Clinical trial results:
A PHASE II, OPEN-LABEL, MULTICENTER, RANDOMIZED STUDY TO INVESTIGATE THE EFFICACY AND SAFETY OF MPDL3280A (ANTI-PD-L1 ANTIBODY) COMPARED WITH DOCETAXEL IN PATIENTS WITH NON-SMALL CELL LUNG CANCER AFTER PLATINUM FAILURE

Summary

EudraCT number	2013-001142-34
Trial protocol	BE DE HU GB ES IT SE FR
Global end of trial date	01 December 2015

Results information

Result version number	v2
This version publication date	08 July 2017
First version publication date	22 May 2016
Version creation reason	

Trial information

Trial identification

Sponsor protocol code	GO28753

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT01903993
WHO universal trial number (UTN)	-
Other trial identifiers	Alias: POPLAR

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 AG, F. Hoffmann-La Roche AG, 41 616878333, global.trial_information@roche.com
Scientific contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, 41 616878333, global.trial_information@roche.com

Notes:

Paediatric regulatory details

Is trial part of an agreed paediatric investigation plan (PIP)	No
Does article 45 of REGULATION (EC) No 1901/2006 apply to this trial?	No
Does article 46 of REGULATION (EC) No 1901/2006 apply to this trial?	No

Notes:

Results analysis stage

Analysis stage	Interim
Date of interim/final analysis	07 May 2015
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	01 December 2015
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the efficacy and safety of atezolizumab compared with docetaxel in subjects with locally advanced or metastatic non-small cell lung cancer (NSCLC) who have progressed during or following a platinum-containing regimen.

Protection of trial subjects:

The study was conducted in accordance with the principles of the "Declaration of Helsinki" and Good Clinical Practice (GCP) according to the regulations and procedures described in the protocol.

Background therapy: -

Evidence for comparator:

Docetaxel is an approved standard 2nd line treatment with demonstrated survival benefit in Cancer.

Actual start date of recruitment	05 August 2013
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	3 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	France: 16
Country: Number of subjects enrolled	Thailand: 15
Country: Number of subjects enrolled	Canada: 5
Country: Number of subjects enrolled	Turkey: 7
Country: Number of subjects enrolled	United States: 132
Country: Number of subjects enrolled	Korea, Republic of: 16
Country: Number of subjects enrolled	Poland: 27
Country: Number of subjects enrolled	Spain: 18
Country: Number of subjects enrolled	Sweden: 1
Country: Number of subjects enrolled	United Kingdom: 11
Country: Number of subjects enrolled	Belgium: 10
Country: Number of subjects enrolled	Germany: 24
Country: Number of subjects enrolled	Italy: 5
Worldwide total number of subjects	287
EEA total number of subjects	112

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)	174
From 65 to 84 years	113
85 years and over	0

Subject disposition

Recruitment

Recruitment details: -

Pre-assignment

Screening details:

A total of 527 subjects were screened, of whom 287 subjects were randomised. 143 subjects to the docetaxel arm and 144 subjects to the atezolizumab arm. Overall, 10 subjects (8 in the docetaxel arm and 2 in the atezolizumab arm) did not receive any study treatment.

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:

Subjects received docetaxel 75 milligram per meter square (mg/m^2) administered intravenously on Day 1 of each 21 day cycle until disease progression or unacceptable toxicity or death.

Arm type	Experimental
Investigational medicinal product name	Docetaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Injection
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received starting dose of 75 mg/m^2 every three week (q3w) until disease progression, unacceptable toxicity or death. Dose modifications were according to the locally approved label. Subjects randomized to receive docetaxel had to be premedicated with corticosteroids according to local practice.

Arm title	Atezolizumab

Arm description:

Subjects were administered atezolizumab intravenously on Day 1 of each 21 day cycle at a fixed dose of 1200 mg. Atezolizumab treatment were to continued as long as subjects were experiencing clinical benefit as assessed by the investigator.

