1   **SUPPLEMENTARY MATERIAL**

2   **Supplementary Table 1. Completion and compliance rates for patient-reported outcome questionnaires among patients with PD-L1 CPS**

3   **≥1**

	QLQ-C30		QLQ-BR23		EQ-5D	
Neoadjuvant Phase	**Pembrolizumab + Chemotherapy** $N = 635$	**Placebo + Chemotherapy** $N = 312$	**Pembrolizumab + Chemotherapy** $N = 632$	**Placebo + Chemotherapy** $N = 311$	**Pembrolizumab + Chemotherapy** $N = 635$	**Placebo + Chemotherapy** $N = 312$
Baseline						
Completion, n (%)[a]	582 (91.7)	298 (95.5)	577 (91.3)	293 (94.2)	587 (92.4)	299 (95.8)
Compliance, n/N (%)[b]	582/635 (91.7)	298/311 (95.8)	577/632 (91.3)	293/310 (94.5)	587/635 (92.4)	299/311 (96.1)
Week 12						
Completion, n (%)[a]	530 (83.5)	266 (85.3)	526 (83.2)	265 (85.2)	538 (84.7)	272 (87.2)
Compliance, n/N (%)[b]	530/588 (90.1)	266/294 (90.5)	526/586 (89.8)	265/293 (90.4)	538/588 (91.5)	272/295 (92.2)
Week 21						
Completion, n (%)[a]	501 (78.9)	251 (80.4)	497 (78.6)	249 (80.1)	502 (79.1)	253 (81.1)
Compliance, n/N (%)[b]	501/569 (88.0)	251/287 (87.5)	497/567 (87.7)	249/286 (87.1)	502/569 (88.2)	253/287 (88.2)

Adjuvant Phase	Pembrolizumab N = 444	Placebo N = 256	Pembrolizumab N = 443	Placebo N = 254	Pembrolizumab N = 445	Placebo N = 258
Baseline						
Completion, n (%)[a]	399 (89.9)	232 (90.6)	397 (89.6)	231 (90.9)	404 (90.8)	234 (90.7)
Compliance, n/N (%)[b]	399/444 (89.9)	232/256 (90.6)	397/443 (89.6)	231/254 (90.9)	404/445 (90.8)	234/258 (90.7)
Week 12						
Completion, n (%)[a]	398 (89.6)	221 (86.3)	396 (89.4)	219 (86.2)	398 (89.4)	226 (87.6)
Compliance, n/N (%)[b]	398/435 (91.5)	221/251 (88.0)	396/434 (91.2)	219/249 (88.0)	398/436 (91.3)	226/253 (89.3)
Week 24						
Completion, n (%)[a]	363 (81.8)	204 (79.7)	361 (81.5)	202 (79.5)	363 (81.6)	204 (79.1)
Compliance, n/N (%)[b]	363/398 (91.2)	204/233 (87.6)	361/397 (90.9)	202/231 (87.4)	363/399 (91.0)	204/235 (86.8)

1 CPS, combined positive score; EQ-5D, EuroQol 5-Dimension Questionnaire; PD-L1, programmed cell death ligand 1; PRO, patient-reported

2 outcome; QLQ-BR23, European Organisation for Research and Treatment of Cancer Breast Cancer–Specific Quality of Life Questionnaire;

3 QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30.

4 [a]Completion rate: number of patients who completed ≥1 score/item over the number of patients in the PRO full analysis set population with PD-

5 L1 CPS ≥1 at each time point.

6 [b]Compliance rate: number of patients who completed ≥1 score/item over the number of patients expected to complete at each time point

7 excluding those missing by design (eg, due to death, discontinuation, translation unavailable etc.).

