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Abstract 9506

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CheckMate 067: 6.5-year outcomes in patients (pts) with advanced melanoma.

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Background: In the phase 3 CheckMate 067 trial, a durable and sustained clinical benefit was achieved with nivolumab (NIVO) + ipilimumab (IPI) and NIVO alone vs IPI at 5-y of follow-up (overall survival [OS] and progression-free survival [PFS] rates: 52%, 44%, 26% and 36%, 29%, 8%, respectively). Here we report 6.5-y efficacy and safety outcomes.

Methods: Eligible pts with previously untreated unresectable stage III or IV melanoma were randomly assigned in a 1:1:1 ratio and stratified by PD-L1 status, *BRAF* mutation status, and metastasis stage. Pts received NIVO 1 mg/kg + IPI 3 mg/kg for 4 doses Q3W followed by NIVO 3 mg/kg Q2W (n = 314), NIVO 3 mg/kg Q2W + placebo (n = 316), or IPI 3 mg/kg Q3W for 4 doses + placebo (n = 315) until progression or unacceptable toxicity. Co-primary endpoints were PFS and OS with NIVO + IPI or NIVO vs IPI. Secondary endpoints included objective response rate (ORR), descriptive efficacy assessments of NIVO + IPI vs NIVO alone, and safety.

Results: With a minimum follow-up of 6.5 y, median OS was 72.1 mo with NIVO + IPI, 36.9 mo with NIVO, and 19.9 mo with IPI (table). Median time from randomization to subsequent systemic therapy was not reached (NR; 95% CI, 59.6–NR) with NIVO + IPI, 25.2 mo (95% CI, 16.0–43.2) with NIVO, and 8.0 mo (95% CI, 6.5–8.7) with IPI; 36%, 49%, and 66% of pts, respectively, received any subsequent systemic therapy. Median treatment-free interval (which excluded pts who discontinued follow-up prior to initiation of subsequent systemic therapy) was 27.6 mo (range, 0–83.0), 2.3 mo (range, 0.2–81.6), and 1.9 mo (range, 0.1–81.9) with NIVO + IPI, NIVO, and IPI, respectively. Of the pts alive and in follow-up, 112/138 (81%; NIVO + IPI), 84/114 (74%; NIVO), and 27/63 (43%; IPI) were off treatment and never received subsequent systemic therapy; 7, 8, and 0 pts, respectively, were still on treatment. Grade 3/4 treatment-related adverse events were reported in 59% of NIVO + IPI-treated pts, 24% of NIVO-treated pts, and 28% of IPI-treated pts. Since the 5-y analysis, no new safety signals were observed and no additional treatment-related deaths occurred.

	NIVO + IPI (N = 314)	NIVO (N = 316)	IPI (N = 315)
Median OS: all pts, mo (95% CI)	72.1 (38.2–NR)	36.9 (28.2–NR)	19.9 (16.8–24.6)
6.5-y OS rate: all pts, % (95% CI)	49 (44–55)	42 (37–42)	23 (19–28)
***BRAF* mutant**	57 (47–66)	43 (33–53)	25 (17–34)
Median PFS: all pts, mo (95% CI)	11.5 (8.7–19.3)	6.9 (5.1–10.2)	2.9 (2.8–3.2)
6.5-y PFS rate: all pts, % (95% CI)	34 (29–40)	29 (23–34)	7 (4–11)
Investigator-assessed ORR, % (95% CI)	58.3 (52.6–63.8)	44.9 (39.4–50.6)	19.0 (14.9–23.8)
Duration of response, mo (95% CI)	NR (61.9–NR)	NR (45.7–NR)	19.3 (8.8–47.4)

Conclusions: This 6.5-y analysis represents the longest follow-up from a phase 3 melanoma trial in the modern checkpoint inhibitor combination therapy and targeted therapy era. The results show durable improved outcomes with NIVO + IPI and NIVO vs IPI in pts with advanced melanoma. We observed improvement in OS, PFS, and ORR with NIVO + IPI over NIVO alone.

Clinical trial information: NCT01844505.

Abstract Disclosures
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