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Session B. Melanoma and skin cancer

B07 Effect of nivolumab (NIVO) on quality of life (QoL) in patients (pts) with treatment-naïve advanced melanoma (MEL): results of a phase III study (CheckMate 066)

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Background: While treatments exist that extend survival in advanced MEL, the quality of that survival is not often evaluated. There is a need for treatments that demonstrate increased survival while preserving long-term QoL. In a phase III, randomized, double-blind study, NIVO (a PD-1 immune checkpoint inhibitor; 3 mg/kg every 2 weeks [wks; Q2W]) improved overall survival compared with dacarbazine (DTIC; 1,000 mg/m2 Q3W) in treatment-naïve pts with advanced MEL.

Methods: In this study, QoL measured by European Organisation for Research and Treatment of Cancer Quality of Life Questionnaire (EORTC QLQ-C30) and the EuroQol-five dimension questionnaire (EQ-5D) was evaluated at baseline (BL) and at treatment cycles Q6W. Mean changes and non-parametric comparisons are reported. Further analyses are planned to examine longitudinal QoL and the relationship between clinical and pt outcomes.

Results: A total of 418 pts were randomized to NIVO (n = 210) or DTIC (n = 208). Adjusted completion rates at BL for EQ-5D utilities were 69.5% with NIVO and 64.9% with DTIC, and those for EORTC QLQ-C30 were 70.0% with NIVO and 64.9% with DTIC. While rates remained similar throughout the study, analysis of QoL involving DTIC was not feasible after wk 13 due to a high attrition rate in the DTIC arm ($n \leq 41$). Mean BL QoL scores were similar for NIVO versus DTIC (EQ-5D utilities: 0.778 vs 0.711; EQ-5D visual analog scale [VAS] scores: 70.9 vs 69.1; EORTC Global Health: 68.9 vs 66.2). No QoL change was noted for DTIC prior to study dropout. For NIVO, improvements from BL were noted in EQ-5D utilities from wk 7 (0.027; n = 132; P = 0.011) through wk 49 (0.045; n = 38; P = 0.034), and in EQ-5D VAS scores at wks 25, 31, 37, 49 and 61 ($P \leq 0.03$). EORTC subscale scores did not change over time.

Conclusions: These results demonstrate that NIVO does not impair QoL and may enhance it compared with BL, while also conferring survival benefits, in treatment-naïve pts with advanced MEL. Dropout rates in DTIC after wk 13 limited QoL data interpretation for this treatment group.

abstracts

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