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Preliminary Results of a Phase II Study of CC-5013 (Lenalidomide, Revlimid®) in Patients with Cutaneous T-Cell Lymphoma.

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Blood 2005 106:3351;

Abstract

Background: Mycosis fungoides (MF)/Sézary syndrome (SS) represent the most common type of cutaneous T-cell lymphoma (CTCL) comprising 50% of cutaneous lymphomas. No treatment cures patients with CTCL and patients ultimately develop advanced or relapsed disease that is refractory to standard treatment options. The direct antitumor effects associated with potent anti-angiogenic, anti-inflammatory and T-cell co-stimulatory activity and favorable toxicity profile of lenalidomide provided the rationale to use this agent in patients with MF/SS. Preliminary results of this ongoing phase II trial indicate encouraging early signs, responses and manageable toxicity.

Methods: The study is designed to accrue 29 evaluable patients. Nine patients have been enrolled between April and August 2005. Eight patients are evaluable for response and toxicity. Lenalidomide was administered orally on an outpatient basis. Patients received 25 mg daily for 21 days with 7 days rest of a 28-day cycle. Patients with stable disease and partial response will continue treatment with a maximum of 2 years if tolerated or unless unforeseen toxicities occur. Response was assessed after every cycle using Composite Assessment (CA) of Index Lesion Disease Severity for skin lesions, absolute Sézary cell count for quantification of circulating malignant lymphocytes and/or CT scans for evidence of adenopathy or visceral disease.

Results: The median patient age was 60 years (range, 47-69) and patients had received a median of 6 prior treatment regimens (range, 2-9). Preliminary results indicate that a total of 3 patients (38%) have already experienced an objective response (defined as a CA ratio less than or equal to 0.5 with no new clinically abnormal lymph nodes, no progression of existing clinically abnormal lymph nodes, and no new cutaneous tumors) after 1 to 3 cycles of therapy. Four patients have achieved a minor response such as regression of cutaneous tumor lesions and cervical lymphadenopathy in one patient each, and skin improvement from initial generalized erythroderma to less severe erythema with less scaling and remain on therapy. The most common side effects were fatigue (4 patients-grade I) and lower leg edema (3 patients-grade II). GI symptoms (grade I) and anemia (grade II) was noted in one patient each. One patient discontinued treatment after one cycle because of neurological symptoms (slurred speech) possibly related to the study drug and one patient for progressive disease after 3 cycles following a minor response.

Conclusions: In our study lenalidomide has shown encouraging activity in heavily pretreated patients with advanced MF/SS and a mild toxicity profile. Accrual is ongoing. Revlimid® is a registered trademark of Celgene Corporation.

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