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**Clinical Investigation**

**A Pilot Safety Study of Lenalidomide and Radiotherapy for Patients with Newly Diagnosed Glioblastoma Multiforme**

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Received 25 January 2008; revised 22 March 2008; accepted 23 March 2008. Available online 29 May 2008.

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To define the maximum tolerated dose (MTD) of lenalidomide, an analogue of thalidomide with enhanced immunomodulatory and antiangiogenic properties and a more favorable toxicity profile, in patients with newly diagnosed glioblastoma multiforme (GBM) when given concurrently with radiotherapy.

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## Patients and Methods

Patients with newly diagnosed GBM received radiotherapy concurrently with lenalidomide given for 3 weeks followed by a 1-week rest period and continued lenalidomide until tumor progression or unacceptable toxicity. Dose escalation occurred in groups of 6. Determination of the MTD was based on toxicities during the first 12 weeks of therapy. The primary endpoint was toxicity.

## Results

Twenty-three patients were enrolled, of whom 20 were treated and evaluable for both toxicity and tumor response and 2 were evaluable for toxicity only. Common toxicities included venous thromboembolic disease, fatigue, and nausea. Dose-limiting toxicities were eosinophilic pneumonitis and transaminase elevations. The MTD for lenalidomide was determined to be 15 mg/m<sup>2</sup>/d.

## Conclusion

The recommended dose for lenalidomide with radiotherapy is 15 mg/m<sup>2</sup>/d for 3 weeks followed by a 1-week rest period. Venous thromboembolic complications occurred in 4 patients, and prophylactic anticoagulation should be considered.

**Author Keywords:** Lenalidomide; Glioblastoma; Angiogenesis; Radiotherapy; Immunomodulatory

## Article Outline

### Introduction

### Patients and Methods

- Patients
- Pretreatment evaluation
- Treatment and follow-up studies
- Study design
- Assessment of efficacy
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