With a median follow-up of 13.2 (range 0.1-24.0) months, the median number of NIVO+IPI doses per patient was 6 (range 1-17) and the median number of cycles was 3 (range 1-13). Treatment-related safety assessments included frequency and grade of select AEs. The analysis population included all patients who were treated with at least 1 dose of NIVO 1 mg/kg + IPI 1 mg/kg, including 185 patients from CheckMate 069 (n = 93), CheckMate 067 (n = 313), CA209-004 (n = 41; unresectable or metastatic melanoma), and the pooled cohorts from the first 2 cohorts of CheckMate 069 (n = 172) and CheckMate 141 (n = 172), for a total of 641 patients. Safety assessments from the NIVO+IPI combination arm from each of the following trials in patients with unresectable or metastatic melanoma were pooled in this post hoc analysis: CheckMate 067: phase 3 randomized study of NIVO or NIVO+IPI vs IPI in untreated patients (NCT01844505; n = 313); CA209-004: phase 1b open-label dose-escalation study of NIVO+IPI in untreated patients (NCT01024231; n = 41; unresectable or metastatic melanoma). To further describe the safety profile of NIVO+IPI across all melanoma studies using the dose and schedule provided in CheckMate 069 (n = 313), a total of 448 patients were treated with NIVO+IPI, including those who started with IPI alone (n = 24) before dose adjustment to NIVO+IPI based on RECIST 1.1 disease response, and those who did not discontinue to NIVO+IPI arm, as per trial protocol. In the overall study period, 95% of 448 treated patients reported a treatment-related AE of any grade, including 55% with a grade ≥3. Similar to previous findings, colitis was the AE that most frequently led to discontinuation (8% any grade), followed by increased lipase (5%), increased alanine transaminase (4%), and increased aspartate transaminase (3%). Peaks in grade 3/4 AEs were observed at approximately days 50 and 90. Medications used to treat AEs included glucocorticoids, antibiotics, and immunosuppressants. The vast majority of grade 3/4 select AEs were manageable using established algorithms. The nature of treatment-related AEs and AEs leading to discontinuation with NIVO+IPI was typical for an advanced melanoma clinical trial population, with the most common grade 1/2 AEs being rash (38%), vitiligo (12%), and fatigue (12%). Prior to NIVO+IPI, most patients had previously received immuno- and chemotherapy (68% of patients). Three treatment-related deaths in CheckMate 069 due to pneumonitis (n = 1), ventricular arrhythmia (n = 1), and multiorgan failure (n = 1) were reported during the continuation phase. The median time to grade 3/4 treatment-related select AE was 119 days (range 3-840 days) overall and 73 days (range 1-990 days) for grade ≥3 AEs during the continuation phase (≥10% any grade). Table 2. Treatment-related select AEs during overall study period (≥5% any grade, individual term) 4. Conclusions 5. References 6. Acknowledgments

Deaths

- Treatment-related deaths occurring during study entry in 3 patients (4.5%) were deemed related to study drug.
- Three treatment-related deaths in CheckMate 069 did not involve IMM (1 pneumonitis, 1 ventricular arrhythmia, and 1 multiorgan failure).

- The most common grade 1/2 AEs were rash or pruritus, and grade 3/4 AEs were vitiligo, fatigue, and hypothyroidism (≥10% of patients).
- The majority of grade 1/2 cutaneous AEs were manageable using established algorithms.

- Of the 448 patients treated with NIVO+IPI, 427 (96%) had at least 1 grade ≥1 AE.