

Neuro-Oncology Protocol Accrual and Openings - GBM
3/1/2011

| Protocol # | Phase | Study Drug(s) | PI | Res Nurse | Max Relapses | Max Prior Therapies | Visit Freq. | Drug Coverage | Protocol Highlights (Group A - Non-EIAEDs Group B - EIAEDs) |
|--|-------|--------------------------------------|-----------|--------------|--------------------|------------------------|--|--------------------------|---|
| Newly Dx GBM - Pre Resection | | | | | | | | | |
| None | | | | | | | | | |
| Newly Diagnosed GBM - Chemo + XRT | | | | | | | | | |
| RTOG-0825 | III | Bevacizumab/placeb + Temodar +RT | Gilbert | Loch | 0 | 0 | after radiation then q 3 mos | Bevacizumab | Must have at least 1 block of tissue available; analysis of MGMT status/molecular profile must be completed before randomization; treatment with bevacizumab/placebo begins at 4th week of chemoradiation and continues q2wks; must start chemoradiation between 3 to 5 weeks from surgery date |
| NABTC07-01 (Arm 1) | I | VEGF + Temodar | De Groot | Loch | 0 | 0 | Q 2 wks | Only VEGF-Trap provided | 4 slots on first come, first serve basis; VEGF-Trap 4mg/kg IV q2wks beginning 3rd week of chemoradiation and continues thru end of radiation; option to continue through adjuvant period with standard dose temozolomide; PK's required; must be 28 days from surgery prior to 1st dose of VEGF-Trap |
| BTTC 08-01 | II | Bevacizumab + Erlotinib post RT | De Groot | Hanna | 0 | 0 | 4 wks after RT then q 2 wks for infusion | Bevacizumab + Erlotinib | Must have at least 1 block of tissue for confirmation of an unmethylated MGMT promoter to be eligible post RT. Non-EIAED pts only. Avastin q2wks + Erlotinib 150 mg once daily. Pt must sign consent prior to starting RT. |
| Newly Diagnosed GBM - Stable Post XRT | | | | | | | | | |
| None | | | | | | | | | |
| Recurrent GBM - Pre Resection | | | | | | | | | |
| None | | | | | | | | | |
| Recurrent GBM | | | | | | | | | |
| ID01-310 | I | Delta-24-RGD | Lang | Crutcher | Unlimited | unlimited | Surgery Required for Injection | Yes | Group B (Bx/injection followed by resection/injection 14 days later) Cohort 1 is open for accrual. Please contact Neurosurgery on cohort status before presenting it to patients |
| 2009-0597 | II | Avastin | De Groot | Hanna | 3 | 3 | Q 6 Weeks | None | Arm1: Avastin 10mg/kg q 2 weeks, Arm 2: 5mg/kg 1 3 weeks with CCNU 90mg/m2 q 6 weeks. No prior Anit-angiogenic or nitreousurea allowed. |
| 2007-0668 | I | Avastin + CCI799 | Kurzrock | Venus Ilagan | Unlimited | unlimited | Weekly | None | This is Phase I program protocol. CCI799 is given on Days 1, 8 & 15 of 21-day cycle and Avastin is given on Day 1. Please contact Phase I program on cohort status before presenting it to patients. |
| Studies Currently On Hold | | | | | | | | | |
| 2006-0472 | I/II | CPT-11 + Lenalidomide | Puduvalli | Kang | Phase I: unlimited | unlimited | Q 2 wks | Yes | Phase I : open for both Grade 3 & 4 Gliomas; 1 slots at dose level of CPT-11 at 200mg/m2 q 2 weeks and Lenalidomide at 7.5mg qd on days 1-21. PK for first cycle on days 0, 1, and 4. Both drugs provided and given at MDACC. Strict pregnancy requirement for FCBP. |
| RTOG 0627 | II | Dasatinib | Gilbert | Pei | 1 | Only XRT/Temo allowed | Q 8 wks | Yes | Must have prior Temodar/XRT no other tx allowed, 4wks post XRT, 2 wks post TMZ. Tumor tissue express at least 2 known dasatinib targets. No anticoagulants, ibuprofen, H2 blockers, proto pump inhibitors or meds with proarrhythmic potential. PO daily. MRI q 8 wks, wkly labs, Biwkly f/u with local doctor ok |
| 2008-0318 | I/II | Dasatinib + Temodar | De Groot | Hunter | 0 | 0 | after radiation then q 4 weeks | Dasatinib only | 1 opening for -1 dose level due to DLT (PLTs). Dasatinib now 100mg daily. Registration must be performed within 14-28days of surgery w/ treatment begin within 96 hrs of registration; Patients on EIAEDs, proton pump inhibitors, & full-dose anticoagulants are not eligible; Tissue required. |
| 2009-0759 | II | TPI 287 | Conrad | Pei | 2 | TMZ + non-cytotoxic tx | Q 3 wks | Yes | TPI 287 160mg/m2, dose escalation to 185mg/m2 at cycle 2. |
| 2006-0709 | I | Vorinostat+Carboplatin+ Isotretinoin | Puduvalli | Hunter | 2 | NA | Q 4 wks | Only SAHA provided | Dose Level -3: Carbo AUC of 4 (or GFR capped at 125), SAHA 300mg, CRA 100mg/m2. One opening |
| NABTC07-01 (Arm 2 & 3) | I | VEGF + Temodar | De Groot | Loch | 1 | 1 | Q 2 wks | Only VEGF-Trap provided | Arms 2 and 3 temporarily closed. VEGF-Trap4mg/kg q2wks and TMZ 100 mg/m2 days 1-21 q 28 days; PK's required; no prior therapy except chemoradiation and 2 or fewer cycles of adjuvant TMZ; stable or recurrent disease |
| 2005-0910 | I | Avastin + AZD2171 | Hong | Linda Ricks | Unlimited | unlimited | Every 2 weeks | Only AZD2171 is provided | This is Phase I program protocol. Avastin is given bi-weekly, and AZD2171 is given on days 1-21 of 28-day cycle at escalating doses. Please contact Phase I program on cohort status before presenting it to patients. |
| NABTC04-03 | I | SAHA + Temodar | Puduvalli | Hunter | 0 | Only XRT/Temo allowed | Q 4 wks | Only SAHA provided | TMZ 150mg/m2/day X 5 Days (1-5 of 28 days) & SAHA 500 mg daily on Days 1-7 & 15-21 Q28 days 3 openings, first come, first serve |

