



**Sponsor Briefing Document
for the
Oncologic Drugs Advisory Committee**

BLA 761380

TEVIMBRA (tislelizumab)

ERRATA

Meeting Date: 26 September 2024

ADVISORY COMMITTEE BRIEFING MATERIALS: AVAILABLE FOR PUBLIC RELEASE

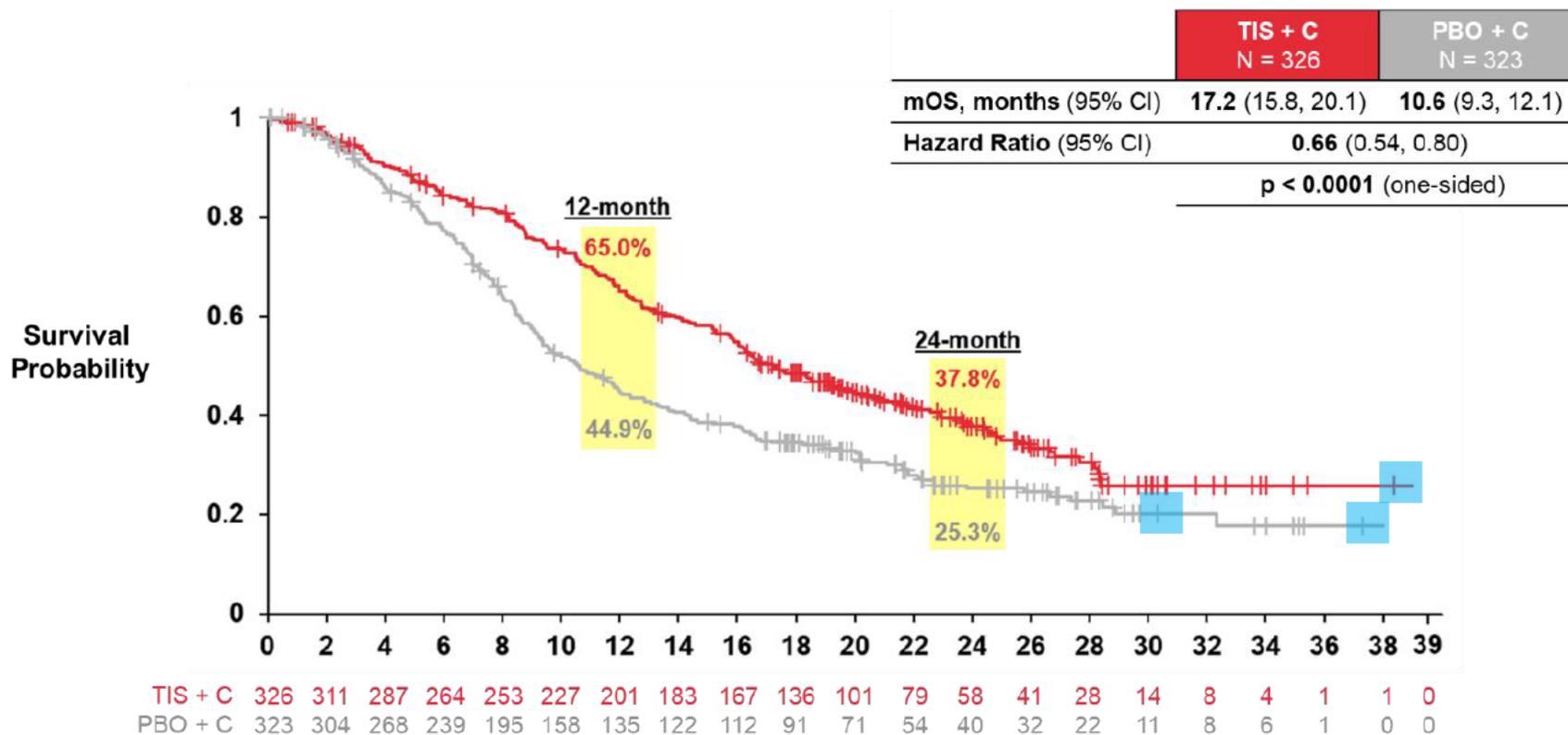
ERRATA TO THE BRIEFING DOCUMENT:

BeiGene would like to provide correction to Figure 4, page 20 in the submitted Briefing Document. The original figure is shown below with the errors in the original curves highlighted by blue boxes. The updated figure contains minor corrections to the end of the survival curves. Statistical summaries including median, HR and p-value remain intact, and the conclusions are unchanged.

BeiGene would also like to provide correction to Table 9 (in Appendix 1), page 48 in the submitted Briefing Document. For categorical variables, earlier drafts of this table had presented both the number of (n) as well as the percentage (%) of the patients in each cell. Out of consideration of the space, it was decided to remove the n value from each cell and only keep the percentage. However, in several cells, the n values were inadvertently not removed. Those numbers are highlighted in yellow in the below original Table 9 and have been deleted in the updated Table 9 shown below.

