Sponsor Briefing Document
for the
Oncologic Drugs Advisory Committee

BLA 761380

TEVIMBRA (tislelizumab)

ERRATA

Meeting Date: 26 September 2024

Baseline PD-L1 Status	≥ 10%		<10%		≥ 5%		<5%		≥ 1%		< 1%		≥ 1% to < 5%		≥ 5% to <10%	
	TIS+C (N = 116)	PBO+C (N = 107)	TIS+C (N = 151)	PBO+C (N = 168)	TIS+C (N = 172)	PBO+C (N = 186)	TIS+C (N = 95)	PBO+C (N = 89)	TIS+C (N = 231)	PBO+C (N = 250)	TIS+C (N = 36)	PBO+C (N = 25)	TIS+C (N = 59)	PBO+C (N = 64)	TIS+C (N = 56)	PBO+C (N = 79)
Time from Initial Diagnosis to Study Entry months																
Median	1.59	1.84	4.96	2.40	1.58	1.66	8.61	10.55	2.00	1.87	1.63	15.44	8.97	6.57	1.58	1.48
Min, Max	0.3, 152.7	0.3, 68.8	0.1, 100.8	0.2, 116.8	0.3, 152.7	0.2, 83.1	0.1, 100.8	0.2, 116.8	0.2, 152.7	0.2, 116.8	0.1, 79.3	0.4, 61.9	0.2, 100.8	0.2, 116.8	0.3, 84.4	0.2, 83.1
Disease Status at Study Entry, Metastatic, %	87.1	89.7	88.1	85.7	86.0	89.2	90.5	83.1	86.6	87.2	94.4	88.0	88.1	81.3	83.9	88.6
Number of Metastatic Sites at Study Entry, %																
0 – 2	85.3	81.3	80.8	72.7	84.9	81.7	78.9	83.1	83.1	81.2	80.6	92.0	78.0	79.7	83.9	82.3
> 2	14.7	18.7	19.2	17.3	15.1	18.3	21.1	16.9	16.9	18.8	19.4	8.0	22.0	20.3	16.1	17.7
Patients with at Least One Prior Definitive Therapy, %	37.1	39.3	47.7	45.8	39.5	39.2	49.5	51.7	43.7	42.0	38.9	56.0	55.9	50.0	44.6	39.2
ICC Option per IRT, %																
Platinum with fluoropyrimidine	42.2	39.3	44.4	48.8	40.1	41.9	49.5	51.7	43.3	46.8	44.4	28.0	52.5	60.9	35.7	45.6
Platinum with paclitaxel	57.8	60.7	55.6	51.2	59.9	58.1	50.5	48.3	56.7	53.2	55.6	72.0	47.5	39.1	64.3	54.4

Data cutoff: 28FEB2022.

Abbreviations: ECOG, Eastern Cooperative Oncology Group; ICC, investigator's choice chemotherapy; IRT, Interactive Response Technology; ITT, intent to treat; PBO+C, placebo + chemotherapy; PD-L1, programmed death ligand 1; TIS+C, tislelizumab + chemotherapy.