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Supplemental Tables for:
CheckMate 141: 1-Year Update and Subgroup Analysis of Nivolumab as First-line Therapy in Patients With Recurrent/Metastatic Head and Neck Cancer
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Table S1. Baseline characteristics among patients randomized to nivolumab or investigator's choice as first-line treatment for recurrent or metastatic squamous cell carcinoma of the head and neck after progressing on or after platinum therapy (within 6 months) in the adjuvant or primary (i.e., with radiation) setting for locally advanced disease.

Characteristics	Nivolumab (*n* = 52)	Investigator's choice (*n* = 26)
Age, median (range), years	57.5 (30–79)	59.5 (28–78)
Age ≥65 years, *n* (%)	13 (25.0)	9 (34.6)
Male, *n* (%)	41 (78.8)	21 (80.8)
Race, *n* (%)		
White	37 (71.2)	24 (92.3)
Black	4 (7.7)	1 (3.8)
Asian	9 (17.3)	1 (3.8)
Other	2 (3.8)	0
Region, *n* (%)		
North America	21 (40.4)	5 (19.2)
Europe	22 (42.3)	18 (69.2)
Rest of the world	9 (17.3)	3 (11.5)
Smoking or tobacco use, *n* (%)		
Current/former	40 (76.9)	17 (65.4)
Never	10 (19.2)	8 (30.8)
Unknown	2 (3.8)	1 (3.8)

Characteristics	Nivolumab (*n* = 52)	Investigator's choice (*n* = 26)
ECOG performance status, *n* (%)		
0	11 (21.2)	5 (19.2)
1	41 (78.8)	20 (76.9)
2	0	1 (3.8)
HPV status, *n* (%)		
Positive	10 (19.2)	6 (23.1)
Negative	15 (28.8)	8 (30.8)
Not tested[a]	27 (51.9)	12 (46.2)
PD-L1 expression, *n* (%)		
≥1%	24 (46.2)	14 (53.8)
<1%	13 (25.0)	7 (26.9)
Not quantifiable	15 (28.8)	5 (19.2)

[a]HPV status testing only required for patients with oropharyngeal cancer.

Abbreviations: ECOG, Eastern Cooperative Oncology Group; HPV, human papillomavirus; PD-L1, programmed death ligand 1.

Table S2. Response among patients receiving nivolumab or investigator's choice as first-line treatment for recurrent or metastatic squamous cell carcinoma of the head and neck after progressing on or after platinum therapy (within 6 months) in the adjuvant or primary (i.e., with radiation) setting for locally advanced disease.

	Nivolumab (*n* = 52)	**Investigator's choice (*n* = 26)**
Best overall response, *n* (%)		
Complete response	2 (3.8)	0
Partial response	8 (15.4)	3 (11.5)
Stable disease	11 (21.2)	8 (30.8)
Progressive disease	18 (34.6)	8 (30.8)
Unable to determine	13 (25.0)	7 (26.9)
ORR, *n* (%)	10 (19.2)	3 (11.5)
[95% CI]	[9.6–32.5]	[2.4-30.2]
Odds ratio (95% CI)	1.83 (0.46–7.31)	
Time to response, median (range), months	2.0 (1.8–6.3)	2.0 (1.9–4.6)

Abbreviations: CI, confidence interval; ORR, objective response rate.

Table S3. Most common TRAEs (≥10% in any arm) and select TRAEs among patients receiving nivolumab or investigator's choice as first-line treatment for recurrent or metastatic squamous cell carcinoma of the head and neck after progressing on or after platinum therapy (within 6 months) in the adjuvant or primary (i.e., with radiation) setting for locally advanced disease.

	Nivolumab (*n* = 51)		**Investigator's choice (*n* = 25)**	
Patients, *n* (%)	**Any grade**	**Grade 3–4**	**Any grade**	**Grade 3–4**
Any event (≥10% in any arm)	35 (68.6)	14 (27.5)	18 (72.0)[a]	8 (32.0)
Fatigue	9 (17.6)	3 (5.9)	3 (12.0)	0
Nausea	7 (13.7)	0	5 (20.0)	0
Pruritus	6 (11.8)	0	0	0
Asthenia	4 (7.8)	0	5 (20.0)	1 (4.0)
Vomiting	3 (5.9)	0	3 (12.0)	0
Dry skin	2 (3.9)	0	3 (12.0)	0
Mucosal inflammation	1 (2.0)	0	5 (20.0)	0
Alopecia	0	0	4 (16.0)	0
Select TRAEs				
Skin	10 (19.6)	0	4 (16.0)	1 (4.0)
Endocrine	4 (7.8)	0	0	0
Gastrointestinal	4 (7.8)	1 (2.0)	2 (8.0)	0
Hepatic	3 (5.9)	0	1 (4.0)	0
Pulmonary	1 (2.0)	0	1 (4.0)	0
Renal	1 (2.0)	0	0	0
Hypersensitivity/infusion reactions	2 (3.9)	0	1 (4.0)	1 (4.0)

[a]Includes 1 grade 5 event of pneumonia.

Abbreviation: TRAE, treatment-related adverse event.

Table S4. Most common TRAEs (≥10% in any arm) and select TRAEs in the overall treated population.

	Nivolumab (*n* = 236)		**Investigator's choice (*n* = 111)**	
Patients, *n* (%)	**Any grade**	**Grade 3–4**	**Any grade**	**Grade 3–4**
Any event (≥10% in any arm)	146 (61.9)	36 (15.3)	88 (79.3)[a]	40 (36.0)
Fatigue	37 (15.7)	5 (2.1)	20 (18.0)	3 (2.7)
Nausea	22 (9.3)	0	23 (20.7)	1 (0.9)
Diarrhea	20 (8.5)	1 (0.4)	16 (14.4)	2 (1.8)
Anemia	12 (5.1)	3 (1.3)	19 (17.1)	6 (5.4)
Asthenia	10 (4.2)	1 (0.4)	17 (15.3)	2 (1.8)
Stomatitis	6 (2.5)	1 (0.4)	12 (10.8)	3 (2.7)
Mucosal inflammation	4 (1.7)	0	15 (13.5)	2 (1.8)
Alopecia	0	0	14 (12.6)	0
Select TRAEs				
Skin	40 (16.9)	0	14 (12.6)	2 (1.8)
Endocrine	22 (9.3)	1 (0.4)	1 (0.9)	0
Gastrointestinal	20 (8.5)	1 (0.4)	17 (15.3)	2 (1.8)
Hepatic	7 (3.0)	2 (0.8)	5 (4.5)	1 (0.9)
Pulmonary	7 (3.0)	2 (0.8)	1 (0.9)	0
Renal	3 (1.3)	0	2 (1.8)	1 (0.9)
Hypersensitivity/infusion reactions	3 (1.3)	0	2 (1.8)	1 (0.9)

[a]Includes 1 grade 5 event of pneumonia.

Abbreviation: TRAE, treatment-related adverse event.