Original Figure 4, page 20 in the submitted Briefing Document

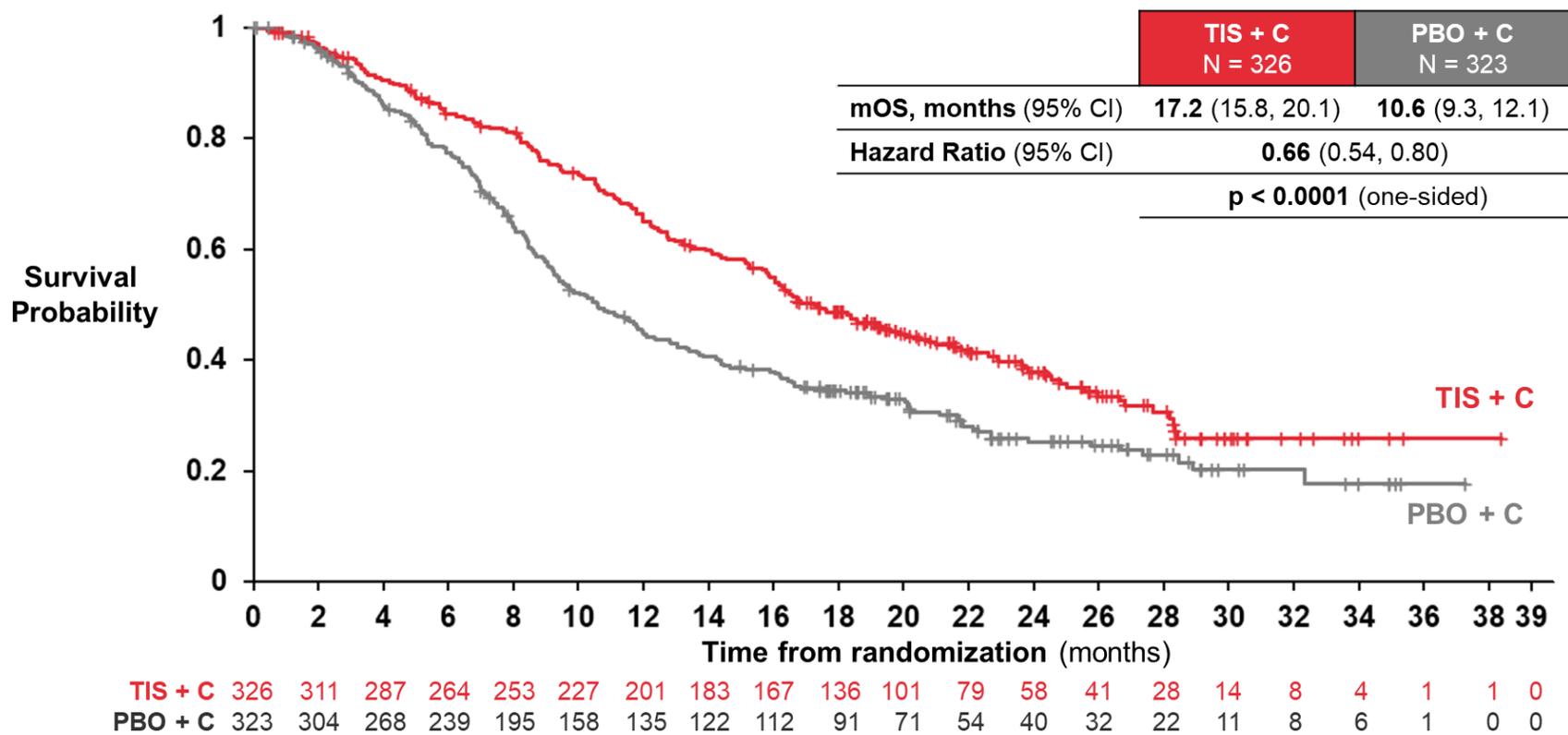
Figure 1: Kaplan-Meier Plot of Overall Survival at the Interim Analysis (ITT Analysis Set)



Data cutoff: 28FEB2022.

Revised Figure 4 with corrections

Figure 2: Kaplan-Meier Plot of Overall Survival at the Interim Analysis (ITT Analysis Set)



Data cutoff: 28FEB2022.

Original Table 9 (in Appendix 1), page 48 in the submitted Briefing Document.

