



Clinical trial results:

An Open-label, Phase IIIb, Single Arm, Multicenter Safety Study of Atezolizumab (Tecentriq) Plus Nab-paclitaxel in the Treatment of Unresectable Locally Advanced or Metastatic Triple-Negative Breast Cancer

Summary

EudraCT number	2019-002488-91
Trial protocol	PT SI FR HU SK IT RO
Global end of trial date	15 December 2024

Results information

Result version number	v1 (current)
This version publication date	12 December 2025
First version publication date	12 December 2025

Trial information

Trial identification

Sponsor protocol code	MO39874
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Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04148911
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	F. Hoffmann-La Roche AG
Sponsor organisation address	Grenzacherstrasse 124, Basel, Switzerland, CH-4058
Public contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.com
Scientific contact	F. Hoffmann-La Roche AG, F. Hoffmann-La Roche AG, +41 616878333, global.trial_information@roche.com

Notes:

Paediatric regulatory details

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

Notes:

Results analysis stage

Analysis stage	Final
Date of interim/final analysis	15 December 2024
Is this the analysis of the primary completion data?	No
Global end of trial reached?	Yes
Global end of trial date	15 December 2024
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

The main objective of the study is to evaluate the safety of atezolizumab plus nab-paclitaxel in participants with programmed death-ligand 1 (PD-L1)-positive unresectable locally advanced or metastatic triple-negative adenocarcinoma of the breast (TNBC) who have not received prior systemic therapy.

Protection of trial subjects:

All study subjects were required to read and sign an Informed Consent Form (ICF).

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	10 December 2019
Long term follow-up planned	Yes
Long term follow-up rationale	Safety
Long term follow-up duration	60 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Argentina: 10
Country: Number of subjects enrolled	Chile: 4
Country: Number of subjects enrolled	Mexico: 6
Country: Number of subjects enrolled	Peru: 12
Country: Number of subjects enrolled	Czechia: 6
Country: Number of subjects enrolled	Spain: 25
Country: Number of subjects enrolled	France: 11
Country: Number of subjects enrolled	Hungary: 10
Country: Number of subjects enrolled	Italy: 46
Country: Number of subjects enrolled	Poland: 13
Country: Number of subjects enrolled	Portugal: 19
Country: Number of subjects enrolled	Romania: 13
Country: Number of subjects enrolled	Slovenia: 7
Worldwide total number of subjects	182
EEA total number of subjects	150

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)	141
From 65 to 84 years	41
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

Participants with unresectable locally advanced or metastatic PD-L1-positive TNBC took part in the study at 67 centers in 13 countries from 10 Dec 2019 to 15 Dec 2024.

Pre-assignment

Screening details:

Participants received atezolizumab in combination with nab-paclitaxel until disease progression (PD) or unacceptable toxicity or loss of clinical benefit. A total of 184 participants were enrolled in the study. However, two participants discontinued the study before receiving any treatment. Hence, data is presented for 182 participants.

Period 1

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

Arms

Arm title	Atezolizumab + Nab-paclitaxel
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Arm description:

Participants received atezolizumab 840 milligrams (mg) as intravenous (IV) infusion on Days 1 and 15 of each 28-day cycle along with nab-paclitaxel, 100 milligrams per square meter (mg/m²) as IV infusion on Days 1, 8 and 15 of each 28-day cycle until PD, unacceptable toxicity, loss of clinical benefit or participant or investigator decision to discontinue treatment.

Arm type	Experimental
Investigational medicinal product name	Nab-paclitaxel
Investigational medicinal product code	
Other name	
Pharmaceutical forms	Solution for infusion
Routes of administration	Intravenous use

Dosage and administration details:

Nab-paclitaxel, 100 mg/m², IV on Days 1, 8 and 15 of each 28-day cycle until PD, unacceptable toxicity, loss of clinical benefit or participant or investigator decision to discontinue treatment.

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

Dosage and administration details:

Atezolizumab, 840 mg, IV on Days 1 and 15 of each 28-day cycle until PD, unacceptable toxicity, loss of clinical benefit or participant or investigator decision to discontinue treatment.

