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## Survival of Patients With Newly Diagnosed Glioblastoma Multiforme Treated With RSR13 and Radiotherapy: Results of a Phase II New Approaches to Brain Tumor Therapy CNS Consortium Safety and Efficacy Study

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**PURPOSE:** The objectives of this phase II study were to determine survival, safety, pharmacokinetics (PK), and pharmacodynamics (PD) of 2,4-[[[(3,5-dimethylanilino)carbonyl]methyl]phenoxy]-2-methylpropionic acid (RSR13, efaproxiral) 100 mg/kg per day administered with standard cranial radiotherapy (RT) for the treatment of glioblastoma multiforme (GBM). RSR13, a synthetic allosteric modifier of hemoglobin, is a radiation-enhancing agent that noncovalently binds to hemoglobin, reduces oxygen-binding affinity, and increases oxygen unloading to hypoxic tissue.

**PATIENTS AND METHODS:** Fifty patients with newly diagnosed GBM (Karnofsky performance status  $\geq$  60) were enrolled onto this multicenter phase II study. Patients received daily RSR13 100 mg/kg intravenously infused for 30 minutes immediately before cranial RT (60 Gy in 30 fractions). Supplemental oxygen was given during RSR13 infusion and continued until after the RT treatment was completed. RT was given within 30 minutes of the end of RSR13 infusion. PK and PD determinations were performed.

**RESULTS:** The median survival for the RSR13-treated patients was 12.3 months with 1-year and 18-month survival rates of 54% and 24%, respectively. Twenty-four percent of patients had greater than grade 2 toxicity, which was generally transient and self-limited. A significant PD effect on hemoglobin-oxygen binding affinity was demonstrated for most patients.

**CONCLUSION:** RSR13 (100 mg/kg) administered immediately before cranial RT is well tolerated and is pharmacodynamically active. Median survival in excess of 1 year is favorable.

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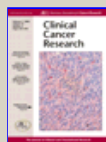
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N. Crockart, B. F. Jordan, C. Baudelet, G. O. Cron, J. Hotton, K. Radermacher, V. Gregoire, N. Beghein, P. Martinive, C. Bouzin, *et al.*  
**Glucocorticoids Modulate Tumor Radiation Response through a Decrease in Tumor Oxygen Consumption**  
 Clin. Cancer Res., January 15, 2007; 13(2): 630 - 635.  
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 L. M. Cher, C. Murone, N. Lawrentschuk, S. Ramdave, A. Papenfuss, A. Hannah, G. J. O'Keefe, J. I. Sachinidis, S. U. Berlangieri, G. Fabinyi, *et al.*  
**Correlation of Hypoxic Cell Fraction and Angiogenesis with Glucose Metabolic Rate in Gliomas Using 18F-Fluoromisonidazole, 18F-FDG PET, and Immunohistochemical Studies**  
 J. Nucl. Med., March 1, 2006; 47(3): 410 - 418.  
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 C. J. Langer and M. P. Mehta  
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 S. M. Evans, K. D. Judy, I. Dunphy, W. T. Jenkins, P. T. Nelson, R. Collins, E. P. Wileyto, K. Jenkins, S. M. Hahn, C. W. Stevens, *et al.*  
**Comparative Measurements of Hypoxia in Human Brain Tumors Using Needle Electrodes and EF5 Binding**  
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