MK-3475-U02: PHASE 1/2 STUDY OF INVESTIGATIONAL AGENTS WITH OR WITHOUT PEMBROLIZUMAB VERSUS PEMBROLIZUMAB MONOTHERAPY IN MELANOMA

Abstracts

Methods MK-3475-U02 is a phase 1/2, rolling arm, multicenter, open-label, adaptive design study to evaluate the safety and efficacy of investigational agents with or without pembrolizumab or pembrolizumab alone for the treatment of melanoma. Patients will be enrolled in 1 of the 3 substudies. Substudy 02A will include patients with programmed death-1 (PD-1)–refractory melanoma (progressed after ≥2 doses of anti-PD-1 programmed death ligand-1 [PD-L1] therapy) randomized equally to treatment arms evaluating ≥1 investigational agent(s) with or without pembrolizumab. Enrollment is planned for up to ~100 patients per arm. Substudy 02B will include patients with unresectable stage III or stage IV melanoma not amenable to local therapy. Patients will be randomized 2:1 to combination (≥1 investigational agent(s) with or without pembrolizumab) or monotherapy (pembrolizumab alone) stratified by baseline lactate dehydrogenase status (normal/elevated) and prior adjuvant therapy with a PD-1 inhibitor (yes/no). Enrollment is planned for ~90 patients in the combination arm and ~45 in the control arm. Substudy 02C will include patients with stage IIIIB/IIIC/IIID melanoma who are candidates for neoadjuvant therapy. Patients will be randomly assigned to combination (≥1 investigational agent(s) with or without pembrolizumab) or monotherapy (pembrolizumab alone). Surgical resection will be performed 6 weeks after the first dose of neoadjuvant study intervention. Enrollment is planned for ~25 patients in combination and ~15 in the pembrolizumab monotherapy arms. Treatment will continue for up to 2 years (up to 1 year neoadjuvant/adjuvant therapy for substudy 02C), until disease progression, unacceptable toxicity, or study discontinuation. The primary end points include safety (adverse events and study intervention discontinuations) for all 3 substudies; objective response rate by blinded independent central review per Response Evaluation Criteria in Solid Tumors 1.1 for substudies 02A and 02B, and pathologic complete response (pCR) as assessed by central review of the pathology results for substudy 02C. Secondary end points include duration of response for substudies 02A and 02B, and recurrence-free survival, near pCR, and pathologic partial response rates for substudy 02C.

Results N/A

Conclusions N/A

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Ethics Approval The study protocol and all amendments were approved by the relevant Institutional Review Board or ethics committee at each study site. All patients provided written informed consent to participate in the clinical trial.

Consent N/A

REFERENCE

N/A

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