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Meeting: 2004 ASCO Annual Meeting
Category: Central Nervous System Tumors

**SubCategory: CNS Tumors** 



Phase I/II trial of a twice-daily regimen of temozolomide and celecoxib for treatment of relapsed/refractory glioblastoma multiforme and anaplastic astrocytoma.

Abstract No: 1549

Citation: Journal of Clinical Oncology, 2004 ASCO Annual Meeting Proceedings

(Post-Meeting Edition). Vol 22, No 14S (July 15 Supplement), 2004:

1549

Author(s): S. Pannullo, S. Hariharan, J. Serventi, R. Hayes, C. Balmaceda, J. Burton;

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Abstract: **Background:** Combination therapy using agents with different

mechanisms of action and non-overlapping toxicity may be a safe and effective strategy in cancer therapy. As seen in Phase I of this trial, BID temozolomide [Temodar (TMZ)] in combination with celecoxib (Celebrex) is a safe treatment regimen for malignant glioma. Phase II of this clinical trial tests the hypothesis that celecoxib combined with a BID schedule of TMZ is a more effective therapy for recurrent/progressive malignant glioma. **Methods:** Patients received a loading dose of 200 mg/m2 of TMZ followed by 9 doses of 90 mg/m2 TMZ BID for 5 days of every 28 day cycle. Celecoxib was given to a maximum dose of 480 mg/m2 for 10 days. The regimen was well-tolerated by most patients. Hematologic toxicity was mild and did not recur following TMZ dose reduction. **Results:** 36 patients (22 M, 14 F) received 141 cycles of therapy. Interim responses were evaluated after 2 cycles. In the 29 patients evaluable for response, 5/29 (17%) had a partial response (PR), 21/29 (72.5%) had stable disease (SD), and 3/29 (10.5%) had progressive

disease, resulting in an overall response rate of 90% at 2 months. One patient had a CR after 7 cycles. One patient had a PR for 13 cycles but developed spinal cord tumor. Average duration of response was 5.2 months (range, 2-13). The 6-month PFS for 23 evaluable patients was 8/23(35%) and 6-month overall survival rate of 19/23(83%).

**Conclusions:** A regimen of twice-daily TMZ and celecoxib is a safe and potentially effective regimen for the treatment of recurrent high-grade

glioma.

#### **Associated Presentation(s):**

1. Phase I/II trial of a twice-daily regimen of temozolomide and celecoxib for treatment of relapsed/refractory glioblastoma multiforme and anaplastic astrocytoma.

Event: 2004 ASCO Annual Meeting

Presenter: S. Pannullo

Session: Central Nervous System Tumors



#### Other Abstracts in this Sub-Category:

1. Concomitant and adjuvant temozolomide (TMZ) and radiotherapy (RT) for newly diagnosed glioblastoma multiforme (GBM). Conclusive results of a

# randomized phase III trial by the EORTC Brain & RT Groups and NCIC Clinical Trials Group.

Meeting: 2004 ASCO Annual Meeting Abstract No: 2 First Author: R. Stupp

2. An intergroup randomized controlled clinical trial (RCT) of chemotherapy plus radiation (RT) versus RT alone for pure and mixed anaplastic oligodendrogliomas: Initial report of RTOG 94-02.

Meeting: 2004 ASCO Annual Meeting Abstract No: 1500 First Author: G. Cairncross

3. Multicentre phase II study of imatinib mesylate in patients with recurrent glioblastoma: An EORTC: NDDG/BTG Intergroup Study.

Meeting: 2004 ASCO Annual Meeting Abstract No: 1501 First Author: E. Raymond

4. A phase II trial of erlotinib (OSI-774) in patients (pts) with recurrent malignant gliomas (MG) not on EIAEDs.

Meeting: 2004 ASCO Annual Meeting Abstract No: 1502 First Author: J. J. Raizer

5. NCCTG phase II trial of CCI-779 in recurrent glioblastoma multiforme (GBM).

Meeting: 2004 ASCO Annual Meeting Abstract No: 1503 First Author: E. Galanis

6. Phase I study of ZD1839 plus temozolomide in patients with malignant glioma. A study of the North American Brain Tumor Consortium.

Meeting: 2004 ASCO Annual Meeting Abstract No: 1504 First Author: M. Prados

- 7. Phase II study of ZD1839 in patients with newly diagnosed grade 4 astrocytoma. Meeting: 2004 ASCO Annual Meeting Abstract No: 1505 First Author: J. H. Uhm
- 8. Interim report of the JROSG99-1 multi-institutional randomized trial, comparing radiosurgery alone vs. radiosurgery plus whole brain irradiation for 1-4 brain metastases.

Meeting: 2004 ASCO Annual Meeting Abstract No: 1506 First Author: H. Aoyama

9. Phase II trial of radiosurgery (RS) for 1 to 3 newly diagnosed brain metastases from renal cell, melanoma, and sarcoma: An Eastern Cooperative Oncology Group Study (E6397).

Meeting: 2004 ASCO Annual Meeting Abstract No: 1507 First Author: R. R. Ma?on

10. <u>Immunohistochemical detection of EGFRvIII and prognostic significance in patients with malignant glioma enrolled in NCCTG clinical trials.</u>

Meeting: 2004 ASCO Annual Meeting Abstract No: 1508 First Author: J. C. Buckner

Other recent articles by S Pannullo:





1. Adoptive cellular immunotherapy for the treatment of malignant gliomas.

Crit Rev Oncol Hematol, Ireland Vol 39, No 1-2 (1/5/2002): pp. 31-42 PMID: 11418300 [PubMed - in process]

## 2. Lumbar stenosis: a clinical review.

Clin Orthop, United States Vol , No 384 (Mar, 2001): pp. 137-43 PMID: 11249158 [PubMed - in process]

## 3. Trigeminal neuralgia: neurosurgical management options.

J Am Dent Assoc, UNITED STATES Vol 127, No 11 (Nov, 1996): pp. 1635-9; quiz 1666 PMID: 8952240 [PubMed - in process]

## 4. MRI changes in intracranial hypotension.

Neurology, UNITED STATES Vol 43, No 5 (May, 1993): pp. 919-26 PMID: 8492946 [PubMed - in process]

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