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Adjuvant nivolumab vs placebo in resected stage IIB/C melanoma: 4-year update from CheckMate 76K

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Background

Patients (pts) with resected stage IIB or IIC melanoma are at high risk of recurrence following surgery. In CheckMate 76K (NCT04099251), treatment with nivolumab (NIVO) demonstrated a statistically significant improvement in recurrence-free survival vs placebo (PBO) in pts with completely resected stage IIB/C melanoma, leading to widespread regulatory approval. Long-term follow-up data are presented here.

Methods

Pts aged ≥ 12 y without evidence of residual disease following resection were stratified by tumor (T) category and randomized 2:1 to receive IV NIVO 480 mg or PBO Q4W for up to 1 y. The primary endpoint was recurrence-free survival (RFS); other endpoints were distant-metastasis free survival (DMFS), safety, and progression-free survival 2 (PFS2).

Results

With a minimum follow-up of 40.2 mo (last pt randomized to cut off) and median follow-ups of 46.8 (NIVO) and 46.4 (PBO) mo (median time from randomization date to death or last alive date), NIVO continued to demonstrate improved RFS and DMFS vs PBO (Table). Of 526 NIVO vs 264 PBO pts, recurrence events occurred in 131 (24.9%) vs 100 (37.9%) pts, respectively, including distant recurrence in 65 (12.4%) vs 52 (19.7%); distant recurrence sites included lung (50 [9.5%] vs 37 [14.0%]), lymph node (23 [4.4%] vs 23 [8.7%]), liver (18 [3.4%] vs 9 [3.4%]), and brain (10 [1.9%] vs 12 [4.5%]). Fewer NIVO pts received subsequent systemic therapy (15.0%) vs PBO (31.4%), and pts receiving adjuvant NIVO had sustained benefit vs PBO beyond first progression (PFS2 medians not yet reached, hazard ratio 0.76 [95% CI, 0.54–1.08]). There were no new safety signals. At this time, overall survival data are still not yet mature. Table: 1610P

	NIVO (n = 526)	PBO (n = 264)
4-y rates, % (95% CI) HR ^a (95% CI)		
RFS	66.1 (61.1–70.6)	55.3 (48.3–61.7)
	0.64 (0.50–0.82)	
DMFS	74.5 (69.7–78.6)	68.8 (62.0–74.6)
	0.73 (0.54–0.98)	

^aNIVO vs PBO (stratified Cox proportional hazards model).

Conclusions

These long-term results at a 4-y follow-up continue to show a positive benefit–risk profile of adjuvant NIVO as a treatment option for pts with resected stage IIB/C melanoma. This long-term benefit confirms NIVO as an effective adjuvant treatment.

Clinical trial identification

NCT04099251.

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Legal entity responsible for the study

Bristol Myers Squibb.

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Disclosure

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