Supplementary Table 2. LS mean score changes from baseline for each PRO in the neoadjuvant and adjuvant treatment phases among patients with PD-L1 CPS ≥1

PRO Instrument	Neoadjuvant Phase		Adjuvant Phase	
	Pembrolizumab + Chemotherapy	Placebo + Chemotherapy	Pembrolizumab	Placebo
QLQ-C30 GHS/QoL				
Mean (SD) at baseline[a]	77.39 (17.64)	78.41 (17.00)	74.00 (15.70)	72.88 (18.12)
	$N = 582$	$N = 298$	$N = 399$	$N = 232$
Mean (SD) at week 21/24[b]	66.55 (19.28)	67.26 (18.14)	75.60 (16.67)	75.65 (16.26)
	$N = 501$	$N = 251$	$N = 363$	$N = 204$
LS mean (95% CI) change from baseline to week 21/24[a,b]	−11.63 (−13.35 to −9.91)	−10.95 (−13.25 to −8.64)	1.88 (0.31 to 3.46)	2.49 (0.47 to 4.51)
	$N = 635$	$N = 312$	$N = 444$	$N = 256$
Difference in LS means (95% CI)	−0.69 (−3.36 to 1.99)		−0.61 (−3.01 to 1.80)	
QLQ-C30 Physical Functioning				
Mean (SD) at baseline[a]	91.98 (12.61)	91.16 (13.34)	83.24 (15.71)	81.52 (16.03)
	$N = 582$	$N = 298$	$N = 399$	$N = 232$
Mean (SD) at week 21/24[b]	76.61 (19.37)	78.51 (17.19)	84.39 (15.93)	85.26 (14.81)
	$N = 501$	$N = 251$	$N = 363$	$N = 204$

LS mean (95% CI) change from baseline to week 21/24[a,b]	−15.86 (−17.37 to −14.35) $N = 635$	−12.86 (−14.96 to −10.75) $N = 312$	1.43 (0.17 to 2.70) $N = 444$	3.31 (1.67 to 4.95) $N = 256$
Difference in LS means (95% CI)	−3.01 (−5.55 to −0.46)		−1.87 (−3.85 to 0.10)	

QLQ-C30 Emotional Functioning

Mean (SD) at baseline[a]	76.06 (19.52) $N = 582$	74.75 (20.79) $N = 298$	81.73 (18.06) $N = 399$	78.16 (20.64) $N = 232$
Mean (SD) at week 21/24[b]	74.09 (20.92) $N = 501$	74.37 (22.11) $N = 251$	78.88 (20.17) $N = 363$	77.70 (20.18) $N = 204$
LS mean (95% CI) change from baseline to week 21/24[a,b]	−1.74 (−3.44 to −0.03) $N = 635$	−0.67 (−2.99 to 1.65) $N = 312$	−1.94 (−3.67 to −0.21) $N = 444$	−0.94 (−3.19 to 1.32) $N = 256$
Difference in LS means (95% CI)	−1.07 (−3.82 to 1.68)		−1.00 (−3.74 to 1.74)	

QLQ-BR23 Breast Symptoms

Mean (SD) at baseline[a]	18.34 (20.03) $N = 577$	18.29 (18.85) $N = 293$	22.19 (18.97) $N = 397$	23.77 (20.51) $N = 231$
Mean (SD) at week 21/24[b]	9.05 (13.22) $N = 497$	9.04 (14.98) $N = 249$	17.29 (17.55) $N = 361$	17.08 (17.71) $N = 202$
LS mean (95% CI) change from baseline to week 21/24[a,b]	−9.43 (−11.03 to −7.84) $N = 632$	−9.19 (−11.17 to −7.21) $N = 311$	−5.47 (−7.26 to −3.67) $N = 443$	−6.27 (−8.53 to −4.00) $N = 254$
Difference in LS means (95% CI)	−0.24 (−2.28 to 1.79)		0.80 (−1.82 to 3.42)	

EQ-5D VAS				
Mean (SD) at baseline[a]	81.17 (18.17) $N = 587$	82.00 (17.51) $N = 299$	78.29 (14.87) $N = 404$	78.69 (14.56) $N = 234$
Mean (SD) at week 21/24[b]	72.37 (17.97) $N = 502$	74.19 (16.68) $N = 253$	80.90 (14.46) $N = 363$	80.81 (13.29) $N = 204$
LS mean (95% CI) change from baseline to week 21/24[a,b]	−9.26 (−10.93 to −7.59) $N = 635$	−7.71 (−9.90 to −5.52) $N = 312$	2.50 (1.29 to 3.71) $N = 445$	2.15 (0.59 to 3.71) $N = 258$
Difference in LS means (95% CI)	−1.55 (−4.03 to 0.93)		0.35 (−1.52 to 2.21)	

CPS, combined positive score; EQ-5D VAS, EuroQoL 5-Dimension Questionnaire Visual Analog Scale; GHS/QoL, global health status/quality of life; LS, least squares; PD-L1, programmed cell death ligand 1; PRO, patient-reported outcome; QLQ-BR23, European Organisation for Research and Treatment of Cancer Breast Cancer–Specific Quality of Life Questionnaire; QLQ-C30, European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire–Core 30; SD, standard deviation.

[a]Baseline refers to the baseline time point for the respective phase (neoadjuvant or adjuvant).

[b]The analysis time point was week 21 in the neoadjuvant phase and week 24 in the adjuvant phase.

1 **Supplementary Figure 1.** Change from baseline to week 21 in the neoadjuvant phase among

2 patients with PD-L1 CPS ≥1: (A) QLQ-C30 GHS/QoL and functional scales, (B) QLQ-C30

3 symptom scales or items, (C) QLQ-BR23 functional scales or items, and (D) QLQ-BR23

4 symptom scales or items. For GHS/QoL score and all functional scales, a higher score

5 denotes better HRQoL or function. For symptoms scales or items, a higher score denotes
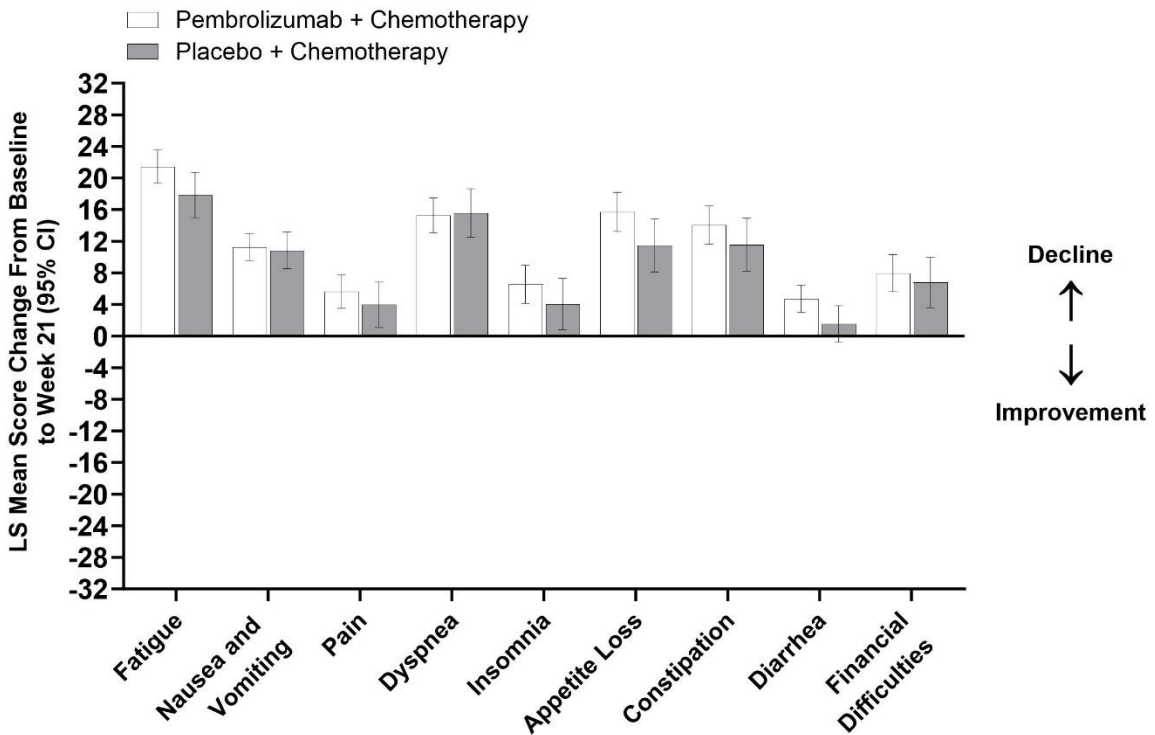
6 worse symptoms.

