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Phase I safety study of lenalidomide and dacarbazine in patients with metastatic melanoma previously untreated with systemic chemotherapy.

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Abstract

This phase I trial assessed the maximal tolerated dose (MTD) of dacarbazine in combination with lenalidomide in metastatic melanoma. Cohorts of three to six patients with metastatic melanoma without brain metastases were enrolled at each of three dose levels of dacarbazine: 600 mg/m, 800 mg/m, and 1000 mg/m administered intravenously every 3 weeks. Lenalidomide (25 mg/day) was administered orally for 14 days followed by a 7-day rest. Safety was assessed every 3 weeks, and tumor response was evaluated every 6 weeks. An additional 10 patients were enrolled in an expansion cohort at MTD level. Twenty-eight chemotherapy-naive patients were enrolled. The MTD was determined to be dose level 2 (800 mg/m). Three patients experienced a grade 4 adverse reaction; two pulmonary emboli and one cerebral ischemia. Two patients had a deep venous thrombosis. Of 27 patients assessable for disease response, two experienced a complete response and four experienced a partial response. The median overall survival was 10.6 months (range 1.6-46.0+ months). One patient had a small brain lesion at the baseline; 10 additional patients developed brain metastasis at 0-10.8 months after completion of study therapy. The combination of dacarbazine and lenalidomide is safe and well tolerated in patients with metastatic melanoma. Clinical activity was seen at the MTD level. Additional measures to prevent brain metastasis are needed for patients who achieve a response.

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