

Supplementary table 1. Treatment-emergent adverse events related to study therapy, according to HIV status

Adverse event grade	HIV	HIV	Total
	POSITIVE	NEGATIVE	No. (%)
	No. (%)	No. (%)	
1	140 (71)	137 (67)	277 (69)
2	42 (21)	55 (27)	97 (24)
3	12 (6)	12 (6)	24 (6)
4	3 (1.5)	0	3 (0.75)
5	1 (0.5)	0	1 (0.25)
Total	198	204	402

Supplementary table 2. Treatment-emergent adverse events related to study therapy, according to CD4+ T-cell counts *

Adverse event grade	CD4	CD4	Total No. (%)
	count	count	
	<350	>=350	
	No. (%)	No. (%)	
1	137 (66)	117 (71)	254 (68)*
2	50 (24)	41 (25)	91 (24)*
3	18 (9)	6 (6)	24 (6)
4	3 (1)	0	3 (0.8)
5	1 (0.5)	0	1 (0.2)
Total	209	164	373

* 5 patients who experienced a total of 29 adverse events of grades 1 and 2 did not have CD4+ T cell counts recorded at baseline

Supplementary table 3. Adverse events related to treatment

Adverse Event	HIV POSITIVE						HIV NEGATIVE			
	Adverse Event Grade						Adverse Event Grade			
	No. (%)						No. (%)			
	1	2	3	4	5	Total	1	2	3	Total
Abdominal pain	2	1	1	0	0	4	0	0	0	
	1.43	2.38	8.33	0.00	0.00	2.02				
Acute kidney injury	1	0	0	0	0	1	0	0	0	
	0.71	0.00	0.00	0.00	0.00	0.51				
Adrenal insufficiency	0	0	0	0	0		0	2	0	2
							0.00	3.64	0.00	0.98
Alanine aminotransferase increased	5	1	0	0	0	6	0	2	1	3
	3.57	2.38	0.00	0.00	0.00	3.03	0.00	3.64	8.33	1.47
Alkaline phosphatase increased	3	2	0	0	0	5	0	0	0	0
	2.14	4.76	0.00	0.00	0.00	2.53				
Anal hemorrhage	0	0	0	0	0		2	0	0	2
							1.46	0.00	0.00	0.98
Alopecia	1	0	0	0	0	1	0.00	0.00	0.00	
	0.71	0.00	0.00	0.00	0.00	0.51				
Anemia	6	4	2	0	0	12	0	11	2	13
	4.29	9.52	16.67	0.00	0.00	6.06	0.00	20.00	16.67	6.37
Anorexia	2	1	0	0	0	3	0	1	0	1
	1.43	2.38	0.00	0.00	0.00	1.52	0.00	1.82	0.00	0.49
Arthralgia	3	1	0	0	0	4	0	1	0	1
	2.14	2.38	0.00	0.00	0.00	2.02	0.00	1.82	0.00	0.49
Aspartate aminotransferase increased	3	1	1	0	0	5	0	2	1	3
	2.14	2.38	8.33	0.00	0.00	2.53	0.00	3.64	8.33	1.47
BUN increased	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				
Blood bilirubin increased	1	0	1	1	0	3	0	0	0	0

	0.71	0.00	8.33	33.33	0.00	1.52				
Blurred vision	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				
Bullous dermatitis	0	0	0	0	0		1	0	0	1
							0.73	0.00	0.00	0.49
CD4 lymphocytes decreased	0	1	1	0	0	2	0	0	0	0
	0.00	2.38	8.33	0.00	0.00	1.01				
CO2 Decreased	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				
CPK increased	3	0	0	0	0	3	0	1	0	1
	2.14	0.00	0.00	0.00	0.00	1.52	0.00	1.82	0.00	0.49
Cardiac troponin I increased	0	0	0	0	0		0	0	1	1
							0.00	0.00	8.33	0.49
Chills	0	0	0	0	0		1	0	0	1
							0.73	0.00	0.00	0.49
Colitis	0	0	0	0	0		0	1	0	1
							0.00	1.82	0.00	0.49
Constipation	2	0	0	0	0	2	0	0	0	0
	1.43	0.00	0.00	0.00	0.00	1.01				
Cough	3	0	0	0	0	3	1	2	0	3
	2.14	0.00	0.00	0.00	0.00	1.52	0.73	3.64	0.00	1.47
Death NOS	0	0	0	0	1	1	0	0	0	0
	0.00	0.00	0.00	0.00	100.00	0.51				
Diarrhea	2	2	0	0	0	4	3	2	0	5
	1.43	4.76	0.00	0.00	0.00	2.02	2.19	3.64	0.00	2.45
Dizziness	2	0	0	0	0	2	2	0	0	2
	1.43	0.00	0.00	0.00	0.00	1.01	1.46	0.00	0.00	0.98
Dry eye	1	0	0	0	0	1	1	0	0	1
	0.71	0.00	0.00	0.00	0.00	0.51	0.73	0.00	0.00	0.49
Dry mouth	0	0	0	0	0		2	0	0	2
							1.46	0.00	0.00	0.98