Arm type	Experimental
Investigational medicinal product name	Atezolizumab
Investigational medicinal product code	MPDL3280A
Other name	
Pharmaceutical forms	Infusion
Routes of administration	Intravenous use

Dosage and administration details:

Subjects received atezolizumab of 1200 mg (equivalent to an average body weight-based dose of 15 milligram per kilogram [mg/kg]) which was administered by IV infusion q3w on Day 1 of each 21 day cycle. Subject were allowed to continue treatment beyond progression per response evaluation criteria in solid tumors (RECIST) v1.1 if they were experiencing clinical benefit per investigator, did not have a decline in performance status, did not have signs or symptoms of unequivocal progression, did not have tumor progression at critical sites, and signed an informed consent signature page acknowledging deferment any standard treatment options that may exist in favor of continuing atezolizumab.

Number of subjects in period 1	Docetaxel	Atezolizumab
Started	143	144
Received Treatment	135	142
Completed	20	49
Not completed	123	95
Consent withdrawn by subject	13	5
Death	108	89
Lost to follow-up	2	1

Baseline characteristics

Reporting groups	
Reporting group title	Docetaxel
Reporting group description:	
Subjects received docetaxel 75 milligram per meter square (mg/m^2) administered intravenously on Day 1 of each 21 day cycle until disease progression or unacceptable toxicity or death.	
Reporting group title	Atezolizumab
Reporting group description:	
Subjects were administered atezolizumab intravenously on Day 1 of each 21 day cycle at a fixed dose of 1200 mg. Atezolizumab treatment were to continued as long as subjects were experiencing clinical benefit as assessed by the investigator.	

Reporting group values	Docetaxel	Atezolizumab	Total
Number of subjects	143	144	287
Age categorical			
Units: Subjects			
Age continuous			
Units: years			
arithmetic mean	61.8	61.5	
standard deviation	± 9.4	± 9.2	-
Gender categorical			
Units: Subjects			
Female	67	51	118
Male	76	93	169

End points

End points reporting groups

Reporting group title	Docetaxel

Reporting group description:

Subjects received docetaxel 75 milligram per meter square (mg/m^2) administered intravenously on Day 1 of each 21 day cycle until disease progression or unacceptable toxicity or death.

Reporting group title	Atezolizumab

Reporting group description:

Subjects were administered atezolizumab intravenously on Day 1 of each 21 day cycle at a fixed dose of 1200 mg. Atezolizumab treatment were to continued as long as subjects were experiencing clinical benefit as assessed by the investigator.

Primary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

Overall Survival (OS) was defined as the time from the date of randomisation to the date of death due to any cause. Data for subjects who were not reported as dead at the time of analysis was censored at the date when they were last known to be alive. Intent-to-treat (ITT) population for efficacy analyses included all randomised subjects, regardless of whether they received any study drug. In the efficacy analyses, the ITT population, subjects were grouped according to the treatment arm to which they were assigned.

End point type	Primary

End point timeframe:

From the time of randomisation to the date of death due to any cause or up to data cut off date: 01 Dec 2015 (up to 28 months)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	144		
Units: months				
median (confidence interval 95%)	9.7 (8.6 to 12)	12.6 (9.7 to 16)		

Statistical analyses

Statistical analysis title	Overall Survival

Statistical analysis description:

Hazard ratios (HR) were estimated by a Cox regression model.

Comparison groups	Docetaxel v Atezolizumab

Number of subjects included in analysis	287
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0106
Method	Log rank (stratified)
Parameter estimate	Hazard ratio (HR)
Point estimate	0.69
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.52
upper limit	0.92

Secondary: Progression-Free Survival (PFS)

End point title	Progression-Free Survival (PFS)

End point description:

PFS was defined as the time (in months) between the date of randomization and the date of first documented disease progression or death, whichever occurs first. Disease progression was determined based on investigator assessment using response evaluation criteria In solid tumors (RECIST) v1.1. Progressive disease (PD): at least a 20% increase in the sum of diameters of target lesions including baseline In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. The appearance of one or more new lesions is also considered progression. ITT population for efficacy analyses included all randomised subjects, regardless of whether they received any study drug. In the efficacy analyses, the ITT population, subjects were grouped according to the treatment arm to which they were assigned.

