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Safety and efficacy of erlotinib in first-relapse glioblastoma: a phase II open-label study.

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Abstract

Erlotinib, an epidermal growth factor receptor (EGFR) tyrosine kinase inhibitor, is active in glioblastoma. We evaluated erlotinib efficacy in patients with first-relapse glioblastoma and assessed whether response was related to EGFR amplification and/or concomitant use of enzyme-inducing antiepileptic drugs (EIAEDs) in a phase II open-label study of glioblastoma patients in first relapse. Patients took erlotinib daily until progression. Starting dose was 150 mg for patients not taking EIAEDs and 300 mg for patients taking EIAEDs. Tumors were radiographically assessed every 8 weeks. Response was evaluated by investigators and confirmed by an independent radiology facility (IRF). The primary efficacy outcome was the objective response (OR) rate, according to the modified WHO criteria. Enrollment (n = 48) was terminated after a planned interim analysis due to an insufficient number of responses. The IRF confirmed 1 complete and 2 partial responses (PRs), for an OR rate of 6.3% (95% confidence interval [CI]: 1.7-17.0). Investigators determined 1 complete response and 3 PRs, median response duration of 7.0 months, 6-month progression-free survival (PFS) of 20% (95% CI: 10.0-32.4), and median survival of 9.7 months (95% CI: 5.9-11.6). Outcomes were not related to EGFR amplification or EIAED status. Diarrhea and rash were the most common adverse events (AEs); 23% of patients experienced grade 3-4 drug-related AEs. Despite the limited number of responses, 6-month PFS and median survival reached or exceeded the previously reported values for patients undergoing chemotherapy for recurrent glioblastoma. EGFR amplification was not associated with erlotinib activity. Given the large CIs and nonrandomized nature of the study, results should be interpreted cautiously.

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