Dry skin	2	0	0	0	0	2	1	1	0	2
	1.43	0.00	0.00	0.00	0.00	1.01	0.73	1.82	0.00	0.98
Dysphagia	0	0	0	0	0		1	0	0	1
							0.73	0.00	0.00	0.49
Dyspnea	0	1	0	1	0	2	2	3	0	5
	0.00	2.38	0.00	33.33	0.00	1.01	1.46	5.45	0.00	2.45
Dysuria	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				
Edema face	0	0	0	0	0		0	1	0	1
							0.00	1.82	0.00	0.49
Edema limbs	0	0	1	0	0	1	1	0	0	1
	0.00	0.00	8.33	0.00	0.00	0.51	0.73	0.00	0.00	0.49
Edema trunk	0	1	0	0	0	1	0	0	0	0
	0.00	2.38	0.00	0.00	0.00	0.51				
Erythema	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				
Epistaxis	0	0	0	0	0		11	1	0	12
							8.03	1.82	0.00	5.88
Facial muscle weakness	0	0	0	0	0		0	1	0	1
							0.00	1.82	0.00	0.49
Facial nerve disorder	0	0	0	0	0		1	0	0	1
							0.73	0.00	0.00	0.49
Fatigue	13	1	0	0	0	14	13	3	0	16
	9.29	2.38	0.00	0.00	0.00	7.07	9.49	5.45	0.00	7.84
Fever	2	3	0	0	0	5	0	0	0	0
	1.43	7.14	0.00	0.00	0.00	2.53				
Flatulence	1	0	0	0	0	1	2	0	0	2
	0.71	0.00	0.00	0.00	0.00	0.51	1.46	0.00	0.00	0.98
Flu like symptoms							3	0	0	3
							2.19	0.00	0.00	1.47
Flushing	0	0	0	0	0		1	0	0	1

							0.73	0.00	0.00	0.49
GFR Decreased	0	1	0	0	0	1	0	0	0	0
	0.00	2.38	0.00	0.00	0.00	0.51				
GGT increased	0	0	1	0	0	1	0	0	0	0
	0.00	0.00	8.33	0.00	0.00	0.51				
Gastroesophageal reflux disease	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				
Genital edema	0	1	0	0	0	1	0	0	0	0
	0.00	2.38	0.00	0.00	0.00	0.51				
Gingival pain	0	0	0	0	0		1	0	0	1
							0.73	0.00	0.00	0.49
Headache	3	0	0	0	0	3	2	0	0	2
	2.14	0.00	0.00	0.00	0.00	1.52	1.46	0.00	0.00	0.98
Hematuria	0	0	0	0	0		3	0	1	4
							2.19	0.00	8.33	1.96
Hemorrhoidal hemorrhage	0	0	0	0	0		2	0	0	2
							1.46	0.00	0.00	0.98
Hepatic toxicity	0	1	0	0	0	1	0	0	0	0
	0.00	2.38	0.00	0.00	0.00	0.51				
Hypercalcemia	1	0	0	0	0	1	1	0	0	1
	0.71	0.00	0.00	0.00	0.00	0.51	0.73	0.00	0.00	0.49
Hyperglycemia	0	1	0	0	0	1	0	0	1	1
	0.00	2.38	0.00	0.00	0.00	0.51	0.00	0.00	8.33	0.49
Hyperkalemia	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				
Hyperthyroidism	0	0	0	0	0		1	0	0	1
							0.73	0.00	0.00	0.49
Hypoalbuminemia	2	0	0	0	0	2	0	0	0	0
	1.43	0.00	0.00	0.00	0.00	1.01				
Hypocalcemia	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				

