

# Brain Tumor Center Update



## Current Clinical Trials for Adults with Brain Tumor

Questions about patients' participation can be directed to Jane Rabbitt or Margaretta Page by calling 415-353-2966, or by email to: [maecm@neurosurg.ucsf.edu](mailto:maecm@neurosurg.ucsf.edu).

### CHEMOTHERAPY PROTOCOLS

A Phase I Study of Gross Total Resection, Permanent Iodine-125 Brachytherapy and Hyperfractionated Radiotherapy for Newly-Diagnosed Glioblastoma Multiforme.

A Phase I Study of Temozolomide (SCH 52365) in the Treatment of Adult Patients with Supratentorial Low Grade Glioma.

Phase I/II Trial of R115777 in Patients with Recurrent Malignant Glioma. (NABTC 9901)

Phase I/II Trial of CPT-11 and Temozolomide (Temodar) in Patients with Recurrent Malignant Glioma. (NABTC 9907)

Phase I/II Trial of STI571 in Patients with Recurrent Malignant Glioma. (NABTC 9908)

Phase I/II Study of Intratumoral Injection of DTI-015 Prior to Tumor Resection in Patients with Recurrent Malignant Glioma or Metastatic Neoplasm to Brain. (DTI 00-02)

Phase I/II Study to Assess the Histologic Effect and Safety of Pre-Operative and Post-Operative Infusions of IL13-PE38QQR Cytotoxin in Patients with Recurrent Resectable Supratentorial Malignant Glioma.

Phase I/II Trial of CCI-779 in Patients with Malignant Glioma. (NABTC 0101)

A Phase I Study of OSI-774 and Temozolomide for the Treatment of Gliomas.

ZD 1893 for Treatment of Recurrent or Progressive Malignant Astrocytoma or Glioblastoma and Recurrent or Progressive Meningioma: A Phase II Study with a Phase I Component for Patients Receiving EIAEDs. (NABTC 00-01)

A Phase I Study of ZD 1839 and Temozolomide for the Treatment of Gliomas. (NABTC 01-02)

A Phase I/III Randomized Study of Radiation Therapy and Temozolomide vs Radiation Therapy and BCNU vs Radiation Therapy and Temozolomide and BCNU for Anaplastic Astrocytoma. (RTOG 9813)

A Multi-Center, Open-Label, Two Part, Dose Escalation Study to Determine the Tolerability of Interferon-Beta Gene Transfer (BG0001) in the Treatment of Recurrent or Progressive Glioblastoma Multiforme. In Development.

A Phase I/II Trial of OSI-774 in Patients with Recurrent Malignant Gliomas and Malignant Gliomas Post Radiation Therapy. (NABTC 01-03) In Development.

A Trial of Dalteparin Low Molecular Weight Heparin for Primary Prophylaxis of Venous Thromboembolism in Brain Tumor Patients.

A Phase II Study of Concurrent Temodar and STI-571 with Radiation For Adult Patients with Newly Diagnosed Glioblastoma. (BTRC0201) In Development.

Phase II Study of PolyICLC plus Radiation for Newly Diagnosed Patients with Glioblastoma Multiforme (NABTC 01-05) In Development.

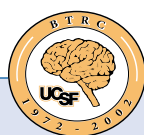
Phase I Study of R115777 plus Radiation for Newly Diagnosed Patients with Glioblastoma Multiforme. (NABTC 0202) In Development.

### NON-CHEMOTHERAPY PROTOCOLS

Assessment of Needs for Complementary Medicine Program for Patients with Brain Tumors.

Study of Distant Healing as an Adjunctive Intervention in Glioblastoma.

San Francisco Bay Area Adult Glioma Prognosis Study.





## Current Clinical Trials For Children With Brain Tumor



UCSF Cancer Center • UCSF Brain Tumor Program  
Department of Neurological Surgery & Brain Tumor Research Center

Questions about patients' participation in the following clinical trials can be directed to Jane Rabbitt or Margaretta Page by calling 415-353-2966, or by email to [malec@neurosurg.ucsf.edu](mailto:malec@neurosurg.ucsf.edu).

