

## Session B. Melanoma and skin cancer

**B08** **CheckMate 067: a phase III randomized double-blind study of nivolumab (NIVO) monotherapy or NIVO combined with ipilimumab (IPI) versus IPI monotherapy in previously untreated patients (pts) with advanced melanoma (MEL)**

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**Background:** Results from a phase I study in MEL pts suggested complementary clinical activity between NIVO (a programmed death-1 [PD-1] immune checkpoint

inhibitor) and IPI (a cytotoxic T lymphocyte antigen-4 [CTLA-4] checkpoint inhibitor), and was used to determine the combination dosing for phase III trials. Combination treatment resulted in a higher frequency of pts with tumor volume reduction and unprecedented rates of 1-yr survival (94%) compared with data from other NIVO (73%) or IPI (47%) trials in a similar population. The combination resulted in a safety profile with similar types of adverse events (AEs) as IPI alone, albeit a greater frequency in some cases. This phase III double-blind study evaluates the contribution of monotherapy components to the combination activity and safety, in order to best characterize this regimen in pts with either BRAF wild-type or V600 mutation-positive advanced MEL.

**Methods:** The co-primary endpoints are PFS and OS in the NIVO + IPI combination group or NIVO alone compared with IPI. Secondary objectives include objective response rate (ORR) and PD ligand-1 (PD-L1) expression correlated with efficacy outcomes. Treatment-naïve pts (N = 945) with metastatic or unresectable MEL were randomized 1:1:1 to receive NIVO 3 mg/kg every 2 weeks (Q2W) + IPI placebo (PBO) Q3W, or NIVO 1 mg/kg Q2W combined with IPI 3 mg/kg Q3W for 4 doses followed by NIVO 3 mg/kg Q2W, or IPI 3 mg/kg Q3W + NIVO PBO Q2W for a total of 4 doses followed by NIVO PBO Q2W until progression or unacceptable toxicity. Pts were stratified by PD-L1 status, BRAF status and M Stage. Tumor assessments first occurred at 12 weeks after randomization, Q6W for 49 weeks and Q12W thereafter. The co-primary endpoint of PFS will be reported with a median follow-up greater than 12 months based on a planned data analysis in early March 2015. Additional endpoints will include ORR, duration of response, tumor burden reduction and PD-L1 correlation with efficacy across prospectively defined pt subgroups. Safety will be reported in all treated pts and will include the incidence and resolution of select AEs. Reused with permission from the American Society of Clinical Oncology (ASCO). This abstract was accepted and previously presented at the 2015 ASCO Annual Meeting. All rights reserved.