Hypokalemia	2	0	0	0	0	2	0	1	0	1
	1.43	0.00	0.00	0.00	0.00	1.01	0.00	1.82	0.00	0.49
Hyponatremia	3	0	0	0	0	3	0	0	0	0
	2.14	0.00	0.00	0.00	0.00	1.52				
Hypophosphatemia	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				
Hypothyroidism	3	5	0	0	0	8	1	6	0	7
	2.14	11.90	0.00	0.00	0.00	4.04	0.73	10.91	0.00	3.43
Increased CK	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				
Insomnia	2	0	0	0	0	2	1	2	0	3
	1.43	0.00	0.00	0.00	0.00	1.01	0.73	3.64	0.00	1.47
Intestinal stoma site bleeding	0	0	0	0	0		1	0	0	1
							0.73	0.00	0.00	0.49
Libido decreased	0	0	0	0	0		1	0	0	1
							0.73	0.00	0.00	0.49
Lipase increased	0	0	0	0	0		0	0	1	1
							0.00	0.00	8.33	0.49
Localized edema	0	2	0	0	0	2	0	0	0	0
	0.00	4.76	0.00	0.00	0.00	1.01				
Loose Stool	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				
Loose Stool (Intermittent)	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				
Loose Stool (intermittent)	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				
Loose stool	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				
Lymphocyte count decreased	2	0	1	0	0	3	1	1	0	2
	1.43	0.00	8.33	0.00	0.00	1.52	0.73	1.82	0.00	0.98
Metallic taste in mouth	1	0	0	0	0	1				

	0.71	0.00	0.00	0.00	0.00	0.51					
Mucositis oral	1	0	0	0	0	1	4	1	0	5	
	0.71	0.00	0.00	0.00	0.00	0.51	2.92	1.82	0.00	2.45	
Myalgia	1	0	0	0	0	1	1	0	0	1	
	0.71	0.00	0.00	0.00	0.00	0.51	0.73	0.00	0.00	0.49	
Myocarditis	0	0	0	0	0		0	0	1	1	
							0.00	0.00	8.33	0.49	
Myositis	0	0	0	0	0		0	1	0	1	
							0.00	1.82	0.00	0.49	
Nasal congestion	1	0	0	0	0	1	1	0	0	1	
	0.71	0.00	0.00	0.00	0.00	0.51	0.73	0.00	0.00	0.49	
Nausea	8	2	0	0	0	10	2	0	0	2	
	5.71	4.76	0.00	0.00	0.00	5.05	1.46	0.00	0.00	0.98	
Neoplasms benign, malignant and unspecified (incl cysts and polyps) - Other, specify	0	0	0	0	0		5	3	0	8	
							3.65	5.45	0.00	3.92	
Neutrophil count decreased	0	2	1	0	0	3	0	0	0	0	
	0.00	4.76	8.33	0.00	0.00	1.52					
Oral hemorrhage	0	0	0	0	0		12	0	0	12	
							8.76	0.00	0.00	5.88	
Pain	2	1	0	0	0	3	0	0	0	0	
	1.43	2.38	0.00	0.00	0.00	1.52					
Pain in extremity	1	1	0	0	0	2	0	0	0	0	
	0.71	2.38	0.00	0.00	0.00	1.01					
Pancreatitis	0	0	1	0	0	1	0	0	0	0	
	0.00	0.00	8.33	0.00	0.00	0.51					
Papulopustular rash	0	0	0	0	0		1	0	0	1	
							0.73	0.00	0.00	0.49	
Peripheral sensory neuropathy	1	0	0	0	0	1	0	0	0	0	
	0.71	0.00	0.00	0.00	0.00	0.51					