### **Pilot Study of Systemic and Intrathecal Chemotherapy Followed by Conformal Radiation for Infants with Embryonal Intracranial Central Nervous System Tumors: A Pediatric Brain Tumor Consortium Protocol (PBTC 001)**

— This is a risk adapted, multi-modality trial for newly diagnosed patients under the age of 3 years with medulloblastoma/PNET, metastatic ependymoma, or other primary intracranial embryonal tumors. It is a collaborative study of the Pediatric Brain Tumor Consortium. For further details: [http://www.pbtc.org/public/PBTC001\\_HP\\_abstract.htm](http://www.pbtc.org/public/PBTC001_HP_abstract.htm).

### **Phase I Trial of Escalating Oral Doses of SCH 66336 in Pediatric Patients with Refractory or Recurrent Brain Tumors (PBTC 003)**

— This is a phase I trial of SCH 66336 for patients 21 years of age or younger who have recurrent or progressive brain tumors. It is a collaborative study of the Pediatric Brain Tumor Consortium. Patients on enzyme inducing anticonvulsant drugs (EIACD) are not eligible. For further details: [http://www.pbtc.org/public/PBTC003\\_HP\\_abstract.htm](http://www.pbtc.org/public/PBTC003_HP_abstract.htm).

### **Phase I Study of Intrathecal Spartaject™-Busulfan in Children with Neoplastic Meningitis (PBTC 004)**

— The alkylating agent busulfan is an extremely hydrophobic compound that precludes intravenous (IV) or intrathecal (IT) administration. Spartaject™-Busulfan is a phospholipid-encapsulated form of

busulfan that can be easily dispersed in water and hence makes it amenable to IT or IV therapy. This phase I study of IT Spartaject™-Busulfan is designed to evaluate the toxicity and pharmacokinetics of administering this drug intrathecally in children with refractory leptomeningeal disease from primary malignant brain tumors, acute lymphoblastic leukemia, and lymphoma. For further details: [http://www.pbtc.org/public/PBTC004\\_HP\\_abstract.htm](http://www.pbtc.org/public/PBTC004_HP_abstract.htm).

### **A Phase I/II Trial of STI571 in Children with Newly Diagnosed Poor Prognosis Brainstem Gliomas and Recurrent Intracranial Malignant Gliomas (PBTC 006)**

— This trial has a dose-finding component and a safety and efficacy component. The children in Stratum 1 will be those with newly diagnosed, localized, poor prognosis brainstem gliomas. Those in Stratum 2 will be children with recurrent intracranial malignant gliomas, including recurrent brainstem gliomas. Children in both strata will receive STI-571. The modified CRM method will be used to estimate the MTD independently in both strata. Patients in Stratum 2 will be sub-stratified based on concurrent use of enzyme-inducing anti-convulsant drugs (EIACDs) into substrata 2A (not receiving) and 2B (receiving EIACD). For further details: [http://www.pbtc.org/public/PBTC006\\_HP\\_abstract.htm](http://www.pbtc.org/public/PBTC006_HP_abstract.htm).



For further details about clinical trials for children being performed at UCSF, visit [http://cc.ucsf.edu/trials/peds\\_brain\\_toc.html](http://cc.ucsf.edu/trials/peds_brain_toc.html).

For further details about clinical trials for children being performed through the Pediatric Brain Tumor Consortium, visit [http://www.pbtc.org/public/protocol\\_summaries.htm](http://www.pbtc.org/public/protocol_summaries.htm).

**Brain Tumor Therapy at UCSF** is a collaboration of UCSF's Neurological Surgery, Neuro-Oncology, Radiation Oncology, Gamma-Knife, and Pediatric Programs, with the support of researchers in UCSF's Brain Tumor Research Center (BTRC) and Michael Douglas Pediatric BTRC, and with close ties to organizations sponsoring support groups and other resources for patients with brain tumors.