HOME | ABOUT ASCO | PRESS CENTER | STATE AFFILIATES | INTERNATIONAL | PDA | SITEMAP | CONTACT US



Search

Knowledge Center

My Shortcuts:

#### News

#### **Meetings & Education**

- ▶ Calendar of Events
- ▶ Annual Meeting
- ▶ Abstracts
- ▶ Symposia & Workshops
- ▶ Virtual Meeting
- ▶ Continuing Education
- ▶ International Affairs

**Policy & Practice** 

**Publications** 

**Practice Guidelines** 

**Career Resources** 



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- ▶ Journal of Oncology Practice
- ▶ The ASCO Foundation
- ► People Living With Cancer

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#### <u>Home</u> > <u>Meetings & Education</u> > <u>Abstracts</u> >

Meeting: 2003 ASCO Annual Meeting
Category: Central Nervous System Tumors

**SubCategory:** CNS Tumors



# Temozolomide in glioblastoma: 4 years' experience with monthly or fortnigthly schedule

Abstract No: 437

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Abstract: Introduction:Temozolomide (TMZ) enhanced life expectancy in

glioblastoma pts. In our institution we valuated a new schedule to verify a low dose activity and the enhance in life expectancy. In literature the efficacy of treatment is dose dependent. The standard schedule (SS)of TMZ in glioblastoma patient was 200 mg/m2 for 5 days every 28 days. We administered 150mg/m2 of TMZ for 7 days every other week "extended schedule" (ES)to reduce toxicity. Methods . In our Hospital from September 98 to December 02 215 pts had the diagnosis of glioblastoma. In 4 years 157 (93 m/64 f) pts were valuated in our Unit ,143 pts had glioblastoma de novo and 14 pts had progression to prior tumor . From September 1998 to 2000: 35 pts made the SS (200mg/m2 for 5 days every 28 days) as adiuvant therapy after surgery (5 stereotactic biopsy-SBIO, 14 partial removal-PR, 15 total removal-TR, 1 not verified-NV) and radiotherapy (21 pts). In the same period 46 pts underwent only surgery (14 SBIO, 13 PR, 16 TR, 3 NV) and radiotherapy (23 pts). Pts who refused the chemotherapy for personal reason were the control group. From 2000 to 2002: 34 pts made the "ES" (150mg/m2 for 7 days every 14 days) as adiuvant therapy in combination of surgery (4 SBIO, 14 PR, 15 TR, 1 NV) and radiotherapy (22 pts). In the same period 42 pts underwent only surgery (5 SBIO, 16 PR, 17 TR, 4 NV) and radiotherapy (26 pts). Results. The "ES" was well tolerated by patients with a low gastric toxicity. We administered 665 cycles and hematological toxicity was: thrombocytopenia grade 1-2 in 31cycles and grade 3-4 in 17 cycles; leukopenia grade 1-2 in 32 cycles and grade 3-4 in 8 cycles. Median survival time (Kaplan-Mayer) of patients treated with the common schedule was 48 weeks (23 weeks of the control patients). Median survival time of pts treated with the "ES" was 63 weeks (26 weeks of the control patients). 42% and 25% of the pts treated with common schedule were alive at 1 and 2 years (20% and 1% of the control pts). 55% and 21% of the pts treated with "ES" were alive at 1 and 2 years (21% and 1% of the control pts). Conclusions. The expected median survival time is quite different 63 weeks versus 48 weeks and the enhancement is evident. Accrual is ongoing.

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

1. Temozolomide in glioblastoma: 4 years' experience with monthly or fortnigthly schedule

Event: 2003 ASCO Annual Meeting Presenter: Luciano Butttolo, MD Session: Central Nervous System (No presentation available)

#### 1. 5-years follow-up in 90 patients with oligodendroglial tumors

Meeting: 2003 ASCO Annual Meeting Abstract No: 435 First Author: M. Frenay

#### 2. A meta-analysis of radiation therapy in adult low-grade glioma

Meeting: 2003 ASCO Annual Meeting Abstract No: 442 First Author: C. C. Leighton; Unversity of Western Ontario

## 3. A phase I trial of CC-5103, a potent thalidomide analog, in patients with recurrent high-grade gliomas and other refractory CNS malignancies

Meeting: 2003 ASCO Annual Meeting Abstract No: 418 First Author: H. A. Fine

# **4.** A phase I trial of extended daily dosing of temozolomide and BCNU for malignant gliomas after radiation therapy.

Meeting: 2003 ASCO Annual Meeting Abstract No: 414 First Author: J. J. Raizer

# 5. A phase I trial of PTK787/ZK 222584 (PTK/ZK), an oral VEGF tyrosine kinase inhibitor, in combination with either temozolomide or lomustine for patients with recurrent glioblastoma multiforme (GBM)

Meeting: 2003 ASCO Annual Meeting Abstract No: 412 First Author: D. Reardon

## 6. A phase I trial of single-agent PTK 787/ZK 222584 (PTK/ZK), an oral VEGFR tyrosine kinase inhibitor, in patients with recurrent glioblastoma multiforme

Meeting: 2003 ASCO Annual Meeting Abstract No: 395 First Author: W. K. A. Yung

### 7. A phase I trial using combination irinotecan and thalidomide for recurrent CNS tumors

Meeting: 2003 ASCO Annual Meeting Abstract No: 489 First Author: W. Adler

# 8. A phase I/II trial and pharmacokinetic study of pyrazoloacridine in adults with newly diagnosed glioblastoma multiforme

Meeting: 2003 ASCO Annual Meeting Abstract No: 485 First Author: G. J. Lesser

# 9. A phase I/II trial of topotecan and radiation therapy for CNS-metastases of patients with solid tumors.

Meeting: 2003 ASCO Annual Meeting Abstract No: 444 First Author: J.-P. Hedde

# 10. A phase II trial of temozolomide and oral VP-16 for adults with recurrent malignant glioma

Meeting: 2003 ASCO Annual Meeting Abstract No: 447 First Author: D. Korones

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