Platelet count decreased	2	0	0	1	0	3	0	0	0	0
	1.43	0.00	0.00	33.33	0.00	1.52				
Pleural effusion	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				
Pneumonitis	2	2	0	0	0	4	0	1	0	1
	1.43	4.76	0.00	0.00	0.00	2.02	0.00	1.82	0.00	0.49
Proteinuria	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				
Pruritus	10	0	0	0	0	10	12	2	0	14
	7.14	0.00	0.00	0.00	0.00	5.05	8.76	3.64	0.00	6.86
Rash acneiform	1	0	0	0	0	1	12	1	0	13
	0.71	0.00	0.00	0.00	0.00	0.51	8.76	1.82	0.00	6.37
Rash maculo-papular	5	1	0	0	0	6	8	0	0	8
	3.57	2.38	0.00	0.00	0.00	3.03	5.84	0.00	0.00	3.92
Rectal hemorrhage	0	0	0	0	0		6	0	0	6
							4.38	0.00	0.00	2.94
Rhinorrhea	0	0	0	0	0		1	0	0	1
							0.73	0.00	0.00	0.49
Skin hypopigmentation	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				
Soft tissue infection	0	1	1	0	0	2	0	0	0	0
	0.00	2.38	8.33	0.00	0.00	1.01				
Tumor hemorrhage	0	0	0	0	0		0	0	1	1
							0.00	0.00	8.33	0.49
Tumor pain	0	0	0	0	0		1	0	0	1
							0.73	0.00	0.00	0.49
Tremor	0	1	0	0	0	1	0	0	0	0
	0.00	2.38	0.00	0.00	0.00	0.51				
Upper gastrointestinal hemorrhage							0	0	2	2
							0.00	0.00	16.67	0.98
Urinary tract obstruction	0	0	0	0	0		0	1	0	1

							0.00	1.82	0.00	0.49
Uterine hemorrhage	0	0	0	0	0		1	0	0	1
							0.73	0.00	0.00	0.49
Vaginal hemorrhage	0	0	0	0	0		4	0	0	4
							2.92	0.00	0.00	1.96
Vomiting	3	0	0	0	0	3	1	0	0	1
	2.14	0.00	0.00	0.00	0.00	1.52	0.73	0.00	0.00	0.49
Weight loss	1	0	0	0	0	1	1	0	0	1
	0.71	0.00	0.00	0.00	0.00	0.51	0.73	0.00	0.00	0.49
White blood cell decreased	2	0	0	0	0	2				
	1.43	0.00	0.00	0.00	0.00	1.01				
Xeroderma	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				
blister mouth	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				
carbon dioxide decreased	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				
night sweats	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				
runny nose	1	0	0	0	0	1	0	0	0	0
	0.71	0.00	0.00	0.00	0.00	0.51				
Total	140	42	12	3	1	198	137	55	12	204
	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00	100.00

Supplementary table 4. Clinical trials evaluating pembrolizumab and durvalumab in advanced anal, cervical, and head/neck cancers.

Study/Author	Drug	HIV status	Tumor type	Number of participants receiving drug	Enrollment dates	Any TEAE, n (%)	Grade $\geq 3\%$ TRAE, n (%)
KEYNOTE-012 /Mehra et al. [1]	Pembrolizumab	Negative	Recurrent and/or metastatic head and neck squamous cell carcinoma	192	June 2013 – October 2014	123 (64%)	24 (13%)
KEYNOTE-040 /Cohen et al. [2]	Pembrolizumab	Negative	Recurrent and/or metastatic head and neck squamous cell carcinoma	246	December 2014 – May 2016	155 (63%)	33 (13%)
KEYNOTE-055 /Bauml et al. [3]	Pembrolizumab	Negative	Recurrent and/or metastatic head and neck squamous cell carcinoma	171	October 2014 – September 2015	109 (64%)	26 (15%)
KEYNOTE-048 /Burtneß et al. [4]	Pembrolizumab	Negative	Recurrent and/or metastatic head and neck squamous cell carcinoma	300	April 2015 – January 2017	175 (58%)*	51 (17%)
HAWK study / Zandberg et al. [5]	Durvalumab	Negative	Recurrent and/or metastatic head	112	October 2014 - March 2016	64 (57.1%)	9 (8%)

			and neck squamous cell carcinoma					
MedImmune study 1108 /Segal et al. [6]	Durvalumab	Negative	Recurrent and/or metastatic head and neck squamous cell carcinoma	62	September 2013 – October 2017	37 (59.7%)	6 (9.7%)	
EAGLE study /Ferris et al. [7]	Durvalumab	Negative	Recurrent and/or metastatic head and neck squamous cell carcinoma	240	November 2015 – July 2017	136 (57.4%)	24 (10.2%)	
CONDOR study /Siu et al. [8]	Durvalumab	Negative	Recurrent and/or metastatic head and neck squamous cell carcinoma	67	April 2015 – March 2016	41 (63.1%)	8 (12.3%)	
KEYNOTE-158 /Chung et al. [9]	Pembrolizumab	Negative	Recurrent or metastatic cervical cancer	98	January 2016 – August 2016	64 (65.3%)	12 (12.2%)	
KEYNOTE-158 /Marabelle et al. [10]	Pembrolizumab	Negative	Advanced or metastatic anal squamous cell carcinoma	112	March 2016 – July 2018	68 (61%)	20 (18%)	

TEAE, treatment-emergent adverse events

* TEAE of any grade with incidence $\geq 10\%$

REFERENCES

1. Mehra R, Seiwert TY, Gupta S, Weiss J, Gluck I, Eder JP, Burtness B, Tahara M, Keam B, Kang H *et al*: **Efficacy and safety of pembrolizumab in recurrent/metastatic head and neck squamous cell carcinoma: pooled analyses after long-term follow-up in KEYNOTE-012.** *Br J Cancer* 2018, **119**(2):153-159.
2. Cohen EEW, Soulières D, Le Tourneau C, Dinis J, Licitra L, Ahn MJ, Soria A, Machiels JP, Mach N, Mehra R *et al*: **Pembrolizumab versus methotrexate, docetaxel, or cetuximab for recurrent or metastatic head-and-neck squamous cell carcinoma (KEYNOTE-040): a randomised, open-label, phase 3 study.** *Lancet (London, England)* 2019, **393**(10167):156-167.
3. Bauml J, Seiwert TY, Pfister DG, Worden F, Liu SV, Gilbert J, Saba NF, Weiss J, Wirth L, Sukari A *et al*: **Pembrolizumab for Platinum- and Cetuximab-Refractory Head and Neck Cancer: Results From a Single-Arm, Phase II Study.** *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 2017, **35**(14):1542-1549.
4. Burtness B, Harrington KJ, Greil R, Soulières D, Tahara M, de Castro G, Psyrri A, Basté N, Neupane P, Bratland Å *et al*: **Pembrolizumab alone or with chemotherapy versus cetuximab with chemotherapy for recurrent or metastatic squamous cell carcinoma of the head and neck (KEYNOTE-048): a randomised, open-label, phase 3 study.** *The Lancet* 2019, **394**(10212):1915-1928.
5. Zandberg DP, Algazi AP, Jimeno A, Good JS, Fayette J, Bouganim N, Ready NE, Clement PM, Even C, Jang RW *et al*: **Durvalumab for recurrent or metastatic head and neck squamous cell carcinoma: Results from a single-arm, phase II study in patients with ≥25% tumour cell PD-L1 expression who have progressed on platinum-based chemotherapy.** *European journal of cancer (Oxford, England : 1990)* 2019, **107**:142-152.
6. Segal NH, Ou SI, Balmanoukian A, Fury MG, Massarelli E, Brahmer JR, Weiss J, Schöffski P, Antonia SJ, Massard C *et al*: **Safety and efficacy of durvalumab in patients with head and neck squamous cell carcinoma: results from a phase I/II expansion cohort.** *European journal of cancer (Oxford, England : 1990)* 2019, **109**:154-161.
7. Ferris RL, Haddad R, Even C, Tahara M, Dvorkin M, Ciuleanu TE, Clement PM, Mesia R, Kutukova S, Zholudeva L *et al*: **Durvalumab with or without tremelimumab in patients with recurrent or metastatic head and neck squamous cell carcinoma: EAGLE, a randomized, open-label phase III study.** *Annals of oncology : official journal of the European Society for Medical Oncology* 2020, **31**(7):942-950.
8. Siu LL, Even C, Mesía R, Remenar E, Daste A, Delord J-P, Krauss J, Saba NF, Nabell L, Ready NE *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 Oncology* 2019, **5**(2):195-203.
9. Chung HC, Ros W, Delord JP, Perets R, Italiano A, Shapira-Frommer R, Manzuk L, Piha-Paul SA, Xu L, Zeigenfuss S *et al*: **Efficacy and Safety of Pembrolizumab in Previously Treated Advanced Cervical Cancer: Results From the Phase II KEYNOTE-158 Study.** *Journal of clinical oncology : official journal of the American Society of Clinical Oncology* 2019, **37**(17):1470-1478.
10. Marabelle A, Cassier PA, Fakih M, Kao S, Nielsen D, Italiano A, Guren TK, van Dongen MGJ, Spencer K, Bariani GM *et al*: **Pembrolizumab for previously treated advanced anal squamous cell carcinoma: results from the non-randomised, multicohort, multicentre, phase 2 KEYNOTE-158 study.** *The lancet Gastroenterology & hepatology* 2022, **7**(5):446-454.