End point type	Secondary

End point timeframe:

From the time of randomisation to the date of death due to any cause or up to data cut off date: 01 Dec 2015 (up to 28 months)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	144		
Units: months				
median (confidence interval 95%)	3.4 (2.8 to 4.1)	2.7 (2 to 4.1)		

Statistical analyses

Statistical analysis title	Progression free survival

Statistical analysis description:

HR were estimated by a Cox regression model. The two treatment comparison was based on a stratified log-rank test.

Comparison groups	Docetaxel v Atezolizumab

Number of subjects included in analysis	287
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.5563
Method	Log rank (stratified)
Parameter estimate	Hazard ratio (HR)
Point estimate	0.92
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.71
upper limit	1.2

Secondary: Objective Response Rate (ORR)

End point title	Objective Response Rate (ORR)

End point description:

ORR was defined as the percentage of subjects with confirmed objective tumor response, complete response (CR) or partial response (PR), as determined by investigator using RECIST v1.1 criteria. CR: disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to < 10 mm. PR: at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum of diameters. ITT population for efficacy analyses included all randomised subjects, regardless of whether they received any study drug. In the efficacy analyses, the ITT population, subjects were grouped according to the treatment arm to which they were assigned.

End point type	Secondary

End point timeframe:

Baseline until date of death due to any cause or up to data cut off date: 01 Dec 2015 (up to 28 months)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	143	144		
Units: percentage of subjects				
number (confidence interval 95%)	15.3 (9.83 to 22.21)	14.7 (9.33 to 21.57)		

Statistical analyses

Statistical analysis title	Objective response rate
Comparison groups	Atezolizumab v Docetaxel
Number of subjects included in analysis	287
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.8884
Method	Cochran-Mantel-Haenszel
Parameter estimate	Difference in Response Rates
Point estimate	0.59

Confidence interval	
level	95 %
sides	2-sided
lower limit	-7.67
upper limit	8.85

Secondary: Duration of Response (DOR)

End point title	Duration of Response (DOR)

End point description:

DOR was defined as the duration from the first tumor assessment that supports the subject's objective response (CR or PR, whichever is first recorded) to disease progression or death due to any cause, whichever occurs first. ITT population for efficacy analyses included all randomised subjects, regardless of whether they received any study drug. In the efficacy analyses, the ITT population, subjects were grouped according to the treatment arm to which they were assigned. Here, 99999 indicates upper limit of confidence interval (CI) for Atezolizumab arm as the CI was not estimable.

End point type	Secondary

End point timeframe:

From the time of randomisation to the date of death due to any cause or up to data cut off date: 01 Dec 2015 (up to 28 months)

End point values	Docetaxel	Atezolizumab		
Subject group type	Reporting group	Reporting group		
Number of subjects analysed	21[1]	22[2]		
Units: months				
median (confidence interval 95%)	7.2 (5.6 to 12.5)	18.6 (11.6 to 99999)		

Notes:

[1] - Number of subjects who were evaluable for this endpoint.

[2] - Number of subjects who were evaluable for this endpoint.

Statistical analyses

Statistical analysis title	Duration of response

Statistical analysis description:

HR were estimated by a unstratified Cox regression model.

Comparison groups	Docetaxel v Atezolizumab
Number of subjects included in analysis	43
Analysis specification	Pre-specified
Analysis type	superiority
P-value	= 0.0028
Method	Log rank (unstratified)
Parameter estimate	Hazard ratio (HR)
Point estimate	0.32
Confidence interval	
level	95 %
sides	2-sided
lower limit	0.15
upper limit	0.7

Secondary: ORR (Modified RECIST)

End point title	ORR (Modified RECIST)[3]

End point description:

ORR was defined as the percentage of subjects with confirmed objective tumor response, CR or PR, as determined by investigator using modified RECIST criteria. CR: disappearance of all target lesions. Any pathological lymph nodes (whether target or non-target) must have reduction in short axis to l< 10 mm. PR: at least a 30% decrease in the sum of diameters of target lesions, taking as reference the baseline sum of diameters.ITT population for efficacy analyses included all randomised subjects, regardless of whether they received any study drug. In the efficacy analyses, the ITT population, subjects were grouped according to the treatment arm to which they were assigned.