Table 1: Key Demographics and Baseline Characteristics by PD-L1 TAP Expression Cuts and Categories (ITT Analysis Set)

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)
Age Group, ≥ 65 years, %	43.1	48.6	44.4	51.8	41.9	47.3	47.4	57.3	43.3	50.8	47.2	48.0	47.5	60.9	39.3	45.6
Sex, %																
Female	19.0	10.3	9.9	13.1	18.0	12.4	6.3	11.2	15.2	12.4	5.6	8.0	6.8	12.5	16.1	15.2
Male	81.0	89.7	90.1	86.9	82.0	87.6	93.7	88.8	84.8	87.6	94.4	92.0	93.2	87.5	83.9	84.8
ECOG Status, %																
0	31.0	30.8	35.8	36.9	29.1	30.6	42.1	42.7	32.5	35.2	41.7	28.0	42.4	48.4	25.0	30.4
1	80 69.0	74 69.2	97 64.2	106 63.1	122 70.9	129 69.4	55 57.9	51 57.3	156 67.5	162 64.8	21 58.3	18 72.0	34 57.6	33 51.6	42 75.0	55 69.6
Tobacco Consumption, %																
Never	20.7	22.4	19.2	25.0	20.3	24.2	18.9	23.6	19.5	24.0	22.2	24.0	16.9	23.4	19.6	26.6
Former	60.3	53.3	60.3	57.7	60.5	55.4	60.0	57.3	60.2	56.4	61.1	52.0	59.3	59.4	60.7	58.2
Current	15.5	17.8	15.9	15.5	15.7	15.6	15.8	18.0	16.5	16.0	11.1	20.0	18.6	17.2	16.1	12.7
Missing	4 3.4	7 6.5	7 4.6	3 1.8	6 3.5	9 4.8	5 5.3	1 1.1	9 3.9	9 3.6	2 5.6	1 4.0	3 5.1	0 0.0	2 3.6	2 2.5
Region, %																
Asia	74.1	84.1	77.5	73.2	77.3	79.0	73.7	74.2	74.9	76.8	83.3	84.0	67.8	70.3	83.9	72.2
China including Taiwan	56.0	70.1	57.6	56.5	58.1	64.5	54.7	56.2	56.3	60.8	61.1	72.0	50.8	50.0	62.5	57.0
Japan	10.3	6.5	11.3	12.5	9.9	8.6	12.6	13.5	10.4	10.4	13.9	8.0	11.9	15.6	8.9	11.4
Korea	7.8	7.5	8.6	4.2	9.3	5.9	6.3	4.5	8.2	5.6	8.3	4.0	5.1	4.7	12.5	3.8
US/Europe/Australia	25.9	15.9	22.5	26.8	22.7	21.0	26.3	25.8	25.1	23.2	16.7	16.0	32.2	29.7	16.1	27.8
Europe	25.9	15.0	21.2	25.6	22.7	19.9	24.2	24.7	24.2	22.0	16.7	16.0	28.8	28.1	16.1	26.6
Australia	0.0	0.9	1.3	0.6	0.0	1.1	2.1	0.0	0.9	0.8	0.0	0.0	3.4	0.0	0.0	1.3

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)
US	0.0	0.0	0.0	0.6	0.0	0.0	0.0	1.1	0.0	0.4	0.0	0.0	0.0	1.6	0.0	0.0
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	43 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.

Updated Table 9.

Table 2: Key Demographics and Baseline Characteristics by PD-L1 TAP Expression Cuts and Categories (ITT Analysis Set)

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)
Age Group, ≥ 65 years, %	43.1	48.6	44.4	51.8	41.9	47.3	47.4	57.3	43.3	50.8	47.2	48.0	47.5	60.9	39.3	45.6
Sex, %																
Female	19.0	10.3	9.9	13.1	18.0	12.4	6.3	11.2	15.2	12.4	5.6	8.0	6.8	12.5	16.1	15.2
Male	81.0	89.7	90.1	86.9	82.0	87.6	93.7	88.8	84.8	87.6	94.4	92.0	93.2	87.5	83.9	84.8
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1	69.0	69.2	64.2	63.1	70.9	69.4	57.9	57.3	67.5	64.8	58.3	72.0	57.6	51.6	75.0	69.6
Tobacco Consumption, %																
Never	20.7	22.4	19.2	25.0	20.3	24.2	18.9	23.6	19.5	24.0	22.2	24.0	16.9	23.4	19.6	26.6
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Missing	3.4	6.5	4.6	1.8	3.5	4.8	5.3	1.1	3.9	3.6	5.6	4.0	5.1	0.0	3.6	2.5
Region, %																
Asia	74.1	84.1	77.5	73.2	77.3	79.0	73.7	74.2	74.9	76.8	83.3	84.0	67.8	70.3	83.9	72.2
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Australia	0.0	0.9	1.3	0.6	0.0	1.1	2.1	0.0	0.9	0.8	0.0	0.0	3.4	0.0	0.0	1.3
US	0.0	0.0	0.0	0.6	0.0	0.0	0.0	1.1	0.0	0.4	0.0	0.0	0.0	1.6	0.0	0.0

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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
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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.