7 CPS, combined positive score; GHS/QoL, global health status/quality of life; HRQoL, health-

8 related quality of life; LS, least squares; PD-L1, programmed cell death ligand 1; QLQ-

9 BR23, European Organisation for Research and Treatment of Cancer Breast Cancer–Specific

10 Quality of Life Questionnaire; QLQ-C30, European Organisation for Research and Treatment

11 of Cancer Quality of Life Questionnaire–Core 30.

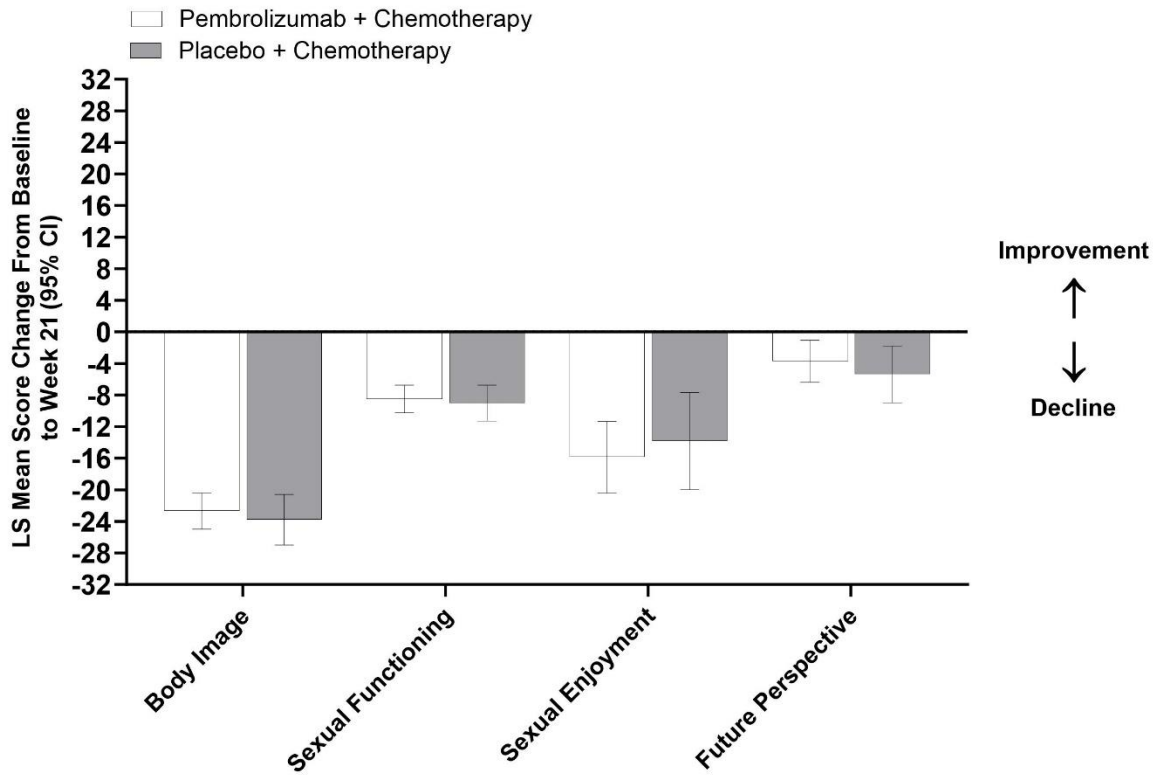1 **A. QLQ-C30 QHS/QoL and functional scales**

2

3 **B. QLQ-C30 symptom scales/items**
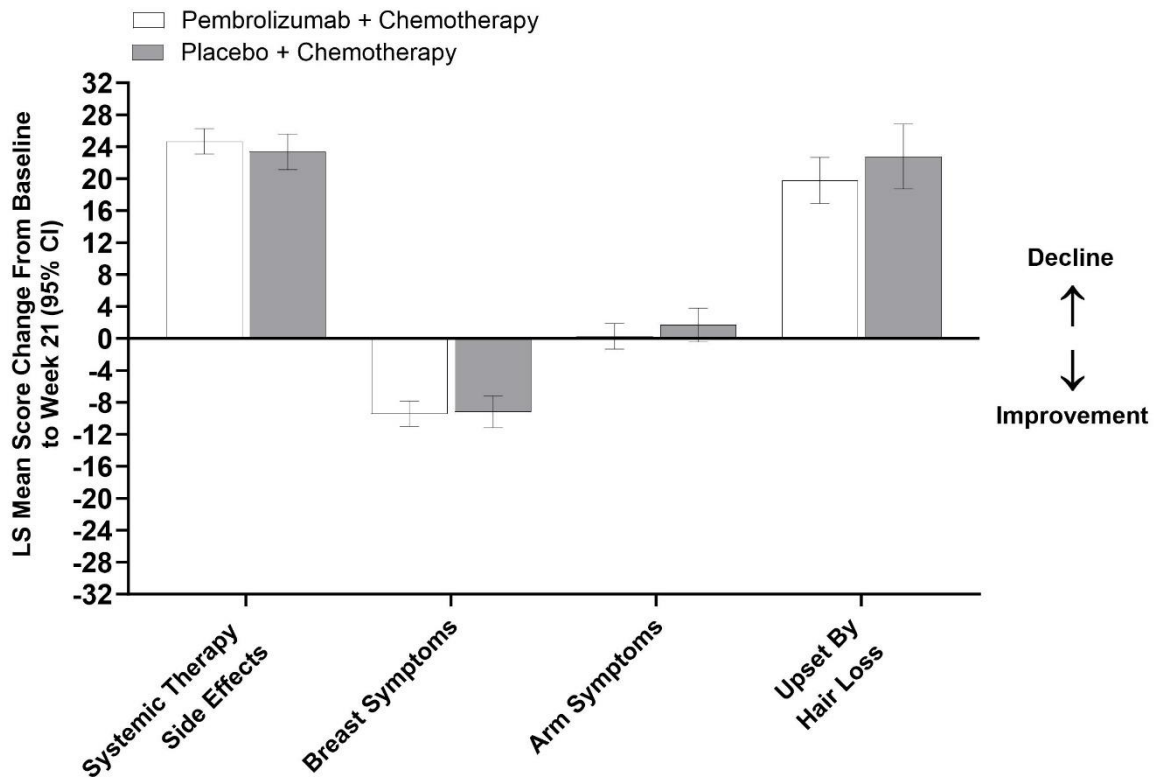

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1   **C. QLQ-BR23 functional scales/items**
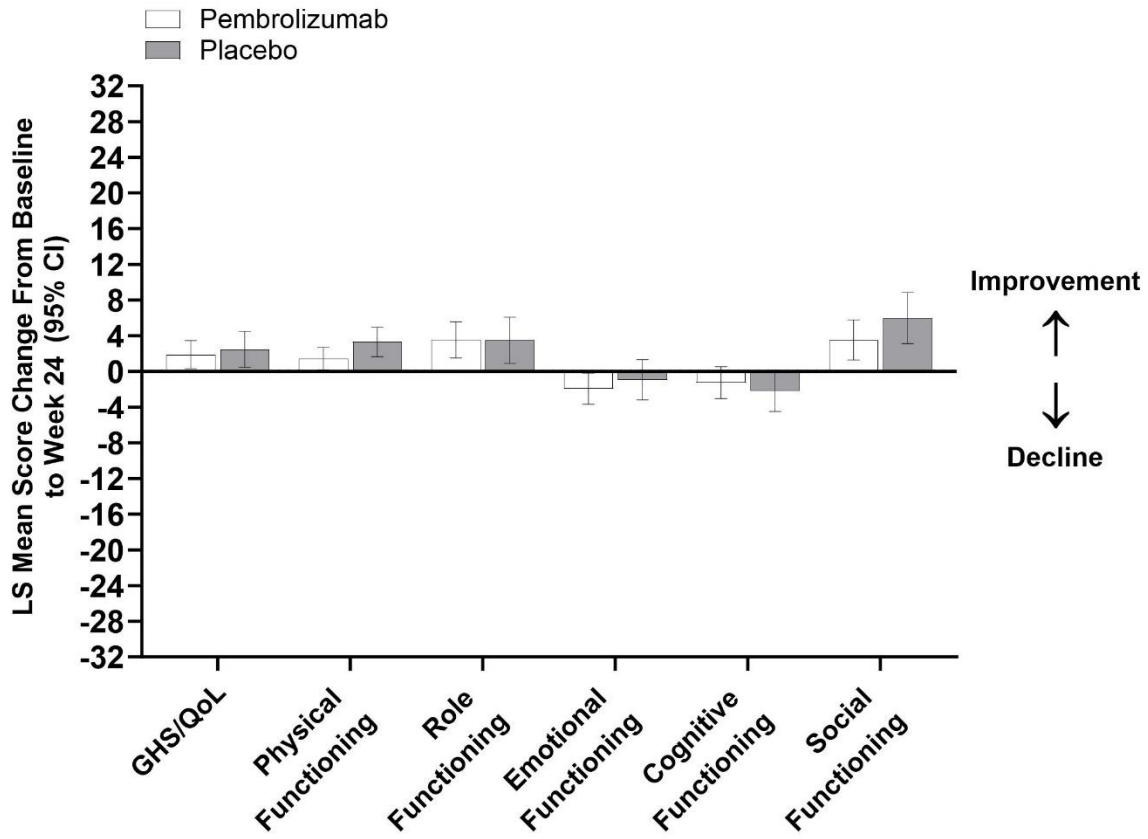

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3   **D. QLQ-BR23 symptom scales/items**

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1   **Supplementary Figure 2.** Change from baseline to week 24 in the adjuvant phase among

2   patients with PD-L1 CPS ≥1: (A) QLQ-C30 GHS/QoL and functional scales, (B) QLQ-C30

3   symptom scales or items, (C) QLQ-BR23 functional scales or items, and (D) QLQ-BR23

4   symptom scales or items. For GHS/QoL score and all functional scales, a higher score

5   denotes better HRQoL or function. For symptoms scales or items, a higher score denotes
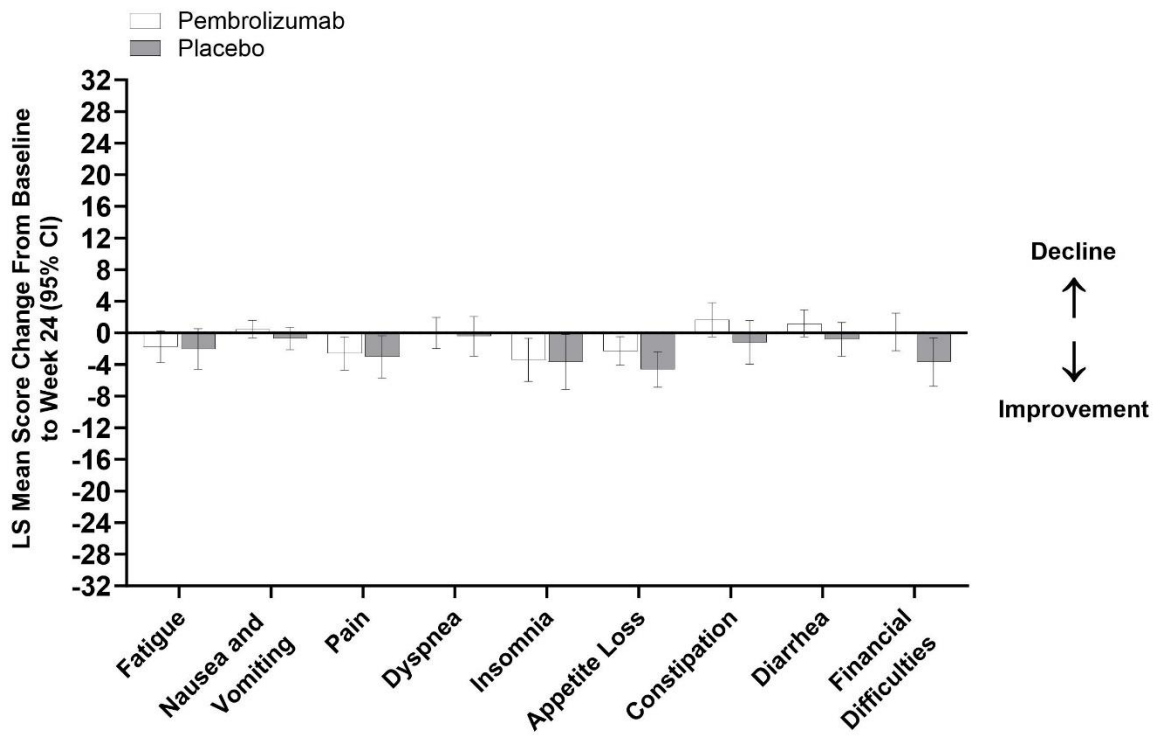
6   worse symptoms.

7   CPS, combined positive score; GHS/QoL, global health status/quality of life; HRQoL, health-

8   related quality of life; LS, least squares; PD-L1, programmed cell death ligand 1; QLQ-

9   BR23, European Organisation for Research and Treatment of Cancer Breast Cancer–Specific

10 Quality of Life Questionnaire; QLQ-C30, European Organisation for Research and Treatment

11 of Cancer Quality of Life Questionnaire–Core 30.

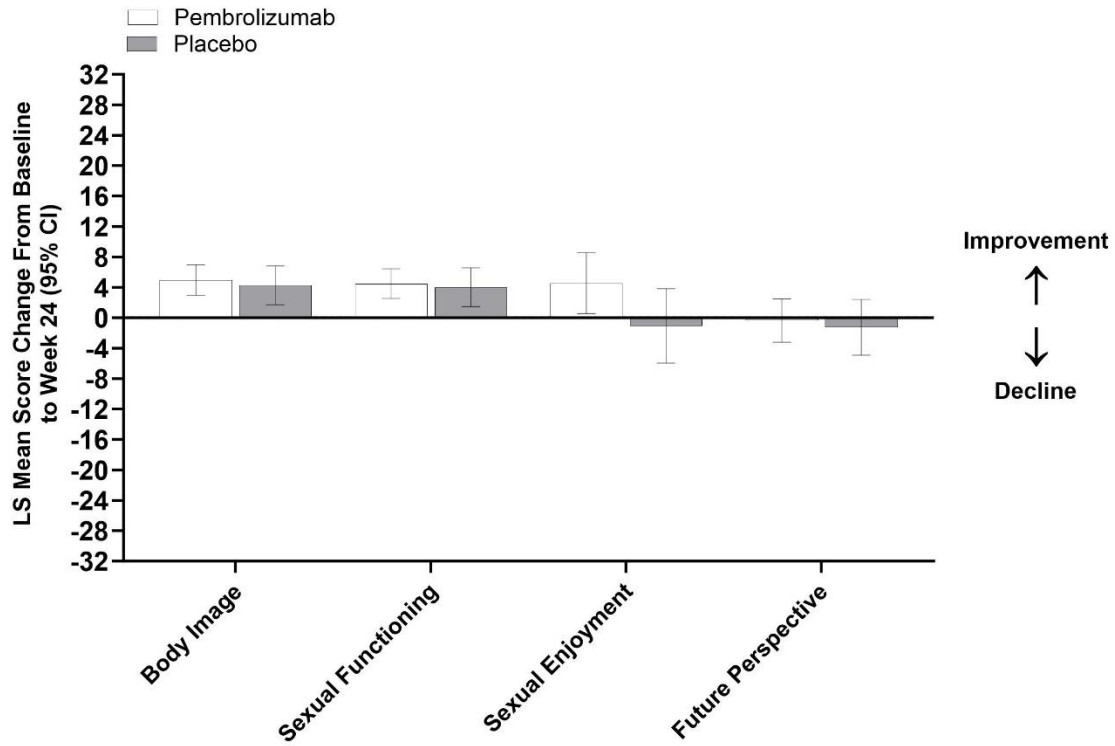1   **A. QLQ-C30 QHS/QoL and functional scales**
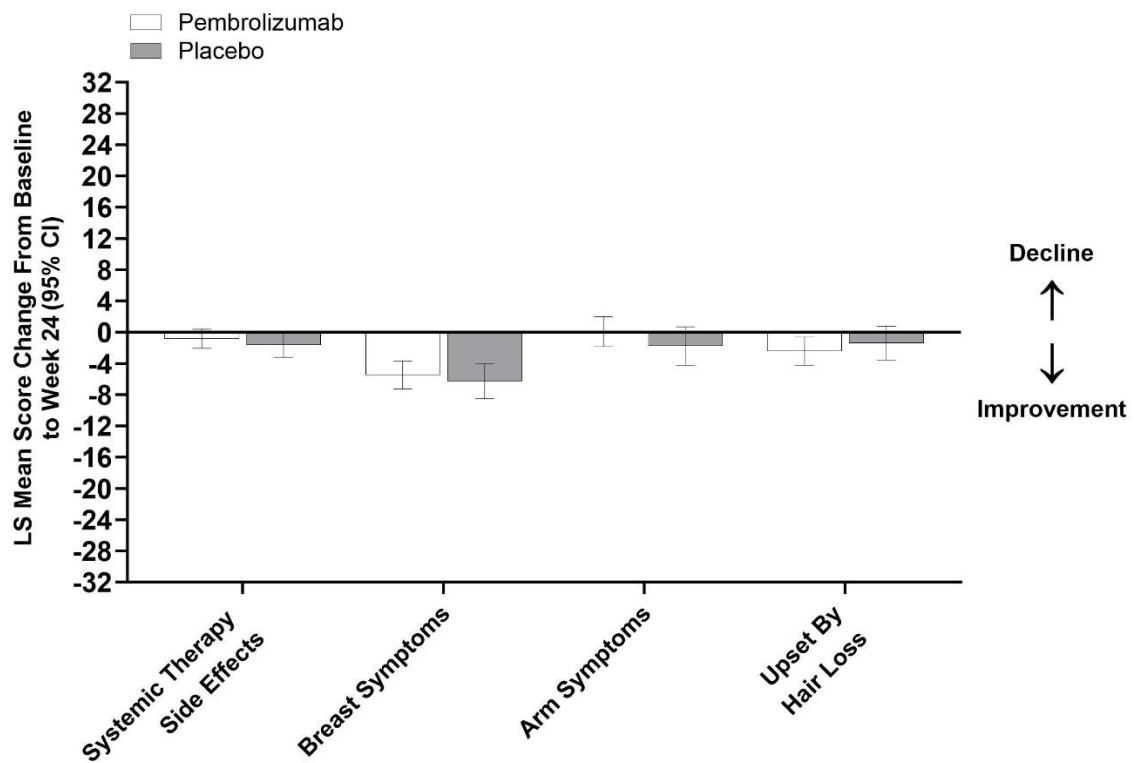

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3   **B. QLQ-C30 symptom scales/items**

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1 **C. QLQ-BR23 functional scales/items**

2

3 **D. QLQ-BR23 symptom scales/items**

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