End point type	Secondary

End point timeframe:

From the time of randomisation to the date of death due to any cause or up to data cut off: 08 May 2015 (up to 21 months)

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	144			
Units: percentage of subjects				
number (confidence interval 95%)	16.7 (10.98 to 23.78)			

Statistical analyses

No statistical analyses for this end point

Secondary: PFS (Modified RECIST)

End point title	PFS (Modified RECIST)[4]

End point description:

PFS was defined as the time (in months) between the date of randomisation and the date of first documented disease progression or death, whichever occurs first. Disease progression was determined based on investigator assessment using modified RECIST criteria. PD: at least a 20% increase in the sum of diameters of target lesions. In addition to the relative increase of 20%, the sum must also demonstrate an absolute increase of at least 5 mm. The appearance of one or more new lesions is also considered progression. ITT population for efficacy analyses included all randomised subjects, regardless of whether they received any study drug. In the efficacy analyses, the ITT population, subjects were grouped according to the treatment arm to which they were assigned.

End point type	Secondary

End point timeframe:

From the time of randomisation to the date of death due to any cause or up to data cut off: 08 May 2015 (up to 21 months)

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	144			
Units: months				
median (confidence interval 95%)	4.2 (3.9 to 6.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: DOR (Modified RECIST)

End point title	DOR (Modified RECIST)[5]

End point description:

DOR was defined as the duration from the first tumor assessment that supports the subject's objective response (CR or PR, whichever is first recorded) to disease progression or death due to any cause, whichever occurs first. ITT population for efficacy analyses included all randomised subjects, regardless of whether they received any study drug. In the efficacy analyses, the ITT population, subjects were grouped according to the treatment arm to which they were assigned. Here, 99999 indicates upper limit of confidence interval (CI) for Atezolizumab arm as the CI was not estimable.

End point type	Secondary

End point timeframe:

From the time of randomisation to the date of death due to any cause or up to data cut off: 08 May 2015 (up to 21 months)

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	24[6]			
Units: months				
median (confidence interval 95%)	14.9 (11.6 to 99999)			

Notes:

[6] - Number of subjects who were evaluable for this endpoint.

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From the first study drug to the data cutoff date: 01 Dec 2015 (up to 28 months)

Adverse event reporting additional description:

Treatment−emergent adverse events are reported here and they include all adverse events that occurred on or after first dose of study drug until 30 days after last administration of study drug or initiation of another non−protocol anti−cancer therapy after the last administration of study drug, or clinical data cutoff date, whichever occurs first.

Assessment type	Systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	18.0

Reporting groups

Reporting group title	Docetaxel

Reporting group description:

Subjects received docetaxel 75 milligram per meter square (mg/m^2) administered intravenously on Day 1 of each 21 day cycle until disease progression or unacceptable toxicity.

Reporting group title	Atezolizumab

Reporting group description:

Subjects were administered atezolizumab intravenously on Day 1 of each 21 day cycle at a fixed dose of 1200 mg. Atezolizumab treatment were to continued as long as subjects were experiencing clinical benefit as assessed by the investigator.

Serious adverse events	Docetaxel	Atezolizumab	
Total subjects affected by serious adverse events			
subjects affected / exposed	46 / 135 (34.07%)	50 / 142 (35.21%)	
number of deaths (all causes)	5	6	
number of deaths resulting from adverse events	3	1	
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Metastatic pain			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Tumour associated fever			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Vascular disorders			
Embolism			

subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 1	
Peripheral embolism			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral ischaemia			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Superior vena cava syndrome			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Venous stenosis			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Death			
subjects affected / exposed	2 / 135 (1.48%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	1 / 2	0 / 1	
deaths causally related to treatment / all	1 / 2	0 / 1	
Device dislocation			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Fatigue			

subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Influenza like illness			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Oedema peripheral			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pain			
subjects affected / exposed	0 / 135 (0.00%)	2 / 142 (1.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pyrexia			
subjects affected / exposed	1 / 135 (0.74%)	3 / 142 (2.11%)	
occurrences causally related to treatment / all	1 / 1	3 / 3	
deaths causally related to treatment / all	0 / 0	0 / 0	
Ulcer haemorrhage			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Respiratory, thoracic and mediastinal disorders			
Acute respiratory distress syndrome			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	2 / 2	0 / 0	
deaths causally related to treatment / all	1 / 1	0 / 0	
Chronic obstructive pulmonary disease			
subjects affected / exposed	2 / 135 (1.48%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	0 / 2	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dyspnoea			

subjects affected / exposed	1 / 135 (0.74%)	6 / 142 (4.23%)	
occurrences causally related to treatment / all	1 / 1	0 / 6	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemoptysis			
subjects affected / exposed	3 / 135 (2.22%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 3	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hypoxia			
subjects affected / exposed	0 / 135 (0.00%)	2 / 142 (1.41%)	
occurrences causally related to treatment / all	0 / 0	1 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleural effusion			
subjects affected / exposed	0 / 135 (0.00%)	4 / 142 (2.82%)	
occurrences causally related to treatment / all	0 / 0	0 / 4	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pleurisy			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonitis			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumothorax			
subjects affected / exposed	0 / 135 (0.00%)	2 / 142 (1.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 3	
deaths causally related to treatment / all	0 / 0	0 / 1	
Pulmonary embolism			
subjects affected / exposed	6 / 135 (4.44%)	2 / 142 (1.41%)	
occurrences causally related to treatment / all	0 / 6	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 1	
Psychiatric disorders			
Confusional state			

subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Delirium			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (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	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Aspartate aminotransferase increased			
subjects affected / exposed	0 / 135 (0.00%)	2 / 142 (1.41%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutrophil count decreased			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Urine output decreased			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Injury, poisoning and procedural complications			
Radiation pneumonitis			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac disorders			
Acute myocardial infarction			

subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Atrial fibrillation			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cardiac failure			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	1 / 1	
Cardiac tamponade			
subjects affected / exposed	0 / 135 (0.00%)	2 / 142 (1.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pericardial effusion			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sinus tachycardia			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nervous system disorders			
Hypoaesthesia			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Paraesthesia			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Peripheral sensory neuropathy			

subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Headache			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Febrile neutropenia			
subjects affected / exposed	7 / 135 (5.19%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	7 / 7	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lymphadenopathy			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Neutropenia			
subjects affected / exposed	2 / 135 (1.48%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	3 / 3	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Gastrointestinal disorders			
Abdominal pain			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Colitis			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Constipation			

subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Diarrhoea			
subjects affected / exposed	1 / 135 (0.74%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 1	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Dysphagia			
subjects affected / exposed	0 / 135 (0.00%)	2 / 142 (1.41%)	
occurrences causally related to treatment / all	0 / 0	0 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Haemorrhoids thrombosed			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Large intestine perforation			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Nausea			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	1 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Small intestinal obstruction			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Upper gastrointestinal haemorrhage			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Skin and subcutaneous tissue disorders			
Rash			

subjects affected / exposed	0 / 135 (0.00%)	2 / 142 (1.41%)	
occurrences causally related to treatment / all	0 / 0	2 / 2	
deaths causally related to treatment / all	0 / 0	0 / 0	
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	1 / 135 (0.74%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	1 / 1	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Back pain			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Myalgia			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal column stenosis			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Spinal osteoarthritis			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infections and infestations			
Bronchitis			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	