Neuro-Oncology Protocol Accrual and Openings - AA/AO
3/1/2011

| Protocol # | Phase | Study Drug(s) | PI | Res Nurse | Max Relapses | Max Prior Therapies | Visit Freq. | Drug Coverage | Protocol Highlights (Group A - Non-EIAEDs Group B - EIAEDs) |
|---|-------|---------------------------------------|-----------|----------------|--------------------|---------------------|--------------------------------|--------------------------|--|
| Newly Dx AA/AO - Pre Resection | | | | | | | | | |
| None | | | | | | | | | |
| Newly Dx Low grade Glioma- Pre resection | | | | | | | | | |
| None | | | | | | | | | |
| Newly Dx AA/AO - Pre XRT | | | | | | | | | |
| RTOG 0834 | III | RT + Temodar | de Groot | Hanna 606-3830 | 0 | 0 | Variable by Arm | Temodar Provided | Arm 1: XRT alone & f/u Q3MOS, Arm 2: XRT +Concurrent temodar, f/u Q3Months post radiation, Arm 3: XRT+Adjuvant Temodar, f/u every 4 weeks, Arm 4: XRT+Concurrent and Adjuvant Temodar. |
| Newly Dx AG Post XRT (Adjuvant - No PD) | | | | | | | | | |
| None | | | | | | | | | |
| Recurrent AA/AO | | | | | | | | | |
| ID01-310 | I | Delta-24-RGD | Lang | Crutcher | Unlimited | unlimited | Surgery Required for Injection | Yes | Group B (Bx/injection followed by resection/injection 14 days later) Cohort 1 is open for accrual. Please contact Neurosurgery on cohort status before presenting it to patients |
| 2005-0910 | I | Avastin + AZD2171 | Hong | Linda Ricks | Unlimited | unlimited | Every 2 weeks | Only AZD2171 is provided | This is Phase I program protocol. Avastin is given bi-weekly, and AZD2171 is given on days 1-21 of 28-day cycle at escalating doses. Please contact Phase I program on cohort status before presenting it to patients. |
| Studies Currently On Hold | | | | | | | | | |
| 2006-0472 | I/II | CPT-11 + Lenalidomide | Puduvalli | Kang | Phase I: unlimited | unlimited | Q 2 wks | Yes | Phase I : open for both Grade 3 & 4 Gliomas; 3 slots at dose level of CPT-11 at 200mg/m2 q 2 weeks and Lenalidomide at 7.5mg qd on days 1-21. PK for first cycle on days 0, 1, and 4. Both drugs provided and given at MDACC. Strict pregnancy requirement for FCBP. |
| NABTC07-01 (arm 1) | I | VEGF + Temodar | De Groot | Loch | 1 | 1 | Q 2 wks | Only VEGF-Trap provided | Tissue Slides or Block must be available prior to registration; Arms 2 and 3 for stable or recurrent. Must have only received chemoradiation and/or 2 cycles of adjuvant Temodar Estimate to reopen: Pending |
| NABTC07-01 (Arm 2 & 3) | I | VEGF + Temodar | De Groot | Loch | 1 | 1 | Q 2 wks | Only VEGF-Trap provided | Arms 2 and 3 temporarily closed. VEGF-Trap4mg/kg q2wks and TMZ 100 mg/m2 days 1-21 q 28 days; PK's required; no prior therapy except chemoradiation and 2 or fewer cycles of adjuvant TMZ; stable or recurrent disease |
| 2006-0709 | I | Vorinostat+Carboplat in+ Isotretinoin | Puduvalli | Hunter | 2 prior | NA | Q 4 wks | Only SAHA provided | Dose Level -2: Carbo AUC of 5 (or GFR capped at 125), SAHA 300mg, CRA 100mg/m2. 1 opening |
| NABTC04-03 | I | SAHA + Temodar | Puduvalli | Hunter | 0 | Only XRT/Temo | Q 4 wks | Only SAHA provided | TMZ 150mg/m2/day X 5 Days (1-5 of 28 days) & SAHA 500 mg daily on Days 1-7 & 15-21 Q28 days Estimate to reopen: Pending |

