Clinical trial results:
A Phase IIIb, Single-arm, Multi-center, International Study of Durvalumab in Combination with Platinum and Etoposide for the First Line Treatment of Patients with Extensive-stage Small Cell Lung Cancer (LUMINANCE)

Summary

EudraCT number	2020-005537-32
Trial protocol	DE BG IT CZ
Global end of trial date	02 January 2025

Results information

Result version number	v1 (current)
This version publication date	31 July 2025
First version publication date	31 July 2025

Trial information

Trial identification

Sponsor protocol code	D419QC00007

Additional study identifiers

ISRCTN number	-
ClinicalTrials.gov id (NCT number)	NCT04774380
WHO universal trial number (UTN)	-

Notes:

Sponsors

Sponsor organisation name	Astrazeneca
Sponsor organisation address	Södertälje, Södertälje, Sweden, 15185
Public contact	Global Clinical Lead, Astrazeneca, +1 877-240-9479, information.center@astrazeneca.com
Scientific contact	Global Clinical Lead, Astrazeneca, +1 877-240-9479, information.center@astrazeneca.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	21 April 2024
Is this the analysis of the primary completion data?	No

Global end of trial reached?	Yes
Global end of trial date	02 January 2025
Was the trial ended prematurely?	No

Notes:

General information about the trial

Main objective of the trial:

To evaluate the safety and tolerability profile of durvalumab plus platinum (cisplatin or carboplatin) plus etoposide (EP) in patients with extensive-stage small cell lung cancer (ES-SCLC).

Protection of trial subjects:

This study was performed in compliance with International Council for Harmonisation (ICH) Good Clinical Practice, including the archiving of essential documents.

Background therapy: -

Evidence for comparator: -

Actual start date of recruitment	11 November 2021
Long term follow-up planned	Yes
Long term follow-up rationale	Safety, Efficacy
Long term follow-up duration	30 Months
Independent data monitoring committee (IDMC) involvement?	No

Notes:

Population of trial subjects

Subjects enrolled per country

Country: Number of subjects enrolled	Bulgaria: 8
Country: Number of subjects enrolled	Czechia: 14
Country: Number of subjects enrolled	Germany: 25
Country: Number of subjects enrolled	Italy: 30
Country: Number of subjects enrolled	Türkiye: 75
Worldwide total number of subjects	152
EEA total number of subjects	77

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)	79
From 65 to 84 years	73
85 years and over	0

Subject disposition

Recruitment

Recruitment details:

The study was conducted at 32 sites in 5 countries (Bulgaria, Czech Republic, Germany, Italy, and Turkey). The data in this report are based on study start date (first participant enrolled; 11-November-2021) till final analysis data cut-off date of 21 April 2024.

Pre-assignment

Screening details:

Participants who met all the inclusion and none of the exclusion criteria were enrolled in this study. All study assessments were performed as per the schedule of assessment.

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	Durvalumab (cisplatin/carboplatin) Etoposide (Durvalumab + EP)

Arm description:

Participants received durvalumab 1500 mg administered via intravenous (IV) infusion concurrently with platinum-based chemotherapy and etoposide every 3 weeks (q3w) up to 6 cycles. Thereafter, durvalumab monotherapy was continued every 4 weeks post-chemotherapy unless specific treatment discontinuation criteria were met.

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

Dosage and administration details:

Participants received durvalumab 1500 mg administered IV infusion concurrently with platinum-based chemotherapy and etoposide every 3 weeks (q3w) up to 6 cycles. Thereafter, durvalumab monotherapy was continued every 4 weeks post-chemotherapy unless specific treatment discontinuation criteria were met.

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

Dosage and administration details:

Participants received durvalumab 1500 mg administered IV infusion concurrently with platinum-based chemotherapy and etoposide every 3 weeks (q3w) up to 6 cycles. Thereafter, durvalumab monotherapy was continued every 4 weeks post-chemotherapy unless specific treatment discontinuation criteria were met.

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

Dosage and administration details:

Participants received durvalumab 1500 mg administered IV infusion concurrently with platinum-based chemotherapy and etoposide every 3 weeks (q3w) up to 6 cycles. Thereafter, durvalumab monotherapy was continued every 4 weeks post-chemotherapy unless specific treatment discontinuation criteria were

met.

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

Dosage and administration details:

Participants received durvalumab 1500 mg administered IV infusion concurrently with platinum-based chemotherapy and etoposide every 3 weeks (q3w) up to 6 cycles. Thereafter, durvalumab monotherapy was continued every 4 weeks post-chemotherapy unless specific treatment discontinuation criteria were met.

Number of subjects in period 1	Durvalumab (cisplatin/carboplatin) Etoposide (Durvalumab + EP)
Started	152
Completed	108
Not completed	44
Patients ongoing study at data cut-off	44

Baseline characteristics

Reporting groups	
Reporting group title	Overall Study
Reporting group description:	
Participants received durvalumab 1500 mg administered via intravenous (IV) infusion concurrently with platinum-based chemotherapy and etoposide every 3 weeks (q3w) up to 6 cycles. Thereafter, durvalumab monotherapy was continued every 4 weeks post-chemotherapy unless specific treatment discontinuation criteria were met.	

Reporting group values	Overall Study	Total	
Number of subjects	152	152	
Age Categorical Units: Subjects			
In utero	0	0	
Preterm newborn infants (gestational age < 37 wks)	0	0	
Newborns (0-27 days)	0	0	
Infants and toddlers (28 days-23 months)	0	0	
Children (2-11 years)	0	0	
Adolescents (12-17 years)	0	0	
Adults (18-64 years)	79	79	
From 65-84 years	73	73	
85 years and over	0	0	
Age Continuous Units: years			
median	64.0		
full range (min-max)	27 to 83	-	
Gender Categorical Units: Subjects			
Female	54	54	
Male	98	98	
Race/Ethnicity Units: Subjects			
White	151	151	
Other	1	1	

End points

End points reporting groups

Reporting group title	Durvalumab (cisplatin/carboplatin) Etoposide (Durvalumab + EP)

Reporting group description:

Participants received durvalumab 1500 mg administered via intravenous (IV) infusion concurrently with platinum-based chemotherapy and etoposide every 3 weeks (q3w) up to 6 cycles. Thereafter, durvalumab monotherapy was continued every 4 weeks post-chemotherapy unless specific treatment discontinuation criteria were met.

Primary: Primary: Number of participants with incidence of Grade 3 or higher adverse events (AEs)

End point title	Primary: Number of participants with incidence of Grade 3 or higher adverse events (AEs)[1]

End point description:

Incidence of Grade 3 or higher adverse events (AEs) to evaluate safety and tolerability profile of durvalumab + Platinum (cisplatin or carboplatin) plus etoposide (EP) treatment was assessed. The safety analysis set (SAF) consisted of all enrolled patients who received at least 1 dose of any study treatment.

End point type	Primary

End point timeframe:

From first dose of study treatment until 90 days after treatment discontinuation, up to 2.5 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: A statistical analysis was not performed for this endpoint.

End point values	Durvalumab (cisplatin/carboplatin) Etoposide (Durvalumab + EP)			
Subject group type	Reporting group			
Number of subjects analysed	152			
Units: Participants				
Number of participants with Grade 3 or higher AEs	91			

Statistical analyses

No statistical analyses for this end point

Primary: Number of participants with incidence of Immune mediated adverse events (imAEs)

End point title	Number of participants with incidence of Immune mediated adverse events (imAEs)[2]

End point description:

Immune mediated adverse events (imAEs) were assessed to evaluate safety and tolerability profile of durvalumab + EP treatment. An imAE is defined as an AESI that is associated with drug exposure and is

consistent with an immune-mediated mechanism of action (MOA) and where there is no clear alternate etiology. The SAF consisted of all enrolled patients who received at least 1 dose of any study treatment.

End point type	Primary

End point timeframe:

From first dose of study treatment until 90 days after treatment discontinuation, up to 2.5 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: A statistical analysis was not performed for this endpoint.

End point values	Durvalumab (cisplatin/carboplatin) Etoposide (Durvalumab + EP)			
Subject group type	Reporting group			
Number of subjects analysed	152			
Units: Participants				
Number of participants with incidence of imAEs	22			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants alive and progression-free at 12 months from first date of treatment (PFS12)

End point title	Percentage of participants alive and progression-free at 12 months from first date of treatment (PFS12)

End point description:

The efficacy of durvalumab + EP treatment by evaluating PFS12 according to RECIST 1.1 was assessed. The SAF consisted of all enrolled patients who received at least 1 dose of any study treatment.

End point type	Secondary

End point timeframe:

From first date of study treatment until 12 months.

End point values	Durvalumab (cisplatin/carboplatin) Etoposide (Durvalumab + EP)			
Subject group type	Reporting group			
Number of subjects analysed	152			
Units: Percentage of participants				
number (confidence interval 95%)	15.0 (9.76 to 21.21)			

Statistical analyses

No statistical analyses for this end point

Secondary: Progression-free survival (PFS)

End point title	Progression-free survival (PFS)

End point description:

Efficacy of durvalumab + EP treatment by evaluating PFS according to Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST 1.1) was assessed. The PFS is the time from the first date of treatment until the date of objective disease progression or death (by any cause in the absence of progression) regardless of whether the participant withdrew from Investigational medicinal product (IMP) or received another anticancer therapy prior to progression.
The SAF consisted of all enrolled patients who received at least 1 dose of any study treatment.

End point type	Secondary

End point timeframe:

From first dose of study treatment until disease progression or death, up to 2.5 years.

End point values	Durvalumab (cisplatin/carboplatin) Etoposide (Durvalumab + EP)			
Subject group type	Reporting group			
Number of subjects analysed	152			
Units: Months				
median (confidence interval 95%)	6.3 (5.75 to 6.47)			

Statistical analyses

No statistical analyses for this end point

Secondary: Objective response rate (ORR)

End point title	Objective response rate (ORR)

End point description:

The efficacy of durvalumab + EP treatment by evaluating ORR according to RECIST 1.1 was assessed. The ORR will be assessed based on Investigator−assessed response to treatment of complete response (CR) and partial response (PR), per RECIST1.1. The SAF consisted of all enrolled patients who received at least 1 dose of any study treatment.

End point type	Secondary

End point timeframe:

From screening until disease progression or the last evaluable assessment in the absence of progression, up to 2.5 years.

End point values	Durvalumab (cisplatin/carboplatin) Etoposide (Durvalumab + EP)			
Subject group type	Reporting group			
Number of subjects analysed	152			
Units: Percentage of participants				
number (confidence interval 95%)	66.4 (58.3 to 73.9)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants remaining in response, 12 months after first documented objective response (DoR12)

End point title	Percentage of participants remaining in response, 12 months after first documented objective response (DoR12)

End point description:

The efficacy of durvalumab + EP treatment by evaluating DoR12 according to RECIST 1.1 was assessed. The SAF consisted of all enrolled patients who received at least 1 dose of any study treatment.

End point type	Secondary

End point timeframe:

From the date of first documented response until the first date of documented progression or death in the absence of disease progression, up to 2.5 years.

End point values	Durvalumab (cisplatin/carboplatin) Etoposide (Durvalumab + EP)			
Subject group type	Reporting group			
Number of subjects analysed	101			
Units: Percentage of Participants				
number (confidence interval 95%)	19.8 (12.70 to 28.06)			

Statistical analyses

No statistical analyses for this end point

Secondary: Duration of response (DoR)

End point title	Duration of response (DoR)

End point description:

The efficacy of durvalumab + EP treatment by evaluating DoR according to RECIST 1.1 was assessed. The DoR is time from the date of first documented response per RECIST1.1 until the first date of

documented progression per RECIST1.1 or death in the absence of disease progression. The SAF consisted of all enrolled patients who received at least 1 dose of any study treatment.

End point type	Secondary

End point timeframe:

From the date of first documented response until the first date of documented progression or death in the absence of disease progression, up to 2.5 years.

End point values	Durvalumab (cisplatin/carboplatin) Etoposide (Durvalumab + EP)			
Subject group type	Reporting group			
Number of subjects analysed	101			
Units: Months				
median (confidence interval 95%)	5.2 (5.03 to 5.59)			

Statistical analyses

No statistical analyses for this end point

Secondary: Percentage of participants alive at 12 months from first date of treatment (OS12)

End point title	Percentage of participants alive at 12 months from first date of treatment (OS12)

End point description:

The efficacy of durvalumab + EP treatment by evaluating OS12 was assessed. The SAF consisted of all enrolled patients who received at least 1 dose of any study treatment.

End point type	Secondary

End point timeframe:

From first dose of study treatment till 12 months.

End point values	Durvalumab (cisplatin/carboplatin) Etoposide (Durvalumab + EP)			
Subject group type	Reporting group			
Number of subjects analysed	152			
Units: Percentage of participants				
number (confidence interval 95%)	59.8 (51.00 to 67.55)			

Statistical analyses

No statistical analyses for this end point

Secondary: Overall Survival (OS)

End point title	Overall Survival (OS)

End point description:

Assessment of the efficacy of durvalumab + EP treatment by evaluating OS. The OS is the time from the first date of treatment until death due to any cause. The SAF consisted of all enrolled patients who received at least 1 dose of any study treatment.

End point type	Secondary

End point timeframe:

From first dose of study treatment to death, up to 2.5 years.

End point values	Durvalumab (cisplatin/carboplatin) Etoposide (Durvalumab + EP)			
Subject group type	Reporting group			
Number of subjects analysed	152			
Units: Months				
median (confidence interval 95%)	16.4 (12.45 to 18.73)			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with adverse events and serious adverse events

End point title	Number of participants with adverse events and serious adverse events

End point description:

To evaluate safety and tolerability profile of durvalumab + EP treatment, adverse events and serious adverse events were assessed.
"r/t" (related to)

End point type	Secondary

End point timeframe:

From first dose of study treatment until 90 days after discontinuation, up to 2.5 years.

End point values	Durvalumab (cisplatin/carboplatin) Etoposide (Durvalumab + EP)			
Subject group type	Reporting group			
Number of subjects analysed	152			
Units: Participants				
Any Adverse event (AE)	142			
Any AE possibly related to any treatment	109			
Any AE of maximum CTCAE grade 3 or grade 4	85			
AE of max CTCAE G3/G4, possibly r/t any treatment	59			
Any AE with outcome of death	15			
AE with outcome death, possibly r/t any treatment	4			
AE with outcome death, possibly r/t durvalumab	0			
Any AE with outcome death, possibly r/t to EP	4			
Any SAE (incl. events with outcome death)	52			
SAE (incl. fatal), possibly r/t any treatment	16			
AE causing durvalumab interruption/discontinuation	40			
Any AE leading to interruption or discont. of EP	41			

Statistical analyses

No statistical analyses for this end point

Secondary: Number of participants with adverse events of special interests

End point title	Number of participants with adverse events of special interests

End point description:

To evaluate safety and tolerability profile of durvalumab + EP treatment, adverse events of special interests were assessed. An AESI is an AE of scientific and medical interest specific to understanding of the IMP. AESIs for durvalumab include, but are not limited to, events with a potential inflammatory or immune-mediated mechanism and which may require more frequent monitoring and/or interventions such as steroids, immunosuppressants, and/or hormone replacement therapy.
This includes adverse events of special/ possible interest.

End point type	Secondary

End point timeframe:

From first dose of study treatment until 90 days after discontinuation, up to 2.5 years.

End point values	Durvalumab (cisplatin/carboplatin) Etoposide (Durvalumab + EP)			
Subject group type	Reporting group			
Number of subjects analysed	152			
Units: Participants	82			

Statistical analyses

No statistical analyses for this end point

Adverse events

Adverse events information

Timeframe for reporting adverse events:

From first dose of study treatment until 90 days after treatment discontinuation, up to 2.5 years.

Assessment type	Non-systematic

Dictionary used

Dictionary name	MedDRA
Dictionary version	27.0

Reporting groups

Reporting group title	Durvalumab (cisplatin/carboplatin) Etoposide (Durvalumab + EP)

Reporting group description:

Participants received durvalumab 1500 mg administered via intravenous (IV) infusion concurrently with platinum-based chemotherapy and etoposide every 3 weeks (q3w) up to 6 cycles. Thereafter, durvalumab monotherapy was continued every 4 weeks post-chemotherapy unless specific treatment discontinuation criteria were met.

Serious adverse events	Durvalumab (cisplatin/carboplatin) Etoposide (Durvalumab + EP)		
Total subjects affected by serious adverse events			
subjects affected / exposed	52 / 152 (34.21%)		
number of deaths (all causes)	85		
number of deaths resulting from adverse events	15		
Vascular disorders			
Embolism arterial			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hypertension			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Peripheral ischaemia			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Superior vena cava syndrome			

subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Surgical and medical procedures			
Intestinal anastomosis			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
General disorders and administration site conditions			
Death			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Swelling			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Respiratory, thoracic and mediastinal disorders			
Bronchospasm			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	1 / 1		
deaths causally related to treatment / all	0 / 0		
Chronic obstructive pulmonary disease			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Dyspnoea			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Pleural effusion			

subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
Pneumonitis				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Pneumothorax				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Respiratory disorder				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			
Pulmonary embolism				
subjects affected / exposed	2 / 152 (1.32%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 0			
Investigations				
Neutrophil count decreased				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Lymphocyte count decreased				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Blood creatinine increased				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Aspartate aminotransferase increased				

subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Alanine aminotransferase increased				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Urine output decreased				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Platelet count decreased				
subjects affected / exposed	3 / 152 (1.97%)			
occurrences causally related to treatment / all	1 / 3			
deaths causally related to treatment / all	0 / 0			
Injury, poisoning and procedural complications				
Tibia fracture				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Spinal fracture				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Cardiac disorders				
Atrial fibrillation				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Nervous system disorders				
Status epilepticus				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 1			

Immune-mediated encephalopathy				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Cerebrovascular accident				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Brain oedema				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Syncope				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Blood and lymphatic system disorders				
Leukopenia				
subjects affected / exposed	3 / 152 (1.97%)			
occurrences causally related to treatment / all	3 / 3			
deaths causally related to treatment / all	0 / 0			
Febrile neutropenia				
subjects affected / exposed	2 / 152 (1.32%)			
occurrences causally related to treatment / all	1 / 2			
deaths causally related to treatment / all	1 / 1			
Anaemia				
subjects affected / exposed	3 / 152 (1.97%)			
occurrences causally related to treatment / all	2 / 3			
deaths causally related to treatment / all	0 / 0			
Neutropenia				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Thrombocytopenia				

subjects affected / exposed	2 / 152 (1.32%)		
occurrences causally related to treatment / all	2 / 2		
deaths causally related to treatment / all	0 / 0		
Eye disorders			
Vision blurred			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	3 / 152 (1.97%)		
occurrences causally related to treatment / all	0 / 3		
deaths causally related to treatment / all	0 / 0		
Constipation			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences causally related to treatment / all	0 / 2		
deaths causally related to treatment / all	0 / 0		
Diarrhoea			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Haematemesis			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Ileus			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Vomiting			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Duodenal ulcer perforation			

subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Hepatobiliary disorders			
Hepatic failure			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 1		
Cholestasis			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Suspected drug-induced liver injury			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Jaundice			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Skin and subcutaneous tissue disorders			
Cellulite			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Renal and urinary disorders			
Acute kidney injury			
subjects affected / exposed	4 / 152 (2.63%)		
occurrences causally related to treatment / all	3 / 5		
deaths causally related to treatment / all	1 / 1		
Musculoskeletal and connective tissue disorders			
Arthralgia			

subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Infections and infestations			
Covid-19 pneumonia			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Abdominal Infection			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Pneumonia			
subjects affected / exposed	9 / 152 (5.92%)		
occurrences causally related to treatment / all	2 / 9		
deaths causally related to treatment / all	2 / 6		
Lower respiratory tract infection			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Postoperative wound infection			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Sepsis			
subjects affected / exposed	2 / 152 (1.32%)		
occurrences causally related to treatment / all	1 / 2		
deaths causally related to treatment / all	0 / 0		
Tooth abscess			
subjects affected / exposed	1 / 152 (0.66%)		
occurrences causally related to treatment / all	0 / 1		
deaths causally related to treatment / all	0 / 0		
Urinary tract infection bacterial			

subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Appendicitis				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Metabolism and nutrition disorders				
Hypernatraemia				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	0 / 2			
deaths causally related to treatment / all	0 / 1			
Hyperglycaemia				
subjects affected / exposed	3 / 152 (1.97%)			
occurrences causally related to treatment / all	0 / 3			
deaths causally related to treatment / all	0 / 0			
Acidosis				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Hyperphosphataemia				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	1 / 1			
deaths causally related to treatment / all	0 / 0			
Hypokalaemia				
subjects affected / exposed	1 / 152 (0.66%)			
occurrences causally related to treatment / all	0 / 1			
deaths causally related to treatment / all	0 / 0			
Hyponatraemia				
subjects affected / exposed	4 / 152 (2.63%)			
occurrences causally related to treatment / all	0 / 4			
deaths causally related to treatment / all	0 / 1			

Frequency threshold for reporting non-serious adverse events: 3 %

Non-serious adverse events	Durvalumab (cisplatin/carboplatin) Etoposide (Durvalumab + EP)		
Total subjects affected by non-serious adverse events			
subjects affected / exposed	136 / 152 (89.47%)		
Neoplasms benign, malignant and unspecified (incl cysts and polyps)			
Tumour pain			
subjects affected / exposed	5 / 152 (3.29%)		
occurrences (all)	5		
Vascular disorders			
Hypotension			
subjects affected / exposed	5 / 152 (3.29%)		
occurrences (all)	5		
General disorders and administration site conditions			
Asthenia			
subjects affected / exposed	10 / 152 (6.58%)		
occurrences (all)	11		
Fatigue			
subjects affected / exposed	24 / 152 (15.79%)		
occurrences (all)	29		
Oedema peripheral			
subjects affected / exposed	6 / 152 (3.95%)		
occurrences (all)	7		
Pyrexia			
subjects affected / exposed	12 / 152 (7.89%)		
occurrences (all)	13		
Respiratory, thoracic and mediastinal disorders			
Haemoptysis			
subjects affected / exposed	6 / 152 (3.95%)		
occurrences (all)	6		
Dyspnoea			
subjects affected / exposed	13 / 152 (8.55%)		
occurrences (all)	13		
Cough			

subjects affected / exposed	15 / 152 (9.87%)		
occurrences (all)	16		
Psychiatric disorders			
Depression			
subjects affected / exposed	5 / 152 (3.29%)		
occurrences (all)	5		
Investigations			
Aspartate aminotransferase increased			
subjects affected / exposed	14 / 152 (9.21%)		
occurrences (all)	18		
Blood alkaline phosphatase increased			
subjects affected / exposed	10 / 152 (6.58%)		
occurrences (all)	13		
Blood creatinine increased			
subjects affected / exposed	18 / 152 (11.84%)		
occurrences (all)	25		
Alanine aminotransferase increased			
subjects affected / exposed	12 / 152 (7.89%)		
occurrences (all)	14		
Amylase increased			
subjects affected / exposed	9 / 152 (5.92%)		
occurrences (all)	9		
Neutrophil count decreased			
subjects affected / exposed	15 / 152 (9.87%)		
occurrences (all)	24		
Lipase increased			
subjects affected / exposed	6 / 152 (3.95%)		
occurrences (all)	6		
Gamma-glutamyltransferase increased			
subjects affected / exposed	15 / 152 (9.87%)		
occurrences (all)	17		
Blood lactate dehydrogenase increased			
subjects affected / exposed	9 / 152 (5.92%)		
occurrences (all)	10		
White blood cell count decreased			

subjects affected / exposed	16 / 152 (10.53%)		
occurrences (all)	25		
Platelet count decreased			
subjects affected / exposed	12 / 152 (7.89%)		
occurrences (all)	19		
Weight decreased			
subjects affected / exposed	8 / 152 (5.26%)		
occurrences (all)	9		
Nervous system disorders			
Headache			
subjects affected / exposed	11 / 152 (7.24%)		
occurrences (all)	13		
Dizziness			
subjects affected / exposed	8 / 152 (5.26%)		
occurrences (all)	8		
Neuropathy peripheral			
subjects affected / exposed	6 / 152 (3.95%)		
occurrences (all)	6		
Peripheral sensory neuropathy			
subjects affected / exposed	7 / 152 (4.61%)		
occurrences (all)	7		
Blood and lymphatic system disorders			
Leukopenia			
subjects affected / exposed	19 / 152 (12.50%)		
occurrences (all)	30		
Neutropenia			
subjects affected / exposed	51 / 152 (33.55%)		
occurrences (all)	91		
Leukocytosis			
subjects affected / exposed	7 / 152 (4.61%)		
occurrences (all)	8		
Anaemia			
subjects affected / exposed	85 / 152 (55.92%)		
occurrences (all)	117		
Thrombocytopenia			

subjects affected / exposed	24 / 152 (15.79%)		
occurrences (all)	44		
Gastrointestinal disorders			
Abdominal pain upper			
subjects affected / exposed	7 / 152 (4.61%)		
occurrences (all)	8		
Constipation			
subjects affected / exposed	30 / 152 (19.74%)		
occurrences (all)	35		
Vomiting			
subjects affected / exposed	8 / 152 (5.26%)		
occurrences (all)	10		
Stomatitis			
subjects affected / exposed	8 / 152 (5.26%)		
occurrences (all)	9		
Nausea			
subjects affected / exposed	37 / 152 (24.34%)		
occurrences (all)	56		
Dyspepsia			
subjects affected / exposed	9 / 152 (5.92%)		
occurrences (all)	9		
Diarrhoea			
subjects affected / exposed	13 / 152 (8.55%)		
occurrences (all)	18		
Skin and subcutaneous tissue disorders			
Dermatitis			
subjects affected / exposed	5 / 152 (3.29%)		
occurrences (all)	6		
Pruritus			
subjects affected / exposed	6 / 152 (3.95%)		
occurrences (all)	6		
Alopecia			
subjects affected / exposed	20 / 152 (13.16%)		
occurrences (all)	20		
Endocrine disorders			

Hyperthyroidism			
subjects affected / exposed	18 / 152 (11.84%)		
occurrences (all)	28		
Hypothyroidism			
subjects affected / exposed	18 / 152 (11.84%)		
occurrences (all)	22		
Musculoskeletal and connective tissue disorders			
Back pain			
subjects affected / exposed	7 / 152 (4.61%)		
occurrences (all)	7		
Arthralgia			
subjects affected / exposed	10 / 152 (6.58%)		
occurrences (all)	11		
Pain in extremity			
subjects affected / exposed	5 / 152 (3.29%)		
occurrences (all)	6		
Infections and infestations			
Upper respiratory tract infections			
subjects affected / exposed	13 / 152 (8.55%)		
occurrences (all)	16		
COVID-19			
subjects affected / exposed	10 / 152 (6.58%)		
occurrences (all)	10		
Metabolism and nutrition disorders			
Decreased appetite			
subjects affected / exposed	13 / 152 (8.55%)		
occurrences (all)	13		
Hypermagnesaemia			
subjects affected / exposed	5 / 152 (3.29%)		
occurrences (all)	5		
Hypomagnesaemia			
subjects affected / exposed	19 / 152 (12.50%)		
occurrences (all)	24		
Hypokalaemia			
subjects affected / exposed	10 / 152 (6.58%)		
occurrences (all)	12		

Hypocalcaemia subjects affected / exposed occurrences (all)	8 / 152 (5.26%) 9		
Hypoalbuminaemia subjects affected / exposed occurrences (all)	10 / 152 (6.58%) 13		
Hyponatraemia subjects affected / exposed occurrences (all)	15 / 152 (9.87%) 21		
Hyperuricaemia subjects affected / exposed occurrences (all)	5 / 152 (3.29%) 6		
Hyperkalaemia subjects affected / exposed occurrences (all)	5 / 152 (3.29%) 6		

More information

Substantial protocol amendments (globally)

Were there any global substantial amendments to the protocol? Yes

Date	Amendment
06 August 2021	Updates to durvalumab risks and safety data; list of countries in which the study is conducted updated; details on study conduct mitigation during disruptions added; inclusion and exclusion criteria revised and clarified; lifestyle restrictions including sun exposure and contraception requirements updated; regulatory reporting requirements for serious adverse events revised; details on concomitant medications revised in appendix.

Notes:

Interruptions (globally)

Were there any global interruptions to the trial? No

Limitations and caveats

None reported