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Phase II Pilot Study of Bevacizumab in Combination With Temozolomide and Regional Radiation Therapy for Up-Front Treatment of Patients With Newly Diagnosed Glioblastoma Multiforme: Interim Analysis of Safety and Tolerability

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Received 4 October 2007; received in revised form 29 November 2007; accepted 30 November 2007. published online 20 March 2008.
Corrected Proof

Purpose

To assess interim safety and tolerability of a 10-patient, Phase II pilot study using bevacizumab (BV) in combination with temozolomide (TMZ) and regional radiation therapy (RT) in the up-front treatment of patients with newly diagnosed glioblastoma.

Methods and Materials

All patients received standard external beam regional RT of 60.0 Gy in 30 fractions started within 3 to 5 weeks after surgery. Concurrently TMZ was given daily at 75 mg/m² for 42 days during RT, and BV was given every 2 weeks at 10 mg/kg starting with the first day of RT/TMZ. After a 2-week interval upon completion of RT, the post-RT phase commenced with resumption of TMZ at 150 to 200 mg/m² for 5 days every 4 weeks and continuation of BV every 2 weeks.

Results

For these 10 patients, toxicities were compiled until study discontinuation or up to ~40 weeks from initial study treatment for those remaining on-study. In terms of serious immediate or delayed neurotoxicity, 1 patient developed presumed radiation-induced optic neuropathy. Among the toxicities that could be potentially treatment related, relatively high incidences of fatigue, myelotoxicity, wound breakdown, and deep venous thrombosis/pulmonary embolism were observed.

Conclusion

The observed toxicities were acceptable to continue enrollment toward the overall target group of 70 patients. Preliminary efficacy analysis shows encouraging mean progression-free survival. At this time data are not sufficient to encourage routine off-label use of BV combined with TMZ/RT in the setting of newly diagnosed glioblastoma without longer follow-up, enrollment of additional patients, and thorough efficacy assessment.

[Bevacizumab](#), [Newly diagnosed glioblastoma](#), [Temozolomide](#), [Radiation](#), [Antiangiogenesis](#)

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Conflict of interest: Drs. Lai and Dr. Cloughesy have served on the Scientific Advisory Board of Genentech.

PII: S0360-3016(07)04746-3

doi:10.1016/j.ijrobp.2007.11.068

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