Cellulitis			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
H1N1 influenza			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Infectious pleural effusion			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lower respiratory tract infection			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Lung infection			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Osteomyelitis			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pharyngitis			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Pneumonia			
subjects affected / exposed	3 / 135 (2.22%)	10 / 142 (7.04%)	
occurrences causally related to treatment / all	2 / 3	3 / 11	
deaths causally related to treatment / all	0 / 0	0 / 1	
Respiratory tract infection			

subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Respiratory tract infection bacterial			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	0 / 1	
deaths causally related to treatment / all	0 / 0	0 / 0	
Sepsis			
subjects affected / exposed	3 / 135 (2.22%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	3 / 5	0 / 0	
deaths causally related to treatment / all	1 / 2	0 / 0	
Metabolism and nutrition disorders			
Dehydration			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	1 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Hyperglycaemia			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Type 2 diabetes mellitus			
subjects affected / exposed	1 / 135 (0.74%)	0 / 142 (0.00%)	
occurrences causally related to treatment / all	0 / 1	0 / 0	
deaths causally related to treatment / all	0 / 0	0 / 0	
Cachexia			
subjects affected / exposed	0 / 135 (0.00%)	1 / 142 (0.70%)	
occurrences causally related to treatment / all	0 / 0	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	Docetaxel	Atezolizumab	
Total subjects affected by non-serious adverse events			
subjects affected / exposed	124 / 135 (91.85%)	126 / 142 (88.73%)	
Vascular disorders			
Hypotension			
subjects affected / exposed	4 / 135 (2.96%)	9 / 142 (6.34%)	
occurrences (all)	4	9	
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	21 / 135 (15.56%)	15 / 142 (10.56%)	
occurrences (all)	27	25	
Chest pain			
subjects affected / exposed	6 / 135 (4.44%)	10 / 142 (7.04%)	
occurrences (all)	8	11	
Fatigue			
subjects affected / exposed	53 / 135 (39.26%)	55 / 142 (38.73%)	
occurrences (all)	85	78	
Oedema peripheral			
subjects affected / exposed	13 / 135 (9.63%)	9 / 142 (6.34%)	
occurrences (all)	18	11	
Pain			
subjects affected / exposed	10 / 135 (7.41%)	5 / 142 (3.52%)	
occurrences (all)	11	6	
Pyrexia			
subjects affected / exposed	15 / 135 (11.11%)	22 / 142 (15.49%)	
occurrences (all)	18	27	
Influenza like illness			
subjects affected / exposed	2 / 135 (1.48%)	8 / 142 (5.63%)	
occurrences (all)	2	10	
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	33 / 135 (24.44%)	40 / 142 (28.17%)	
occurrences (all)	40	49	
Dyspnoea			
subjects affected / exposed	27 / 135 (20.00%)	34 / 142 (23.94%)	
occurrences (all)	32	38	

Dyspnoea exertional			
subjects affected / exposed	3 / 135 (2.22%)	10 / 142 (7.04%)	
occurrences (all)	3	10	
Haemoptysis			
subjects affected / exposed	6 / 135 (4.44%)	14 / 142 (9.86%)	
occurrences (all)	10	19	
Productive cough			
subjects affected / exposed	2 / 135 (1.48%)	8 / 142 (5.63%)	
occurrences (all)	2	10	
Psychiatric disorders			
Insomnia			
subjects affected / exposed	11 / 135 (8.15%)	22 / 142 (15.49%)	
occurrences (all)	12	23	
Investigations			
Weight decreased			
subjects affected / exposed	9 / 135 (6.67%)	16 / 142 (11.27%)	
occurrences (all)	9	20	
Nervous system disorders			
Dizziness			
subjects affected / exposed	11 / 135 (8.15%)	10 / 142 (7.04%)	
occurrences (all)	12	15	
Dysgeusia			
subjects affected / exposed	7 / 135 (5.19%)	1 / 142 (0.70%)	
occurrences (all)	8	1	
Headache			
subjects affected / exposed	10 / 135 (7.41%)	14 / 142 (9.86%)	
occurrences (all)	10	17	
Neuropathy peripheral			
subjects affected / exposed	16 / 135 (11.85%)	3 / 142 (2.11%)	
occurrences (all)	20	5	
Peripheral sensory neuropathy			
subjects affected / exposed	12 / 135 (8.89%)	1 / 142 (0.70%)	
occurrences (all)	21	2	
Blood and lymphatic system disorders			
Anaemia			
subjects affected / exposed	26 / 135 (19.26%)	25 / 142 (17.61%)	
occurrences (all)	37	42	

Neutropenia			
subjects affected / exposed	15 / 135 (11.11%)	2 / 142 (1.41%)	
occurrences (all)	23	2	
Eye disorders			
Lacrimation increased			
subjects affected / exposed	7 / 135 (5.19%)	1 / 142 (0.70%)	
occurrences (all)	9	1	
Gastrointestinal disorders			
Constipation			
subjects affected / exposed	31 / 135 (22.96%)	31 / 142 (21.83%)	
occurrences (all)	33	32	
Diarrhoea			
subjects affected / exposed	37 / 135 (27.41%)	24 / 142 (16.90%)	
occurrences (all)	50	32	
Dyspepsia			
subjects affected / exposed	7 / 135 (5.19%)	3 / 142 (2.11%)	
occurrences (all)	7	3	
Gastrooesophageal reflux disease			
subjects affected / exposed	7 / 135 (5.19%)	8 / 142 (5.63%)	
occurrences (all)	8	9	
Nausea			
subjects affected / exposed	45 / 135 (33.33%)	31 / 142 (21.83%)	
occurrences (all)	63	40	
Stomatitis			
subjects affected / exposed	9 / 135 (6.67%)	3 / 142 (2.11%)	
occurrences (all)	9	3	
Vomiting			
subjects affected / exposed	18 / 135 (13.33%)	20 / 142 (14.08%)	
occurrences (all)	20	25	
Skin and subcutaneous tissue disorders			
Alopecia			
subjects affected / exposed	52 / 135 (38.52%)	3 / 142 (2.11%)	
occurrences (all)	57	3	
Dry skin			
subjects affected / exposed	10 / 135 (7.41%)	3 / 142 (2.11%)	
occurrences (all)	10	3	
Nail disorder			

subjects affected / exposed	9 / 135 (6.67%)	1 / 142 (0.70%)	
occurrences (all)	9	1	
Pruritus			
subjects affected / exposed	5 / 135 (3.70%)	13 / 142 (9.15%)	
occurrences (all)	5	21	
Rash			
subjects affected / exposed	16 / 135 (11.85%)	15 / 142 (10.56%)	
occurrences (all)	19	27	
Endocrine disorders			
Hypothyroidism			
subjects affected / exposed	0 / 135 (0.00%)	9 / 142 (6.34%)	
occurrences (all)	0	9	
Musculoskeletal and connective tissue disorders			
Arthralgia			
subjects affected / exposed	12 / 135 (8.89%)	22 / 142 (15.49%)	
occurrences (all)	16	26	
Back pain			
subjects affected / exposed	10 / 135 (7.41%)	16 / 142 (11.27%)	
occurrences (all)	11	17	
Musculoskeletal chest pain			
subjects affected / exposed	4 / 135 (2.96%)	9 / 142 (6.34%)	
occurrences (all)	5	10	
Musculoskeletal pain			
subjects affected / exposed	7 / 135 (5.19%)	19 / 142 (13.38%)	
occurrences (all)	7	19	
Myalgia			
subjects affected / exposed	18 / 135 (13.33%)	8 / 142 (5.63%)	
occurrences (all)	24	9	
Pain in extremity			
subjects affected / exposed	13 / 135 (9.63%)	9 / 142 (6.34%)	
occurrences (all)	18	11	
Infections and infestations			
Upper respiratory tract infection			
subjects affected / exposed	3 / 135 (2.22%)	10 / 142 (7.04%)	
occurrences (all)	5	14	
Metabolism and nutrition disorders			

Decreased appetite			
subjects affected / exposed	28 / 135 (20.74%)	49 / 142 (34.51%)	
occurrences (all)	35	59	
Dehydration			
subjects affected / exposed	11 / 135 (8.15%)	5 / 142 (3.52%)	
occurrences (all)	11	7	
Hypokalaemia			
subjects affected / exposed	4 / 135 (2.96%)	9 / 142 (6.34%)	
occurrences (all)	4	12	
Hyponatraemia			
subjects affected / exposed	4 / 135 (2.96%)	8 / 142 (5.63%)	
occurrences (all)	4	12	
Hypomagnesaemia			
subjects affected / exposed	5 / 135 (3.70%)	8 / 142 (5.63%)	
occurrences (all)	6	10	