Number of subjects in period 1	Atezolizumab + Nab-paclitaxel
Started	182
Completed	0
Not completed	182
Consent withdrawn by subject	17

Study Ended by Sponsor	56
Death	104
Lost to follow-up	5

Baseline characteristics

Reporting groups

Reporting group title	Atezolizumab + Nab-paclitaxel
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Reporting group description:

Participants received atezolizumab 840 milligrams (mg) as intravenous (IV) infusion on Days 1 and 15 of each 28-day cycle along with nab-paclitaxel, 100 milligrams per square meter (mg/m²) as IV infusion on Days 1, 8 and 15 of each 28-day cycle until PD, unacceptable toxicity, loss of clinical benefit or participant or investigator decision to discontinue treatment.

Reporting group values	Atezolizumab + Nab-paclitaxel	Total	
Number of subjects	182	182	
Age categorical			
Units: participants			
Adults (18-64 years)	141	141	
From 65-84 years	41	41	
Age Continuous			
Units: years			
arithmetic mean	54.8		
standard deviation	± 12.2	-	
Sex: Female, Male			
Units: participants			
Female	182	182	
Male	0	0	
Race (NIH/OMB)			
Units: Subjects			
American Indian or Alaska Native	17	17	
Asian	1	1	
Native Hawaiian or Other Pacific Islander	0	0	
Black or African American	1	1	
White	146	146	
More than one race	0	0	
Unknown or Not Reported	17	17	
Ethnicity (NIH/OMB)			
Units: Subjects			
Hispanic or Latino	40	40	
Not Hispanic or Latino	126	126	
Unknown or Not Reported	16	16	

End points

End points reporting groups

Reporting group title	Atezolizumab + Nab-paclitaxel
Reporting group description:	
Participants received atezolizumab 840 milligrams (mg) as intravenous (IV) infusion on Days 1 and 15 of each 28-day cycle along with nab-paclitaxel, 100 milligrams per square meter (mg/m ²) as IV infusion on Days 1, 8 and 15 of each 28-day cycle until PD, unacceptable toxicity, loss of clinical benefit or participant or investigator decision to discontinue treatment.	

Primary: Percentage of Participants With Treatment-emergent Grade ≥ 3 Adverse Events (AEs)

End point title	Percentage of Participants With Treatment-emergent Grade ≥ 3 Adverse Events (AEs) ^[1]
End point description:	
AE=untoward medical occurrence in participant administered pharmaceutical product (PP), regardless of causal attribution. AE=any unfavorable & unintended sign, symptom/disease temporally associated with the use of PP, whether/not considered related to it. Severity was graded per National Cancer Institute Common Terminology Criteria for Adverse Events version 5.0 (NCI CTCAE v5.0). Grade 1=Mild; asymptomatic/mild symptoms; clinical/diagnostic observations only; intervention not indicated; Grade 2=Moderate; minimal, local/non-invasive intervention indicated; limiting age-appropriate instrumental activities of daily living; Grade 3=Severe/medically significant, but not immediately life-threatening; hospitalization/prolongation of hospitalization; disabling; limiting self-care activities of daily living; Grade 4=Life-threatening consequences/urgent intervention indicated; Grade 5=Death related to AE. Percentages have been rounded off. Safety-evaluable population.	
End point type	Primary
End point timeframe:	
Up to 60 months	
Notes:	
[1] - No statistical analyses have been specified for this primary end point. It is expected there is at least one statistical analysis for each primary end point.	
Justification: Only descriptive statistics were planned for this endpoint	

End point values	Atezolizumab + Nab-paclitaxel			
Subject group type	Reporting group			
Number of subjects analysed	182			
Units: percentage of participants				
number (confidence interval 95%)	46.70 (39.29 to 54.23)			

Statistical analyses

No statistical analyses for this end point

Primary: Percentage of Participants With Treatment-emergent Grade ≥ 2 Immune-mediated AEs (imAEs)

End point title	Percentage of Participants With Treatment-emergent Grade ≥ 2 Immune-mediated AEs (imAEs) ^[2]
End point description:	
AE=any untoward medical occurrence in participant administered PP, regardless of causal attribution.	

AE=any unfavorable and unintended sign, symptom/disease temporally associated with the use of a PP, whether/not considered related to it. Severity was graded per NCI CTCAE v5.0. Grade 1=Mild; asymptomatic/mild symptoms; clinical/diagnostic observations only; or intervention not indicated; Grade 2=Moderate; minimal, local/non-invasive intervention indicated; or limiting age-appropriate instrumental activities of daily living (ADL); Grade 3=Severe/medically significant, but not immediately life-threatening; hospitalization/prolongation of hospitalization indicated; disabling; or limiting self-care ADL; Grade 4=Life-threatening consequences/urgent intervention indicated; Grade 5=Death related to AE. imAEs are events that resemble autoimmune diseases and are known side effects of immune checkpoint inhibitors. Percentages have been rounded off. Safety-evaluable population.

