REAL-WORLD OUTCOMES OF PATIENTS WITH RESECTED STAGE IIIA MELANOMA TREATED WITH ADJUVANT NIVOLUMAB IN A US COMMUNITY SETTING

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Background Nivolumab is approved in the US and EU for the adjuvant treatment of resected stage III-IV melanoma. Limited data is available regarding outcomes of patients with resected stage IIIA melanoma treated with adjuvant nivolumab. This observational study is an update to the prior study evaluating treatment patterns, outcomes, safety, and healthcare resource utilization in a US community oncology setting in resected stage IIIA patients who received adjuvant nivolumab.

Methods A follow-up to the previous study analysis was conducted by including an additional 15 months of follow-up data and newly matriculated patients. Data were sourced from The US Oncology Network chart review data examining patients with resected stage IIIA melanoma, treated with adjuvant nivolumab between 01-Jan-2018 and 31-Dec-2020, and followed until 30-June-2021. Patients were followed up to 42 months after their sentinel lymph node biopsy. Baseline demographic and clinical characteristics, treatment-related adverse events (TRAEs) and healthcare resource utilization were analyzed descriptively. Overall survival (OS), time to treatment discontinuation (TTD), and recurrence-free survival (RFS) were analyzed using the Kaplan-Meier method.

Results 40 stage IIIA melanoma patients treated with adjuvant nivolumab were included. The median age was 55 years (range 19,90+), 52.5% were male, and 77.5% were Caucasian. Among patients with a documented Eastern Cooperative Oncology Group (ECOG) performance status half had an ECOG score of 0 or 1. Median follow-up time was 27.7 months (range 2.8-39.0). Overall survival was not reached as no deaths occurred during the study period. The median TTD and RFS were also not reached. TRAEs were reported in 23 patients. Among all 40 patients, the most frequent TRAEs were rash (12.5%), hypothyroidism (12.5%), fatigue (10.0%), diarrhea (10.0%), and nausea (10.0%); the treatment-related hospitalization rate was 2.5%.

Conclusions This real-world analysis of patients with stage IIIA melanoma treated with adjuvant nivolumab demonstrated that the vast majority of patients were recurrence free and all patients were alive at the end of the study period, suggesting a favorable prognosis and low rates of healthcare resource utilization. Additional follow-up and investigations with other real-world data sources are warranted to substantiate the clinically relevant outcomes reported in this study of patients with resected stage IIIA melanoma.

Ethics Approval The study was approved by US Oncology, Inc. Institutional Review Board, approval number 20-020E-2020-0224-01.