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
28 July 2013	1. Inclusion Criteria: a) The window for prior treatment with immunostimulatory agents has been adjusted to be consistent with the exclusion criterion covering this prior therapy b) The criterion for liver function test results has been modified to be consistent with the docetaxel US Package Insert c) The formula for estimated glomerular filtration rate has been corrected with regard to numbers and variables that should be superscripted 2.Exclusion Criteria: a) Exclusion for subjects with known or untreated central nervous system (CNS) metastases clarified to indicate that subjects must not have active or untreated CNS metastases as determined by computerized tomography (CT) or magnetic resonance imaging (MRI) evaluation during screening and prior radiographic assessments. Additionally, subjects must not have had stereotactic radiation or whole-brain radiation within 28 days prior to Cycle 1, Day 1 b) Exclusion added for known hypersensitivity or allergy to Chinese hamster ovary cell products or any component of the MPDL3280A formulation as a safety precaution c) Exclusion added for subjects with prior allogeneic bone marrow transplantation or prior solid organ transplantation as a safety precaution d) Exclusion added for subjects having a positive Human immunodeficiency virus (HIV) test as a safety precaution e) Exclusion criterion for subjects with active hepatitis B clarified with respect to definitive serology results f) Exclusion criteria for subjects with active hepatitis C broken out into its own criterion for clarity
30 January 2014	Study design, determination of sample size, and administrative structure were revised to reflect the continuation of enrollment of subjects until a minimum of approximately 54 subjects Programmed death - ligand 1 (PD-L1) −positive.
20 May 2014	1. Treatment duration for atezolizumab was modified to allow subjects to be treated until clinical benefit was no longer being experienced; accordingly, the 16-cycle or 12-month initial treatment, follow-up, and re-treatment periods no longer applied. 2. The frequency of tumor assessments after 36 weeks changed from every 12 weeks to every 9 weeks (± 1 week) to be more consistent with clinical practice in non−small cell lung cancer. 3. The timing of the interim safety and efficacy data evaluation by the Internal Monitoring Committee changed from when 30 and 60 deaths were observed to when approximately 30 and 100 deaths had occurred. The change to evaluate at 100 deaths was determined to be more appropriate than 60 with regard to estimating efficacy in both the PD-L1 IC2/IC3 and overall study populations. 4. The terms "PD-L1 positive" and "PD-L1 negative" were replaced with "PD-L1 (Tumor-infiltrating immune cell 2/Tumor-infiltrating immune cell 3 (IC2/IC3)" and "PD-L1 IC0/IC1," respectively, to clarify that these categorizations did not necessarily reflect a final definition of positivity for PD-L1 expression using this diagnostic assay. 5. The AE/safety follow-up period changed from 90 to 30 days in order to harmonize safety data collection across the atezolizumab clinical development program. The follow-up period was shortened because of the low frequency of significant drugrelated AEs following treatment discontinuation across studies. 6. Statistical considerations and the analysis plan were changed to reflect the increase in study size that was put into place in Version 3 of this protocol.
24 July 2014	The safety follow-up period was changed back to the original 90 days to maintain a consistent follow-up period throughout the study and to allow further evaluation of safety after treatment discontinuation in this Phase II trial.

24 February 2015	1. Adjusted the event threshold for the primary analysis to approximately 180 death events and converted the originally planned analysis at approximately 150 death events to an interim analysis. This change was made in order to allow for an improved evaluation of late events in the survival curves of atezolizumab compared with docetaxel. 2. Clarified that stratification by PD-L1 immunohistochemistry (IHC) status was based on PD-L1 expression on tumor-infiltrating immune cells. 3. In addition to the primary analyses on the ITT population and the subgroup of subjects with PD-L1 IHC 2 or IHC 3 expression status in ICs, the protocol was amended to allow for subgroup analyses based on other categories of PD-L1 expression (e.g., including expression on tumor cells [TCs]).

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported