects affected / exposed	15 / 609 (2.46%)	29 / 578 (5.02%)	
occurrences (all)	18	45	
Mucosal inflammation			

subjects affected / exposed	9 / 609 (1.48%)	41 / 578 (7.09%)	
occurrences (all)	13	61	
Oedema peripheral			
subjects affected / exposed	55 / 609 (9.03%)	82 / 578 (14.19%)	
occurrences (all)	58	108	
Pyrexia			
subjects affected / exposed	108 / 609 (17.73%)	70 / 578 (12.11%)	
occurrences (all)	145	89	
Eye disorders			
Lacrimation increased			
subjects affected / exposed	6 / 609 (0.99%)	33 / 578 (5.71%)	
occurrences (all)	7	36	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	23 / 609 (3.78%)	33 / 578 (5.71%)	
occurrences (all)	27	40	
Constipation			
subjects affected / exposed	111 / 609 (18.23%)	82 / 578 (14.19%)	
occurrences (all)	126	101	
Diarrhoea			
subjects affected / exposed	100 / 609 (16.42%)	138 / 578 (23.88%)	
occurrences (all)	147	190	
Nausea			
subjects affected / exposed	110 / 609 (18.06%)	131 / 578 (22.66%)	
occurrences (all)	133	189	
Stomatitis			
subjects affected / exposed	21 / 609 (3.45%)	62 / 578 (10.73%)	
occurrences (all)	23	81	
Vomiting			
subjects affected / exposed	75 / 609 (12.32%)	61 / 578 (10.55%)	
occurrences (all)	93	74	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	146 / 609 (23.97%)	107 / 578 (18.51%)	
occurrences (all)	200	124	
Dyspnoea			

subjects affected / exposed	117 / 609 (19.21%)	108 / 578 (18.69%)	
occurrences (all)	146	122	
Haemoptysis			
subjects affected / exposed	40 / 609 (6.57%)	28 / 578 (4.84%)	
occurrences (all)	50	35	
Productive cough			
subjects affected / exposed	36 / 609 (5.91%)	21 / 578 (3.63%)	
occurrences (all)	37	22	
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	5 / 609 (0.82%)	205 / 578 (35.47%)	
occurrences (all)	5	232	
Dry skin			
subjects affected / exposed	30 / 609 (4.93%)	34 / 578 (5.88%)	
occurrences (all)	32	36	
Nail disorder			
subjects affected / exposed	1 / 609 (0.16%)	30 / 578 (5.19%)	
occurrences (all)	1	30	
Pruritus			
subjects affected / exposed	57 / 609 (9.36%)	18 / 578 (3.11%)	
occurrences (all)	90	29	
Rash			
subjects affected / exposed	65 / 609 (10.67%)	51 / 578 (8.82%)	
occurrences (all)	94	66	
Psychiatric disorders			
Depression			
subjects affected / exposed	31 / 609 (5.09%)	6 / 578 (1.04%)	
occurrences (all)	32	6	
Insomnia			
subjects affected / exposed	56 / 609 (9.20%)	43 / 578 (7.44%)	
occurrences (all)	66	55	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	80 / 609 (13.14%)	59 / 578 (10.21%)	
occurrences (all)	113	75	
Back pain			

subjects affected / exposed	70 / 609 (11.49%)	41 / 578 (7.09%)	
occurrences (all)	81	45	
Musculoskeletal pain			
subjects affected / exposed	69 / 609 (11.33%)	24 / 578 (4.15%)	
occurrences (all)	85	26	
Myalgia			
subjects affected / exposed	44 / 609 (7.22%)	90 / 578 (15.57%)	
occurrences (all)	48	116	
Pain in extremity			
subjects affected / exposed	56 / 609 (9.20%)	38 / 578 (6.57%)	
occurrences (all)	73	43	
Musculoskeletal chest pain			
subjects affected / exposed	33 / 609 (5.42%)	7 / 578 (1.21%)	
occurrences (all)	38	7	
Infections and infestations			
Nasopharyngitis			
subjects affected / exposed	39 / 609 (6.40%)	21 / 578 (3.63%)	
occurrences (all)	51	24	
Upper respiratory tract infection			
subjects affected / exposed	41 / 609 (6.73%)	15 / 578 (2.60%)	
occurrences (all)	54	25	
Urinary tract infection			
subjects affected / exposed	22 / 609 (3.61%)	30 / 578 (5.19%)	
occurrences (all)	28	34	
Bronchitis			
subjects affected / exposed	34 / 609 (5.58%)	24 / 578 (4.15%)	
occurrences (all)	46	33	
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	150 / 609 (24.63%)	135 / 578 (23.36%)	
occurrences (all)	179	202	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
10 February 2014	The exclusion criterion for participants with a positive human immunodeficiency virus (HIV) test was updated. The timing of vital signs with the intravenous infusions of atezolizumab or docetaxel was clarified and made consistent throughout the protocol.
05 August 2014	The treatment duration for atezolizumab was modified to allow participants to be treated until participants are no longer experiencing clinical benefit, accordingly, the 16-cycle or 12-month initial treatment, follow-up, and re-treatment periods no longer apply. An exclusion criterion regarding known tumor PD-L1 expression status from other clinical trials was added to ensure a natural distribution of the prevalence of PD-L1 expression levels. All instances of "PD-L1 positive" were replaced by "moderate or high PD-L1 staining (IHC 2/3)" and all instances of "PD-L1 negative" were replaced by "no or low PD-L1 staining (IHC 0/1)".
02 December 2014	Planned PD-L1 expression subgroups for analysis were amended to include PD-L1 expression on TCs in addition to ICs. The sample size was increased from 850 to 1100 participants to allow for testing participants with TC3 or IC3 as first step in the hierarchy. The statistical section was amended to change the procedure used to control the type I error.
06 October 2015	The name of the test product, MPDL3280A, was changed to atezolizumab throughout the document because this is now the world health organization (WHO)-approved nonproprietary name. The recent update to the Atezolizumab Investigator's Brochure (IB) has outlined more stringent approaches for the management of immune-mediated toxicity. Systemic immune activation (SIA) was identified as a potential risk of atezolizumab when given in combination with other immunomodulating agents.
28 January 2016	The statistical section was amended to reflect changes in the statistical testing procedure on the basis of the primary analysis of the POPLAR study (Study GO28753). The primary analysis population was changed to the 850 first randomized participants, which would provide sufficient power to detect targeted OS benefits in all 850 first randomized participants and the TC1/2/3 or IC1/2/3 subgroup among these 850 participants with adequate follow-up.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported