Supplementary Appendix

This appendix has been provided by the authors to give readers additional information about their work.

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SUPPLEMENTARY APPENDIX

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Supplementary Statistical Analysis

As described in detail in section 4.1.2 of the statistical analysis plan (SAP), a multiple testing procedure was used to define which significance levels should be applied to the interpretation of the raw P values for the two primary endpoints of PFS and OS and the key secondary endpoints OS24 (overall survival rate at 24 months) and ORR. The family-wise error rate is strongly controlled at 5% for these endpoints.

The testing procedure is hierarchical in that it starts with testing the co-primary endpoints PFS and OS. The overall 5% Type I error was equally split between the co-primary endpoints OS and PFS. An alpha level of 2.5% was allocated to OS analysis and an alpha level of 2.5% was allocated to the PFS analysis. For each co-primary endpoint, there is interim analyses planned (1 interim analysis for PFS and 2 interim analyses for OS), and the 2.5% alpha level was controlled at the interim and primary analysis time points by using the Lan-DeMets spending function that approximates an O'Brien Fleming approach. The 2.5% alpha can be re-cycled between PFS and OS, as described below.

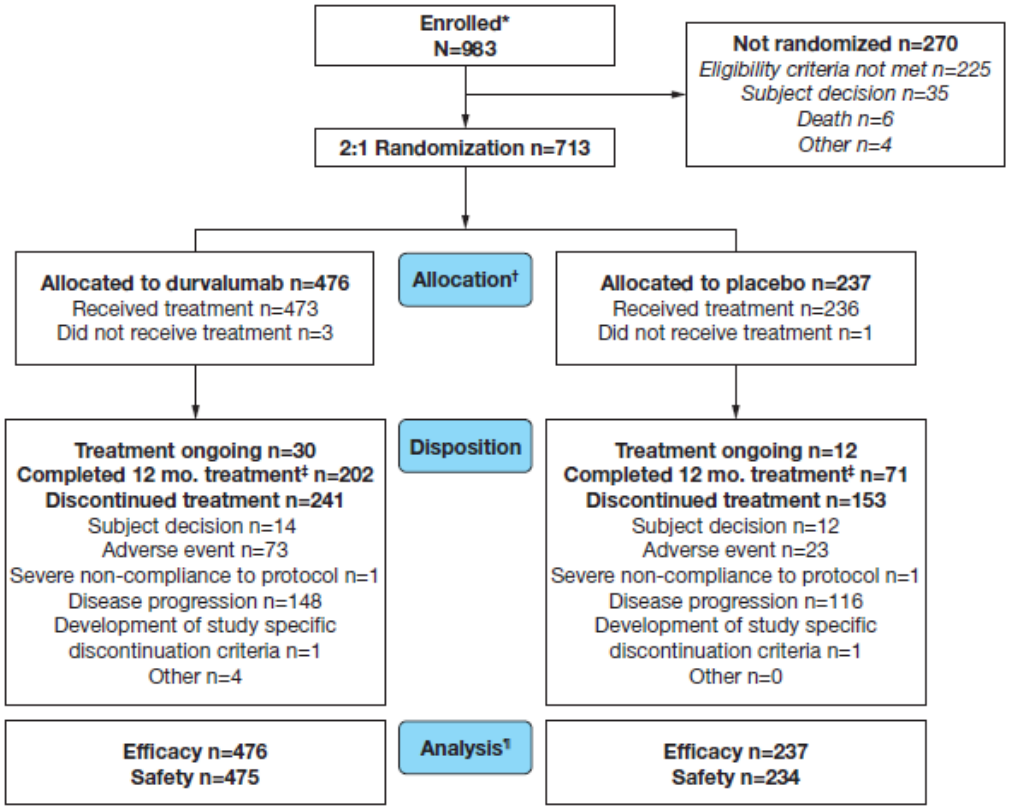
The first OS interim analysis is at the time of the PFS final analysis (i.e. there is no OS analysis at the time of the PFS interim analysis, due to the low maturity of OS data). Therefore, the following alpha re-cycling approach is used:

- If the PFS analysis is significant at either the interim analysis or the final analysis, the 2.5% alpha allocated to PFS will be re-cycled to OS, and a 5% alpha level will be used for OS analysis, by re-adjusting the O'Brien Fleming boundaries for the OS interim and final analyses using an overall alpha of 5%.
- If the OS analysis is significant at the first interim analysis (i.e. at the time of the PFS final analysis), the 2.5% alpha allocated to OS will be re-cycled to PFS, and a 5% alpha level will be used for PFS analysis, by re-adjusting the O'Brien Fleming boundaries. At this point, since the PFS interim analysis has already passed, the

alpha level for the PFS interim analysis will not change, but the alpha level for the PFS primary analysis will be re-calculated based on an overall alpha of 5%.

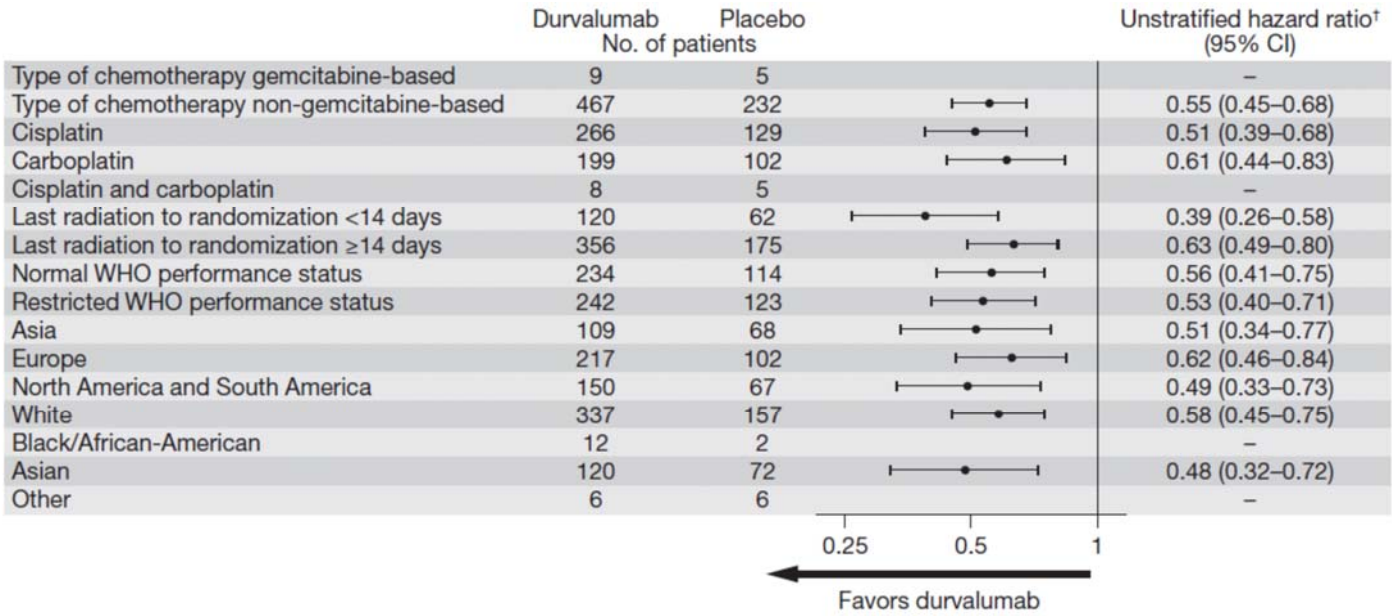
OS24 and ORR will not be tested unless the null hypotheses for both PFS and OS are rejected according to the procedure described above. After both PFS and OS are rejected the OS24 will be tested with 5% alpha level. ORR will only be tested after the null hypothesis of PFS, OS, and OS24 are all rejected and ORR will be tested at a 5% level.

Figure S1. CONSORT Diagram.



*Informed consent received.
†Four patients (3 in the durvalumab group and 1 in the placebo group) were randomized but did not receive treatment because of patient decision (n=2), neutropenia (n=1), and worsening chronic obstructive pulmonary disease (n=1).
‡Patients who completed 12 months of treatment reported the maximum cycle of immunotherapy reached on the eCRF.
¶Two patients randomized to placebo received one dose of durvalumab and were included in the safety analysis set.
eCRF, electronic case report form.

Figure S2. Progression-free survival* Subgroup Analysis of Additional Factors in the Intention-to-Treat Population (BICR).



*Defined by RECIST v1.1. †Hazard ratio and 95% CI is not calculated if the subgroup level has less than 20 events.
BICR, blinded independent central review; CI, confidence interval.

Figure S3. Time to Death or Distant Metastasis in the Intention-to-Treat Population (BICR).

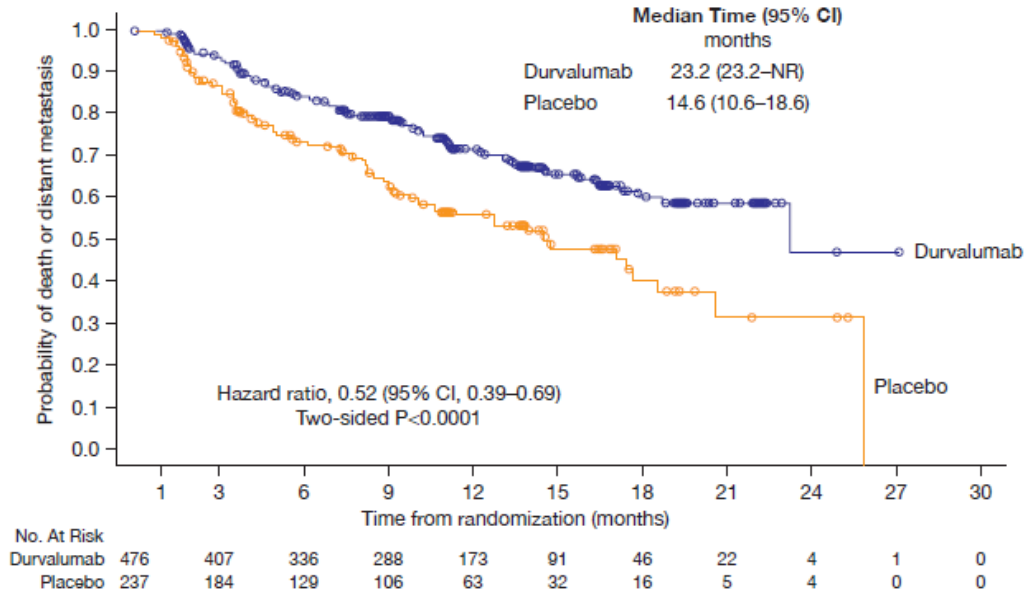


Figure S4. Duration of Response in the Intention-to-Treat Population (BICR).

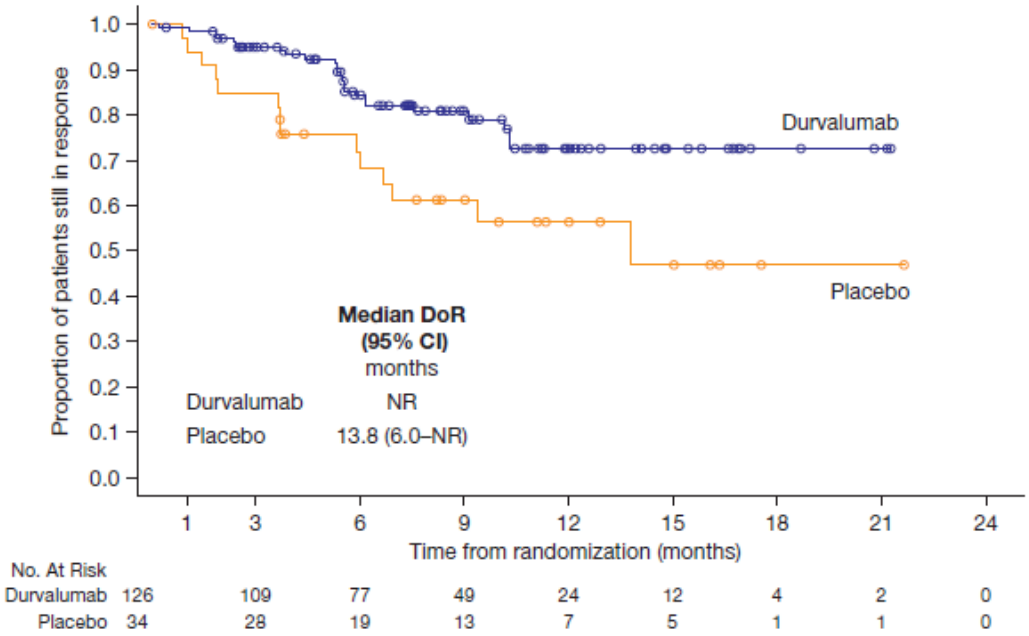


Table S1. Baseline Characteristics, Stratification Factors and Prior Therapy (Intention-to-Treat population; Complete Listing).*

	Durvalumab (N = 476)	Placebo (N = 237)	Total (N = 713)
Age – yr			
Median (range)	64 (31–84)	64 (23–90)	64 (23–90)
Age category – no. (%)			
≥65	215 (45.2)	107 (45.1)	322 (45.2)
Sex – no. (%)			
Male	334 (70.2)	166 (70.0)	500 (70.1)
Female	142 (29.8)	71 (30.0)	213 (29.9)
Race – no. (%)			
White	337 (70.8)	157 (66.2)	494 (69.3)
Black or African-American	12 (2.5)	2 (0.8)	14 (2.0)
Asian	120 (25.2)	72 (30.4)	192 (26.9)
Other	6 (1.3)	6 (2.5)	12 (1.68)
Not reported	1 (0.2)	0	1 (0.1)
Disease stage			
IIIA	252 (52.9)	125 (52.7)	377 (52.9)
IIIB	212 (44.5)	107 (45.1)	319 (44.7)
Other†	12 (2.5)	5 (2.1)	17 (2.4)
WHO performance-status score — no. (%)‡			
0	234 (49.2)	114 (48.1)	348 (48.8)
1	240 (50.4)	122 (51.5)	362 (50.8)
Not reported	2 (0.4)	1 (0.4)	3 (0.4)
Histology – no. (%)			
Squamous	224 (47.1)	102 (43.0)	326 (45.7)
Non-squamous	252 (52.9)	135 (57.0)	387 (54.3)
Smoking status – no. (%)			
Current smoker	79 (16.6)	38 (16.0)	117 (16.4)
Former smoker	354 (74.4)	178 (75.1)	532 (74.6)
Never smoked	43 (9.0)	21 (8.9)	64 (9.0)
Geographic region – no. (%)			
North America	144 (30.3)	67 (28.3)	211 (29.6)
South America	6 (1.3)	0	6 (0.8)
Europe	217 (45.6)	102 (43.0)	319 (44.7)
Asia	109 (22.9)	68 (28.7)	177 (24.8)
Prior radiotherapy – no. (%)¶			
<54 Gy	3 (0.6)	0	3 (0.4)
≥54–≤66 Gy	442 (92.9)	217 (91.6)	659 (92.4)
>66–≤74 Gy	30 (6.3)	19 (8.0)	49 (6.9)
>74 Gy	0	0	0
Missing£	1 (0.2)	1 (0.4)	2 (0.3)
Number of previous chemotherapy regimens – no. (%)			
1	444 (93.3)	224 (94.5)	668 (93.7)
2	32 (6.7)	13 (5.5)	45 (6.3)
Prior chemotherapy – no. (%)§			
Adjuvant	3 (0.6)	1 (0.4)	4 (0.6)
Induction	123 (25.8)	68 (28.7)	191 (26.8)
Concurrent with radiation	475 (99.8)	236 (99.6)	711 (99.7)
Best response to previous cCRT – no. (%)			
Complete response	9 (1.9)	7 (3.0)	16 (2.2)
Partial response	232 (48.7)	111 (46.8)	343 (48.1)
Stable disease	222 (46.6)	114 (48.1)	336 (47.1)
Progression	2 (0.4)	0	2 (0.3)
Non-evaluable	9 (1.9)	4 (1.7)	13 (1.8)

Not applicable	2 (0.4)	1 (0.4)	3 (0.4)

*The intention-to-treat population included all patients who underwent randomization. There were no statistically significant (P<0.05) between-group differences in the baseline characteristics listed here. Percentages may not total 100 because of rounding.

†'Other' disease stages included 12 patients in the durvalumab arm (4 stage IV; 4 stage IIB; 3 stage IIA; and 1 stage IA) and 5 patients in the placebo arm (2 stage IIB; 1 stage IIA; and 2 stage IB).

‡World Health Organization (WHO) performance status (PS) scores range from 0 to 5, with 0 indicating no symptoms and higher scores indicating increased disability.

¶The actual dose decision was based on investigator/radiologist assessment for each individual patient, resulting in doses that differed from the inclusion criteria; all radiation was administered concurrently with chemotherapy.

£For the two patients with missing data, the biologically effective radiotherapy dose could not be calculated, primarily because their radiotherapy treatment planning data were neither collected nor accessible.

§Patients may have received prior chemotherapy in more than one context.

Table S2. Prior Definitive Chemotherapy Regimens (Intention-to-Treat population).

	Durvalumab (N=476)	Placebo (N=237)	Total (N=713)
Total – no. (%)	**473 (99.4)**	**236 (99.6)**	**709 (99.4)**
Cisplatin*	266 (55.9)	129 (54.4)	395 (55.4)
Cisplatin + etoposide	106 (22.3)	49 (20.7)	155 (21.7)
Cisplatin + vinorelbine	77 (16.2)	34 (14.3)	111 (15.6)
Cisplatin + vinorelbine ditartrate	26 (5.5)	14 (5.9)	40 (5.6)
Cisplatin + docetaxel	26 (5.5)	8 (3.4)	34 (4.8)
Cisplatin + paclitaxel	13 (2.7)	15 (6.3)	28 (3.9)
Cisplatin + pemetrexed	11 (2.3)	5 (2.1)	16 (2.2)
Cisplatin + nab-paclitaxel	1 (0.2)	0	1 (0.1)
Cisplatin + vinblastine	1 (0.2)	0	1 (0.1)
Cisplatin + other	1 (0.2)	0	1 (0.1)
Carboplatin†	199 (41.8)	102 (43.0)	301 (42.2)
Carboplatin + paclitaxel	158 (33.2)	84 (35.4)	242 (33.9)
Carboplatin + vinorelbine	8 (1.7)	4 (1.7)	12 (1.7)
Carboplatin + etoposide	8 (1.7)	2 (0.8)	10 (1.4)
Carboplatin + vinorelbine ditartrate	7 (1.5)	5 (2.1)	12 (1.7)
Carboplatin + pemetrexed	7 (1.5)	4 (1.7)	11 (1.5)
Carboplatin + docetaxel	2 (0.4)	1 (0.4)	3 (0.4)
Carboplatin + nab-paclitaxel	2 (0.4)	0	2 (0.3)
Carboplatin + pemetrexed disodium	1 (0.2)	0	1 (0.1)
Carboplatin + other	2 (0.4)	1 (0.4)	3 (0.4)
Cisplatin / carboplatin	8 (1.7)	5 (2.1)	13 (1.8)
Cisplatin / carboplatin + vinorelbine	2 (0.4)	1 (0.4)	3 (0.4)
Cisplatin / carboplatin + etoposide	2 (0.4)	0	2 (0.3)
Cisplatin / carboplatin + pemetrexed	1 (0.2)	1 (0.4)	2 (0.3)
Cisplatin / carboplatin + docetaxel	1 (0.2)	0	1 (0.1)
Cisplatin / carboplatin + vinorelbine ditartrate	1 (0.2)	0	1 (0.1)
Cisplatin / carboplatin + other	1 (0.2)	3 (1.3)	4 (0.6)

*Cisplatin alone was received by 4 patients in each group (0.8% and 1.7% in the durvalumab and placebo groups, respectively).
†Carboplatin alone was received by 4 patients (0.8%) in the durvalumab group and 1 patient (0.4%) in the placebo group.

Table S3. Prevalence by PD-L1 Expression and EGFR Mutation Status (Intention-to-Treat Population).*

	Durvalumab (N=476)	Placebo (N=237)
PD-L1 status – no. (%)		
TC <25%	187 (39.3)	105 (44.3)
TC ≥25%	115 (24.2)	44 (18.6)
Unknown†	174 (36.6)	88 (37.1)
EGFR mutation status – no. (%)		
Positive	29 (6.1)	14 (5.9)
Negative	315 (66.2)	165 (69.6)
Unknown†	132 (27.7)	58 (24.5)

*There were no statistically significant (P<0.05) between-group differences in either PD-L1 expression or EGFR mutation status.
†No sample collected or no valid test result.
EGFR, epidermal growth factor receptor; PD-L1, programmed cell death ligand-1; TC, tumor cell; TC ≥25%, ≥25% PD-L1 expression on tumor cells; TC <25%, <25% PD-L1 expression on tumor cells.

Table S4. Patient Disposition.

	Durvalumab (N=476)	Placebo (N=237)
Received treatment – no. (%)*	473 (99.4)	236 (99.6)
Treatment ongoing at data cutoff – no. (%)†	30 (6.3)	12 (5.1)
Completed 12 months treatment – no. (%)†	202 (42.7)	71 (30.1)
Discontinued study treatment – no. (%)†	241 (51.0)	153 (64.8)
Subject decision	14 (3.0)	12 (5.1)
Adverse event	73 (15.4)	23 (9.7)
Severe non-compliance to protocol	1 (0.2)	1 (0.4)
Condition under investigation worsened	148 (31.3)	116 (49.2)
Development of study specific discontinuation criteria	1 (0.2)	1 (0.4)
Other	4 (0.8)	0
Ongoing at data cutoff – no. (%)†	346 (73.2)	144 (61.0)
Completed study – no. (%)†	6 (1.3)	0
Discontinued study – no. (%)†,‡	121 (25.6)	92 (39.0)
Received subsequent therapy after discontinuation – no. (%)*	145 (30.5)	102 (43.0)

*Percentages are calculated based on the number of patients in the full analysis set.
†Percentages are calculated based on the number of patients who received treatment.
‡Details unavailable since this ongoing study remains blinded to overall survival.

Table S5. Summary of Durvalumab Serum Concentrations

Nominal time	Concentration (μg/mL)	Geometric mean (n, geometric %CV)
Week 0	Peak concentration	191.00 (n=385, 72.4%)
Week 8	Trough concentration	120.00 (n=289, 62.2%)
Week 24	Trough concentration	177.00 (n=224, 47.8%)
Week 24	Peak concentration	373.00 (n=207, 43.6%)
Week 48	Trough concentration	189.00 (n=166, 71.8%)

*Trough concentrations on Weeks 8, 24 and 48 are the pre-dose concentrations of Week 8, 24 and 48, respectively. Peak concentrations on Weeks 0 and 24 are the post-dose concentrations of Weeks 0 and 24, respectively.
n, number of patients; CV, coefficient of variance.

Table S6. Incidence of New Lesions in the Intention-to-Treat Population (BICR).*

New lesion site†	**Durvalumab (N=476)**	**Placebo (N=237)**
	number of patients (percent)	
Any new lesion	97 (20.4)	76 (32.1)
Lung	56 (11.8)	41 (17.3)
Lymph nodes	27 (5.7)	27 (11.4)
Brain	26 (5.5)	26 (11.0)
Liver	9 (1.9)	8 (3.4)
Bone	8 (1.7)	6 (2.5)
Adrenal	3 (0.6)	5 (2.1)
Other	9 (1.9)	5 (2.1)

*According to RECIST v1.1.
†A patient may have had more than one new lesion site.
BICR, Blinded Independent Central Review; RECIST, Response Evaluation Criteria In Solid Tumors.

Table S7. Summary of Serious Adverse Events.

Event*	Durvalumab (N=475)	Placebo (N=234)
	number of patients with an event (percent)	
Patients with any SAE	136 (28.6)	53 (22.6)
Infections and infestations	52 (10.9)	21 (9.0)
Chest wall abscess	1 (0.2)	0
Endotoxemia	1 (0.2)	0
Gastroenteritis	1 (0.2)	1 (0.4)
Haemophilus infection	1 (0.2)	0
Herpes zoster	3 (0.6)	0
Influenza	1 (0.2)	0
Lower respiratory tract infection bacterial	1 (0.2)	0
Lung abscess	2 (0.4)	0
Lung infection	6 (1.3)	2 (0.9)
Necrotizing fasciitis	0	1 (0.4)
Peritonitis	0	1 (0.4)
Pneumocystis jirovecii pneumonia	2 (0.4)	0
Pneumonia	27 (5.7)	12 (5.1)
Pneumonia adenoviral	1 (0.2)	0
Pneumonia bacterial	1 (0.2)	0
Pneumonia haemophilus	1 (0.2)	0
Pneumonia necrotizing	0	2 (0.9)
Pneumonia pneumococcal	1 (0.2)	0
Pneumonia streptococcal	1 (0.2)	1 (0.4)
Sepsis	4 (0.8)	2 (0.9)
Septic shock	2 (0.4)	0
Sinusitis	1 (0.2)	0
Skin infection	1 (0.2)	0
Upper respiratory tract infection	2 (0.4)	0
Viral upper respiratory tract infection	1 (0.2)	0
West Nile viral infection	0	1 (0.4)
Neoplasms benign, malignant, and unspecified (including cysts and polyps)	8 (1.7)	2 (0.9)
Bladder cancer	1 (0.2)	0
Cancer pain	1 (0.2)	0
Giant cell tumor of tendon sheath	1 (0.2)	0
Malignant melanoma	1 (0.2)	0
Papillary thyroid cancer	1 (0.2)	1 (0.4)
Prostate cancer	2 (0.4)	0
Small intestine carcinoma	1 (0.2)	0
Squamous cell carcinoma	0	1 (0.4)
Squamous cell carcinoma of skin	1 (0.2)	0
Blood and lymphatic system disorders	3 (0.6)	0
Anemia	2 (0.4)	0
Thrombocytopenia	1 (0.2)	0
Immune system disorders	1 (0.2)	0
Sarcoidosis	1 (0.2)	0
Metabolism and nutrition disorders	2 (0.4)	1 (0.4)
Decreased appetite	0	1 (0.4)
Iron overload	1 (0.2)	0
Type 1 diabetes mellitus	1 (0.2)	0
Psychiatric disorders	2 (0.4)	0
Adjustment disorder with mixed anxiety and depressed mood	1 (0.2)	0

Alcohol withdrawal syndrome	1 (0.2)	0
Nervous system disorders	4 (0.8)	2 (0.9)
Carotid artery stenosis	1 (0.2)	0
Cerebrovascular accident	2 (0.4)	0
Metabolic encephalopathy	0	1 (0.4)
Syncope	1 (0.2)	1 (0.4)
Eye disorders	0	1 (0.4)
Macular hole	0	1 (0.4)
Cardiac disorders	21 (4.4)	5 (2.1)
Acute coronary syndrome	0	1 (0.4)
Acute myocardial infarction	2 (0.4)	0
Angina pectoris	2 (0.4)	0
Arrhythmia supraventricular	1 (0.2)	0
Arteriospasm coronary	0	1 (0.4)
Atrial fibrillation	4 (0.8)	0
Atrioventricular block complete	0	1 (0.4)
Cardiac arrest	2 (0.4)	1 (0.4)
Cardiac disorder	1 (0.2)	0
Cardiac failure	1 (0.2)	0
Cardiac failure congestive	4 (0.8)	0
Cardiogenic shock	1 (0.2)	0
Cardiomyopathy	1 (0.2)	0
Cardiopulmonary failure	1 (0.2)	0
Eosinophilic myocarditis	0	1 (0.4)
Myocardial infarction	3 (0.6)	0
Myocardial ischemia	1 (0.2)	0
Pericardial effusion	2 (0.4)	0
Right ventricular failure	1 (0.2)	0
Ventricular tachycardia	1 (0.2)	0
Vascular disorders	5 (1.1)	1 (0.4)
Aortic dissection	1 (0.2)	0
Hypertension	1 (0.2)	0
Hypotension	1 (0.2)	0
Jugular vein thrombosis	1 (0.2)	0
Peripheral ischemia	0	1 (0.4)
Shock	1 (0.2)	0
Vena cava thrombosis	1 (0.2)	0
Respiratory, thoracic, and mediastinal disorders	36 (7.6)	12 (5.1)
Acquired tracheo-esophageal fistula	1 (0.2)	1 (0.4)
Acute interstitial pneumonitis	1 (0.2)	0
Acute respiratory failure	2 (0.4)	0
Bronchial obstruction	0	1 (0.4)
Chronic obstructive pulmonary disease	5 (1.1)	0
Dyspnea	2 (0.4)	0
Emphysema	1 (0.2)	0
Hemoptysis	2 (0.4)	1 (0.4)
Hypoxia	2 (0.4)	0
Interstitial lung disease	0	1 (0.4)
Pleural effusion	1 (0.2)	0
Pneumonia aspiration	0	1 (0.4)
Pneumonitis	16 (3.4)	7 (3.0)
Pneumothorax	2 (0.4)	1 (0.4)
Pulmonary embolism	2 (0.4)	0
Pulmonary fibrosis	0	1 (0.4)
Respiratory distress	1 (0.2)	0
Respiratory failure	2 (0.4)	0
Gastrointestinal disorders	9 (1.9)	6 (2.6)
Abdominal pain lower	1 (0.2)	0

Abdominal pain upper	1 (0.2)	0
Diarrhea	1 (0.2)	2 (0.9)
Diverticulum	1 (0.2)	0
Enteritis	1 (0.2)	0
Gastric ulcer	0	1 (0.4)
Hemorrhoidal hemorrhage	0	1 (0.4)
Hemorrhoids	0	1 (0.4)
Inguinal hernia	2 (0.4)	0
Intestinal obstruction	0	1 (0.4)
Nausea	1 (0.2)	0
Esophageal stenosis	1 (0.2)	0
Esophagitis	1 (0.2)	0
Vomiting	2 (0.4)	0
Hepatobiliary disorders	1 (0.2)	0
Cholecystitis	1 (0.2)	0
Musculoskeletal and connective tissue disorders	3 (0.6)	2 (0.9)
Flank pain	1 (0.2)	0
Intervertebral disc degeneration	0	1 (0.4)
Musculoskeletal pain	0	1 (0.4)
Myopathy	1 (0.2)	0
Polymyalgia rheumatica	1 (0.2)	0
Renal and urinary disorders	6 (1.3)	0
Acute kidney injury	2 (0.4)	0
Acute prerenal failure	1 (0.2)	0
Glomerulonephritis membranous	1 (0.2)	0
Nephrolithiasis	1 (0.2)	0
Renal tubular acidosis	1 (0.2)	0
Reproductive system and breast disorders	1 (0.2)	0
Calculus prostatic	1 (0.2)	0
General disorders and administration site conditions	7 (1.5)	4 (1.7)
Asthenia	0	1 (0.4)
Death	1 (0.2)	1 (0.4)
Fatigue	0	2 (0.9)
Influenza-like illness	1 (0.2)	0
Infusion site extravasation	1 (0.2)	0
Mucosal inflammation	1 (0.2)	0
Non-cardiac chest pain	1 (0.2)	1 (0.4)
Pyrexia	2 (0.4)	0
Investigations	2 (0.4)	1 (0.4)
Brain natriuretic peptide increased	1 (0.2)	0
Ejection fraction decreased	0	1 (0.4)
Myocardial necrosis marker increased	1 (0.2)	0
Injury, poisoning, and procedural complications	20 (4.2)	7 (3.0)
Fall	0	1 (0.4)
Femoral neck fracture	0	1 (0.4)
Infusion-related reaction	1 (0.2)	0
Post-procedural fistula	0	1 (0.4)
Radiation esophagitis	0	1 (0.4)
Radiation pneumonitis	17 (3.6)	3 (1.3)
Spinal compression fracture	0	1 (0.4)
Spinal fracture	1 (0.2)	0
Traumatic intracranial hemorrhage	1 (0.2)	0

*Sorted by international order for system organ class and alphabetically for preferred term. Patients with multiple serious
adverse events are counted once for each system organ class/preferred term.

Table S8. Treatment-Related Adverse Events Reported in ≥5% of Patients in Either Treatment Group.

Event	Durvalumab (N=475)		Placebo (N=234)	
	Any Grade*	Grade 3 or 4	Any Grade*	Grade 3 or 4
	number of patients with an event (percent)			
Any event	322 (67.8)	56 (11.8)	125 (53.4)	10 (4.3)
Fatigue	62 (13.1)	1 (0.2)	26 (11.1)	0
Hypothyroidism	50 (10.5)	1 (0.2)	1 (0.4)	0
Diarrhea	46 (9.7)	2 (0.4)	19 (8.1)	2 (0.9)
Pneumonitis	43 (9.1)	6 (1.3)	8 (3.4)	2 (0.9)
Rash	37 (7.8)	1 (0.2)	13 (5.6)	0
Pruritus	33 (6.9)	0	5 (2.1)	0
Hyperthyroidism	30 (6.3)	0	3 (1.3)	0
Asthenia	28 (5.9)	3 (0.6)	15 (6.4)	0
Dyspnea	28 (5.9)	3 (0.6)	8 (3.4)	0
Decreased appetite	27 (5.7)	0	7 (3.0)	1 (0.4)
Nausea	26 (5.5)	0	14 (6.0)	0
Cough	25 (5.3)	0	4 (1.7)	0

*Grade 5 treatment-related adverse events occurred in 7 patients (1.5%) receiving durvalumab (n=4 [0.8%] with pneumonitis and n=1 each [0.2%] with the following: cardiomyopathy, right ventricular failure, respiratory distress, respiratory failure, brain natriuretic peptide increased, and radiation pneumonitis). Grade 5 treatment-related adverse events occurred in 3 patients (1.3%) receiving placebo (n=2 [0.9%] with pneumonitis and n=1 [0.4%] with unknown cause).

Table S9. Any-Grade Immune-Mediated Adverse Events* Reported in ≥1% of Patients in Either Treatment Group.

Event†	Durvalumab (N=475)		Placebo (N=234)	
	Any Grade‡	Grade 3 or 4	Any Grade‡	Grade 3 or 4
	number of patients with an event (percent)			
Any event	115 (24.2)	16 (3.4)	19 (8.1)	6 (2.6)
Pneumonitis	51 (10.7)	8 (1.7)	16 (6.8)	6 (2.6)
Hypothyroidism	44 (9.3)	1 (0.2)	3 (1.3)	0
Hyperthyroidism	13 (2.7)	0	0	0
Rash	5 (1.1)	2 (0.4)	1 (0.4)	0
Dermatitis	5 (1.1)	0	0	0

*An adverse event of special interest requiring the use of systemic steroids or other immunosuppressants, and/or, for specific endocrine events, endocrine therapy, consistent with an immune-mediated mechanism of action, and where there is no clear alternate etiology.
†Composite terms.
‡Grade 5 immune-mediated AEs occurred in 4 patients (0.8%) receiving durvalumab and 3 patients (1.3%) receiving placebo.