

## Journal Article




## Phase II study of carboplatin and erlotinib (Tarceva, OSI-774) in patients with recurrent glioblastoma

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**Abstract** Targeting the epidermal growth factor receptor (EGFR) may be effective in a subset of glioblastoma patients. This phase II study assessed the clinical activity of erlotinib plus carboplatin and to determine molecular predictors of response. The primary endpoint was progression free survival (PFS). Patients with recurrent glioblastoma with no more than two prior relapses received carboplatin intravenously on day 1 of every 28-day cycle (target AUC of 6 mg × ml/min). Daily erlotinib at 150 mg/day was dose escalated to 200 mg/day, as tolerated. Clinical and MRI assessments were made every 4 and 8 weeks, respectively. Tumor tissue was evaluated for EGFR, AKT and phosphatase and tensin homolog (PTEN) status. One partial response (PR) was observed out of 43 assessable patients. Twenty patients (47%) had stable disease (SD) for an average of 12 weeks. Median PFS was 9 weeks. The 6-month PFS rate was 14%. Median overall survival (OS) was 30 weeks. This regimen was well tolerated with grade 3/4 toxicities of fatigue, leukopenia, thrombocytopenia and rash requiring dose reductions. A recursive partitioning analysis (RPA) predicted that patients with KPS ≥90 treated with more than 1 prior regimen had the highest OS. No correlation was observed between EGFR, Akt or PTEN expression and either PFS or OS. Carboplatin plus erlotinib is well tolerated but has modest activity in unselected patients. Future trials should be stratified based on optimal molecular or clinical characteristics.

**Keywords** EGFR - PTEN - Erlotinib - Carboplatin - Glioblastoma

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