MELANOMA AND MELANOCYTIC NAEVI

PHASE 3 KEYNOTE-716 STUDY: ADJUVANT THERAPY WITH PEMBROLIZUMAB VERSUS PLACEBO IN RESECTED HIGH-RISK STAGE II MELANOMA

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Introduction: Adjuvant pembrolizumab showed significantly longer recurrence-free survival (RFS) versus placebo in resected stage III melanoma in KEYNOTE-054. Phase 3 KEYNOTE-716 (NCT03553836) was designed to assess adjuvant pembrolizumab in surgically resected high-risk stage II melanoma.

Objective: To compare RFS between pembrolizumab and placebo arms.

Materials and Methods: Patients ≥12 years of age with newly diagnosed, completely resected stage IIB/IIC cutaneous melanoma were included. Patients with mucosal or uveal melanoma or who had previously received treatment for melanoma beyond resection of

primary disease within 12 weeks of study therapy start were not eligible. In part 1 (double-blind), patients will be randomly assigned 1:1 to receive pembrolizumab 200 mg for patients ≥18 years or 2 mg/kg for patients 12-17 years (maximum dose, 200 mg) or placebo every 3 weeks for 17 cycles. There will be 1 stratum for pediatric patients and 3 strata for adult patients per T stage (T3b/T4a/T4b). Study treatment will begin within 12 weeks of complete resection. Tumor imaging will occur every 24 weeks during treatment, at end of treatment, every 6 months for the first 3 years off treatment, then yearly for ≤2 years or until recurrence (≤5 years total). Adverse events will be graded per NCI Common Terminology Criteria for Adverse Events, version 4.0. In part 2 (unblinded), patients with confirmed recurrence can be rechallenged (part 1 pembrolizumab patients) or can cross over to pembrolizumab (part 1 placebo patients). Resected local/distant recurrence or unresectable disease will receive additional treatment for 17 or 35 cycles, respectively. Part 2 tumor imaging will occur every 12 weeks during treatment. The primary endpoint is RFS; secondary endpoints are distant metastasis-free survival, overall survival, and safety. The trial will be reviewed/approved by institutional review boards and independent ethics committees at each site. Approximately 954 patients will be enrolled.

Results: N/A

Conclusions: N/A