Neuro-Oncology Protocol Accrual and Openings - Other
3/1/2011

| Protocol # | Phase | Study Drug(s) | PI | Res Nurse | Max Relapses | Max Prior Therapies | Visit Freq. | Drug Coverage | Protocol Highlights (Group A - Non-EIAEDs Group B - EIAEDs) |
|---|-------|---------------------------------|----------|--------------|--------------|---------------------|---|----------------------------|---|
| LMD | | | | | | | | | |
| 2009-0122 | I | Avastin | Groves | Pei | NA | NA | Q 2 wks | Yes | LMD from Breast, NSCLC, and Melanoma. Avastin q2wks. CSF eval q 2 wks for first 6 wks, then q 6 wks. |
| Meningioma | | | | | | | | | |
| RTOG 0539 | II | none | Colman | Pei | Unlimited | N/A | Group I: q 6 month, Group II: q 3 month | N/A | Group I is closed to new pt entry. Group II patients will receive EBRT to a total dose of 54 Gy. Group III patients will receive EBRT using IMRT only, the number of fractions will be 30. the dose will vary depending on PTV |
| Primary CNS Lymphoma | | | | | | | | | |
| None | | | | | | | | | |
| Metastatic Tumors | | | | | | | | | |
| 2007-0668 | I | Avastin + CCI779 | Kurzrock | Terri Warren | Unlimited | unlimited | Weekly | None | This is Phase I program protocol. CCI779 is given on Days 1, 8 & 15 of 21-day cycle and Avastin is given on Day 1. Please contact Phase I program on cohort status before presenting it to patients. |
| 2005-0910 | I | Avastin + AZD2171 | Hong | Linda Ricks | Unlimited | unlimited | Every 2 weeks | Only AZD2171 is provided | This is Phase I program protocol. Avastin is given bi-weekly, and AZD2171 is given on days 1-21 of 28-day cycle at escalating doses. Please contact Phase I program on cohort status before presenting it to patients. |
| 2009-0582 | I | WBRT+RO4929097 or SRS+RO4929097 | Groves | Hanna | Unlimited | Unlimited | Wks 4, 6, & q6wks X 3, then Q12wks | RO4929097 Provided | Phase I protocol for Breast Cancer w/ newly Dx Brain Mets. Pts must be ER negative. ≥4 Lesions WBRT+ RO4929097 (3D on /4D off) . ≤3 Lesions SRS+ RO4929097 (Wks 1&2 of 1st cycle 7on 7 off, then 3Days on / 4Days off). Must have at least 1 measurable lesion. NO COUMADIN ALLOWED. Must not have Hx of hepatitis or liver dx. |
| Other | | | | | | | | | |
| CERN 08-02 | II | Temodar + Lapatinib | Gilbert | Kang | NA | NA | Q 8 weeks | Only Lapatinib is provided | For ependymoma. Must have 1 block of tissue available. |
| ID01-310 | I | Delta-24-RGD | Lang | Crutcher | Unlimited | unlimited | Surgery Required for Injection | Yes | For Anaplastic Ependymoma. Cohort 3 is open for accrual. Please contact Neurosurgery on cohort status before presenting it to patients |
| Studies Currently On Hold | | | | | | | | | |
| Please contact Neuro-department at 713/792-2883 | | | | | | | | | |