End point type	Primary
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End point timeframe:

Up to 60 months

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: Only descriptive statistics were planned for this endpoint

End point values	Atezolizumab + Nab-paclitaxel			
Subject group type	Reporting group			
Number of subjects analysed	182			
Units: percentage of participants				
number (confidence interval 95%)	12.09 (7.73 to 17.73)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With all Treatment-emergent AEs

End point title	Percentage of Participants With all Treatment-emergent AEs
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End point description:

An AE was any untoward medical occurrence in a participant administered a pharmaceutical product and which does not necessarily have to have a causal relationship with the treatment. An AE can therefore be any unfavorable and unintended sign (including abnormal laboratory values or abnormal clinical test results), symptoms, or disease temporally associated with the use of a pharmaceutical product, whether or not considered related to the PP. Percentages have been rounded off. Safety-evaluable population included all enrolled participants who had received at least one dose of any study treatment (atezolizumab/nab-paclitaxel).

End point type	Secondary
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End point timeframe:

Up to 60 months

End point values	Atezolizumab + Nab-paclitaxel			
Subject group type	Reporting group			
Number of subjects analysed	182			
Units: percentage of participants				
number (confidence interval 95%)	95.60 (91.52 to 98.08)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of Participants With all Treatment-emergent Serious Adverse Events (SAEs)

End point title	Percentage of Participants With all Treatment-emergent Serious Adverse Events (SAEs)
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End point description:

AE=untoward medical occurrence in a participant administered PP and which does not necessarily have to have a causal relationship with the treatment. An AE can therefore be any unfavorable and unintended sign (including abnormal laboratory values or abnormal clinical test results), symptoms, or disease temporally associated with the use of PP, whether or not considered related to the pharmaceutical product. SAEs were defined as any AE that fulfilled any of the following criteria: fatal (resulted in death), life-threatening, required in-patient hospitalization or prolongation of existing hospitalization, resulted in persistent or significant disability/incapacity, was a congenital anomaly/ birth defect, was medically significant or required intervention to prevent any of the other outcomes listed here. Percentages have been rounded off. Safety-evaluable population included all enrolled participants who had received at least one dose of any study treatment.

End point type	Secondary
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End point timeframe:

Up to 60 months

End point values	Atezolizumab + Nab-paclitaxel			
Subject group type	Reporting group			
Number of subjects analysed	182			
Units: percentage of participants				
number (confidence interval 95%)	16.48 (11.41 to 22.69)			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS) in Safety-evaluable Population

End point title	Overall Survival (OS) in Safety-evaluable Population
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End point description:

OS was defined as time from initiation of study treatment to death from any cause. OS was estimated using Kaplan-Meier (K-M) method. Safety-evaluable population included all enrolled participants who had received at least one dose of any study treatment (atezolizumab/nab-paclitaxel).

End point type	Secondary
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End point timeframe:

Up to 60 months

End point values	Atezolizumab + Nab-paclitaxel			
Subject group type	Reporting group			
Number of subjects analysed	182			
Units: months				
median (confidence interval 95%)	27.0 (22.0 to 33.8)			

Statistical analyses

No statistical analyses for this end point

Secondary: OS in PD-L1-positive Population

End point title	OS in PD-L1-positive Population
End point description:	
OS was defined as time from initiation of study treatment to death from any cause. OS was estimated using K-M method. PD-L1 positive population included all participants with centrally confirmed PD-L1 positive tumor status. 999=Median and upper limit of 95% CI were not estimable due to an insufficient number of participants with events.	
End point type	Secondary
End point timeframe:	
Up to 60 months	

End point values	Atezolizumab + Nab-paclitaxel			
Subject group type	Reporting group			
Number of subjects analysed	66			
Units: months				
median (confidence interval 95%)	999 (29.4 to 999)			

Statistical analyses

No statistical analyses for this end point

Secondary: Progression Free Survival (PFS) in Safety-evaluable Population

End point title	Progression Free Survival (PFS) in Safety-evaluable Population
End point description:	
PFS was defined as the time from initiation of study treatment to the first occurrence of PD, as determined by the investigator according to Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST v1.1), or death from any cause, whichever occurs first. PD was defined as at least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum of diameters at prior timepoints (including baseline), and must also demonstrate an absolute increase of ≥ 5 millimeters	

(mm). PFS was estimated using K-M method. Safety-evaluable population included all enrolled participants who had received at least one dose of any study treatment (atezolizumab/nab-paclitaxel).

End point type	Secondary
End point timeframe:	
Up to 60 months	

End point values	Atezolizumab + Nab-paclitaxel			
Subject group type	Reporting group			
Number of subjects analysed	182			
Units: months				
median (confidence interval 95%)	7.4 (5.6 to 10.6)			

Statistical analyses

No statistical analyses for this end point

Secondary: PFS in PD-L1-positive Population

End point title	PFS in PD-L1-positive Population
End point description:	
PFS was defined as the time from initiation of study treatment to the first occurrence of PD, as determined by the investigator according to RECIST v1.1, or death from any cause, whichever occurs first. PD was defined as at least a 20% increase in the sum of diameters of target lesions, taking as reference the smallest sum of diameters at prior timepoints (including baseline), and must also demonstrate an absolute increase of ≥ 5 mm. PFS was estimated using K-M method. PD-L1 positive population included all participants with centrally confirmed PD-L1 positive tumor status.	
End point type	Secondary
End point timeframe:	
Up to 60 months	

End point values	Atezolizumab + Nab-paclitaxel			
Subject group type	Reporting group			
Number of subjects analysed	66			
Units: months				
median (confidence interval 95%)	11.1 (7.4 to 16.8)			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

Up to 60 months

Adverse event reporting additional description:

Safety-evaluable population included all enrolled participants who had received at least one dose of any study treatment (atezolizumab/nab-paclitaxel).

Assessment type	Systematic
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Dictionary used

Dictionary name	MedDRA
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Dictionary version	27.1
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Reporting groups

Reporting group title	Atezolizumab + Nab-paclitaxel
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Reporting group description:

Participants received atezolizumab 840 mg as IV infusion on Days 1 and 15 of each 28-day cycle along with nab-paclitaxel, 100 mg/m² as IV infusion on Days 1, 8 and 15 of each 28-day cycle until PD, unacceptable toxicity, loss of clinical benefit or participant or investigator decision to discontinue treatment.

Serious adverse events	Atezolizumab + Nab-paclitaxel		
Total subjects affected by serious adverse events			
subjects affected / exposed	30 / 182 (16.48%)		
number of deaths (all causes)	104		
number of deaths resulting from adverse events	0		
Investigations			
Transaminases increased			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
White blood cell count decreased			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Blood creatinine increased			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Injury, poisoning and procedural complications			

Vascular access site inflammation subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Subdural haematoma subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Cardiac disorders Cardio-respiratory arrest subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
General disorders and administration site conditions Oedema peripheral subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Fatigue subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pyrexia subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Chest pain subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Device related thrombosis subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Gastrointestinal disorders			
Dysphagia			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Diverticular perforation			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Colitis			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Acute interstitial pneumonitis			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Hypoxia			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary oedema			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Bronchospasm			

subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pulmonary embolism			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumothorax			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonitis			
subjects affected / exposed	3 / 182 (1.65%)		
occurrences causally related to treatment / all	2 / 3		
deaths causally related to treatment / all	0 / 1		
Renal and urinary disorders			
Urinary tract obstruction			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Endocrine disorders			
Adrenal insufficiency			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Vascular device infection			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infected skin ulcer			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

Device related sepsis			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Soft tissue infection			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Postoperative wound infection			
subjects affected / exposed	2 / 182 (1.10%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Myelitis			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Subcutaneous abscess			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin infection			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Metabolism and nutrition disorders			
Hypokalaemia			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Electrolyte imbalance			

subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Dehydration			
subjects affected / exposed	1 / 182 (0.55%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		

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

Non-serious adverse events	Atezolizumab + Nab-paclitaxel		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	167 / 182 (91.76%)		
Vascular disorders			
Hypertension			
subjects affected / exposed	10 / 182 (5.49%)		
occurrences (all)	10		
Lymphoedema			
subjects affected / exposed	12 / 182 (6.59%)		
occurrences (all)	12		
General disorders and administration site conditions			
Oedema peripheral			
subjects affected / exposed	15 / 182 (8.24%)		
occurrences (all)	25		
Fatigue			
subjects affected / exposed	34 / 182 (18.68%)		
occurrences (all)	50		
Pyrexia			
subjects affected / exposed	32 / 182 (17.58%)		
occurrences (all)	42		
Mucosal inflammation			
subjects affected / exposed	14 / 182 (7.69%)		
occurrences (all)	21		
Asthenia			

subjects affected / exposed	61 / 182 (33.52%)		
occurrences (all)	106		
Reproductive system and breast disorders			
Breast pain			
subjects affected / exposed	10 / 182 (5.49%)		
occurrences (all)	11		
Respiratory, thoracic and mediastinal disorders			
Cough			
subjects affected / exposed	19 / 182 (10.44%)		
occurrences (all)	24		
Dyspnoea			
subjects affected / exposed	11 / 182 (6.04%)		
occurrences (all)	12		
Psychiatric disorders			
Insomnia			
subjects affected / exposed	10 / 182 (5.49%)		
occurrences (all)	12		
Investigations			
Alanine aminotransferase increased			
subjects affected / exposed	29 / 182 (15.93%)		
occurrences (all)	53		
White blood cell count decreased			
subjects affected / exposed	18 / 182 (9.89%)		
occurrences (all)	60		
Aspartate aminotransferase increased			
subjects affected / exposed	24 / 182 (13.19%)		
occurrences (all)	32		
Blood lactate dehydrogenase increased			
subjects affected / exposed	13 / 182 (7.14%)		
occurrences (all)	14		
Neutrophil count decreased			
subjects affected / exposed	15 / 182 (8.24%)		
occurrences (all)	82		
Blood alkaline phosphatase increased			

subjects affected / exposed	11 / 182 (6.04%)		
occurrences (all)	18		
Nervous system disorders			
Neuropathy peripheral			
subjects affected / exposed	24 / 182 (13.19%)		
occurrences (all)	32		
Paraesthesia			
subjects affected / exposed	27 / 182 (14.84%)		
occurrences (all)	33		
Dysgeusia			
subjects affected / exposed	12 / 182 (6.59%)		
occurrences (all)	13		
Headache			
subjects affected / exposed	24 / 182 (13.19%)		
occurrences (all)	28		
Dizziness			
subjects affected / exposed	13 / 182 (7.14%)		
occurrences (all)	13		
Blood and lymphatic system disorders			
Neutropenia			
subjects affected / exposed	44 / 182 (24.18%)		
occurrences (all)	118		
Leukopenia			
subjects affected / exposed	27 / 182 (14.84%)		
occurrences (all)	45		
Anaemia			
subjects affected / exposed	68 / 182 (37.36%)		
occurrences (all)	160		
Gastrointestinal disorders			
Vomiting			
subjects affected / exposed	22 / 182 (12.09%)		
occurrences (all)	33		
Dyspepsia			
subjects affected / exposed	10 / 182 (5.49%)		
occurrences (all)	16		
Abdominal pain upper			

subjects affected / exposed	12 / 182 (6.59%)		
occurrences (all)	16		
Constipation			
subjects affected / exposed	34 / 182 (18.68%)		
occurrences (all)	42		
Nausea			
subjects affected / exposed	50 / 182 (27.47%)		
occurrences (all)	87		
Diarrhoea			
subjects affected / exposed	49 / 182 (26.92%)		
occurrences (all)	73		
Abdominal pain			
subjects affected / exposed	12 / 182 (6.59%)		
occurrences (all)	12		
Skin and subcutaneous tissue disorders			
Rash			
subjects affected / exposed	22 / 182 (12.09%)		
occurrences (all)	26		
Alopecia			
subjects affected / exposed	72 / 182 (39.56%)		
occurrences (all)	73		
Pruritus			
subjects affected / exposed	14 / 182 (7.69%)		
occurrences (all)	18		
Erythema			
subjects affected / exposed	14 / 182 (7.69%)		
occurrences (all)	18		
Endocrine disorders			
Hyperthyroidism			
subjects affected / exposed	14 / 182 (7.69%)		
occurrences (all)	15		
Hypothyroidism			
subjects affected / exposed	34 / 182 (18.68%)		
occurrences (all)	40		
Musculoskeletal and connective tissue disorders			

Bone pain subjects affected / exposed occurrences (all)	10 / 182 (5.49%) 12		
Arthralgia subjects affected / exposed occurrences (all)	30 / 182 (16.48%) 37		
Pain in extremity subjects affected / exposed occurrences (all)	17 / 182 (9.34%) 17		
Back pain subjects affected / exposed occurrences (all)	19 / 182 (10.44%) 20		
Myalgia subjects affected / exposed occurrences (all)	30 / 182 (16.48%) 47		
Infections and infestations COVID-19 subjects affected / exposed occurrences (all)	28 / 182 (15.38%) 31		
Urinary tract infection subjects affected / exposed occurrences (all)	18 / 182 (9.89%) 21		
Metabolism and nutrition disorders Hypokalaemia subjects affected / exposed occurrences (all)	10 / 182 (5.49%) 11		
Decreased appetite subjects affected / exposed occurrences (all)	15 / 182 (8.24%) 19		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
13 February 2020	The following updates were included as per the latest Atezolizumab Investigator's Brochure (IB) v15: The latest safety updates from studies evaluating atezolizumab in combination with chemotherapy in participants with TNBC (including studies GP28328 and WO29522 [IMpassion 130]); Results of the second interim analysis of overall survival (OS) for Study WO29522 (IMpassion 130); An update on immunogenicity test results ADA development in clinical trials of atezolizumab. - Corrected previous inconsistency within the protocol, to clarify that confirmed ORR (C-ORR) and duration of response for confirmed responders (C-DoR) will be analysed based on two consecutive investigator assessments (after 8 weeks for the first 12 months following enrolment, and after 6 months [as opposed to 12 weeks] thereafter). - A second footnote was added for completeness, to indicate additional reasons for study treatment discontinuation. - Corrected previous inconsistency within the protocol, to clarify that the treatment-free interval (TFI) to be observed prior to the first dose of study treatment (Cycle 1, Day 1) is 12 months for PD-1/PD-L1-based regimens. - Inclusion criterion #6 was updated to indicate that Chinese traditional medicines with an approved indication for cancer treatment are permitted as long as the last administration occurred at least 2 weeks prior to enrolment. - For consistency within the protocol, exclusion criterion #25 was updated to confirm that the exclusion of prior immune checkpoint blockade therapies do not include anti-PD-1 or anti-PD-L1 antibodies.

08 February 2021	- The list of approved indications for atezolizumab was updated to include unresectable or metastatic hepatocellular carcinoma and BRAF V600 mutation-positive unresectable or metastatic melanoma. - The following updates were included as per the latest Atezolizumab IB v17: The latest efficacy and safety updates from studies evaluating atezolizumab in combination with chemotherapy in participants with TNBC (including studies WO29522 [IMpassion130] and MO39196 [IMpassion131]); An update on immunogenicity test results ADA development) in clinical trials of atezolizumab. - Subgroup efficacy analysis based on centrally confirmed PD-L1-positive tumor status was added as a secondary objective. - All references to paclitaxel being a combination therapy option were removed from the protocol. - AE reporting period was clarified in Sections 3.1.1 and 5.1: The total length of the study was updated from 4 to 4.5 years; The anticipated length of recruitment was revised from 18 to 19 months; The number of participating countries was updated from 20 to approximately 15. - Inclusion criterion #4a was updated to clarify that HER2-negativity is to be determined according to the current ASCO-CAP guideline. - Inclusion criterion #12 was updated to clarify the requirements for hepatitis B testing at screening. - Exclusion criterion #23: It was clarified that the restriction related to receiving a live, attenuated vaccine applies to, the duration of atezolizumab treatment and within 5 months following the last dose of atezolizumab. - It was clarified that AEs will be reported until 30 days after the last dose of study treatment. - The estimated timeline for the primary analysis was clarified (approximately 36 months after the last patient was enrolled). - The sample size was revised from 280 to 180 participants. - The estimated number of screened participants were updated from approximately 700 to approximately 450 participants .
20 February 2022	- Text was added regarding exclusion of subjects with any active infection 4 weeks prior to the first dose of the study treatment at the investigator's discretion. - The risk associated with nab-paclitaxel was updated. - The AE management guidelines were updated to align with the atezolizumab IB, Version 18.
22 February 2023	- The list of identified risks for atezolizumab were revised to include pericardial disorders, myelitis, and facial paresis. - To provide additional flexibility for participants and study sites, the timing of the Day 8 and Day 15 study treatment administrations was extended to Days 8-11 and Days 15-18, respectively. - The adverse event management guidelines were updated to align with the Atezolizumab Investigator's Brochure, Version 19, including Addenda 1 and 2. -
10 November 2023	- The list of approved indications for atezolizumab were updated to include alveolar soft part sarcoma. - The AE management guidelines were updated to align with the atezolizumab IB, Version 20

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported