Supplementary Online Content

Siu LL, Even C, Ricard M, et al. Safety and efficacy of durvalumab with or without tremelimumab in patients with PD-L1–low/negative recurrent or metastatic HNSCC: the phase 2 CONDOR randomized clinical trial. *JAMA Oncol*. Published online November 1, 2018. doi:10.1001/jamaoncol.2018.4628

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

eAppendix. Eligibility criteria

Patients were required to have measurable disease per Response Evaluation Criteria in Solid Tumors version 1.1 (RECIST version 1.1) and adequate organ and bone marrow function.

Key exclusion criteria included: confirmed squamous cell carcinoma of any other primary anatomic location in the head and neck or of unknown primary squamous or nonsquamous histology; received more than 1 systemic palliative regimen for R/M disease; received only chemoradiation with curative intent for treatment of locally advanced or R/M disease; had a history of brain metastases, spinal cord compression, leptomeningeal carcinomatosis, another primary malignancy, active primary immunodeficiency, autoimmune disease, or previous clinical diagnosis of tuberculosis, or had active infection including hepatitis B, hepatitis C, or HIV; any prior exposure to immune-mediated therapy, including other anti–CTLA-4, anti–PD-1, anti–PD-L1, or anti–PD-L2 antibodies; or current or prior use of immunosuppressive medication within 14 days before the first dose of assigned investigational treatment; prior exposure to therapeutic anticancer vaccines was permitted.

eTable. Patient Disposition

	Durvalumab + tremelimumab	Durvalumab	Tremelimumab	Total
Patients screened, N[a]				393
Patients who were not randomized, n				126
Patients randomized, n	133	67	67	267 (68)
Patients who received study treatment, n (%)	133 (100)	65 (97.0)	65 (97.0)	263 (98.5)
Patients completing 12 months of treatment, n (%)[b]	11 (8.3)	7 (10.8)	0	18 (6.8)
Patients who discontinued study treatment, n (%)[b]	122 (91.7)	58 (89.2)	65 (100)	245 (93.2)
Progression	100 (75.2)	50 (76.9)	46 (70.8)	196 (74.5)
Adverse event	17 (12.8)	2 (3.1)	8 (12.3)	27 (10.3)
Subject decision	3 (2.3)	3 (4.6)	6 (9.2)	12 (4.6)
Development of discontinuation criteria	2 (1.5)	2 (3.1)	1 (1.5)	5 (1.9)
Other	0	1 (1.5)	4 (6.2)	5 (1.9)
Evaluable patients, n[c]	129	65	63	257

[a]Informed consent received.
[b]Percentages are based on number of patients who received treatment.
[c]Includes all patients who received at least 1 dose of study treatment who have a baseline tumor assessment and have measurable disease. Reasons for exclusion from evaluable analysis set include not receiving treatment (n = 2 in durvalumab arm; n = 2 in tremelimumab arm), no baseline tumor assessment (n = 2 in combination arm; n = 1 in tremelimumab arm), no measurable disease at baseline according to BICR (n = 1 in combination arm; n = 1 in tremelimumab arm).

eFigure. Best Percentage Change in Tumor Size Based on BICR Assessment According to RECIST v1.1 (EAS)