Phase 2 study of temozolomide and Caelyx in patients with recurrent glioblastoma multiforme

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< previous article | next article > View Table of Contents

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Abstract:

Temozolomide has established activity in the treatment of recurrent glioblastoma multiforme (GBM). Caelyx (liposomal doxorubicin) has established activity in a broad range of tumors but has not been extensively evaluated in the treatment of GBM. Phase 1 data suggest that temozolomide and Caelyx can be combined safely at full dose. In this phase 2 study, combination temozolomide (200 mg/m^2 orally, days 1-5) and Caelyx (40 mg/m^2 i.v., day 1) was given every 4 weeks to a cohort of 22 patients with recurrent GBM, who received a total of 109 cycles (median 3.5 cycles). The median age of the patients was 55 years (range, 31-80 years), and 17 were male. All patients had received radiotherapy, but only 2 had received prior chemotherapy. One patient (5%) had a complete response, 3 patients (14%) had a partial response, and 11 patients (50%) had stable disease. The median time to progression for the cohort was 3.2 months (range, 1-13 months). Median overall survival was 8.2 months (range, 1-16+ months). Seven patients (32%) were progression free at 6 months. Hematological toxicity included grade 3/4 neutropenia in 4 patients (18%) and grade 3/4 thrombocytopenia in 4 patients (18%). Grade 3 non-hematologic toxicity included rash in 3 patients (14%), nausea and vomiting in 1 patient (4%), hypersensitivity reaction to Caelyx in 3 patients (14%), and palmar-plantar toxicity in 1 patient (4%). We conclude that the combination of temozolomide and Caelyx is well tolerated, results in a modest objective response rate, but has encouraging disease stabilization in the treatment of recurrent GBM.

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< previous article | next article > View Table of Contents