

Neuro-Oncology Trials

Recurrent Anaplastic Astrocytoma and LGG					
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Bota	Sherin Mathew	UCI 16-56: Phase II, Single Arm Study Of NOVOTTF-200A In Bevacizumab-Naive Subjects With Recurrent WHO Grade III Malignant Astrocytoma	TTF device	Recurrent AA, no prior treatment with anti-angiogenic agents, presence of 1p19q LOH is exclusionary, chemotherapy within 4 weeks of day 1	Open to Accrual
Kong	Mehir Tharani	ETCTN 10129: A Phase II Study of the PARP Inhibitor Olaparib (AZD2281) in IDH1 and IDH2 Mutant Advanced Solid Tumors	PARP inhibitor	Histological evidence of glioma, cholangiocarcinoma or other solid tumors IDH1 or IDH2 mutation	Open to Accrual (some cohorts closed)
Newly Diagnosed Anaplastic Glioma/Low grade Glioma					
Kong	Sherin Mathew	N0577: Phase III Intergroup Study of Radiotherapy with Concomitant and Adjuvant Temozolomide versus Radiotherapy with Adjuvant PCV Chemotherapy in Patients with 1p/19q Co-deleted Anaplastic Glioma or Low Grade Glioma	1p/19q codeleted oligodendroglioma patients	1p/19q Co-deletion and IDH Mutation Newly diagnosed and ≤ 3 months from surgical diagnosis Histological evidence of WHO grade III anaplastic glioma or WHO grade II low grade glioma with locally diagnosed combined 1p/19q loss and the presence of an either IDH1 or IDH2	Open to Accrual

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Newly Diagnosed Glioblastoma					
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Bota	Mehir Tharani	UCI 19-99: A Randomized, Double-Blind, Placebo-Controlled Phase 3 Study of Enzastaurin Added to Temozolomide During and Following Radiation Therapy in Newly Diagnosed Glioblastoma Patients Who Possess the Novel Genomic Biomarker DGM1	Inhibitor of protein kinase C beta (PKC-β)	Newly diagnosed, IDH mutant excluded Biopsy only excluded Randomization within 5 weeks of resection	Open to Accrual
Kong	Mehir Tharani	NRG BN007: A Randomized Phase II/III Open-Label Study of Ipilimumab and Nivolumab versus Temozolomide in Patients with Newly Diagnosed MGMT (Tumor O-6-Methylguanine DNA Methyltransferase) Unmethylated Glioblastoma	Immunotherapy	Newly diagnosed unmethylated MGMT Prior treatment for low grade excluded IDH mutations excluded	Open to Accrual
Bota	Sherin Mathew	UCI 20-65: EF-32: Randomized, Open-Label Study of Tumor Treating Fields (Optune®, 200kHz) Concomitant with Radiation Therapy and Temozolomide for the Treatment of Newly Diagnosed Glioblastoma	TTF device	Newly diagnosed GBM No infratentorial or leptomeningial disease No active implanted medical devices, bullet fragment, skull defects	Open to Accrual
Recurrent Glioblastoma					
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Bota	Sherin Mathew	UCI 21-18: A Multicenter, OpenLabel Study with a Randomized Control Arm of the Efficacy, Safety, and Pharmacokinetics of Intravenously Infused Berubicin in Adult Patients with Recurrent Glioblastoma Multiforme (WHO Grade IV) After Failure of Standard First Line Therapy	Anthracycline-crosses blood brain barrier	1st recurrence only; Prior bevacizumab is exclusionary; tumor location supratentorial	Open to Accrual

Newly Diagnosed Meningioma					
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Kong	Mehir Tharani	NRG BN003: Phase III Trial of Observation versus Irradiation for a Gross Totally Resected Grade II Meningioma	Radiation Therapy	Newly diagnosed unifocal intracranial meningioma Gross totally resected Central Pathology Review for confirmation of histology	Open to Accrual
Recurrent Meningioma					
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Bota	Daniel Na	A071401: Phase II Trial of SMO/AKT/NF2 Inhibitors in Progressive Meningiomas with SMO/ AKT/ NF2 Mutations	SMO competitive antagonist, FAK inhibitor	Central pathology review for SMO/Ptch1/NF2 mutation Progressive or residual disease in Meningioma Measurable disease per RANO criteria	Temporarily suspended
Craniopharyngiomas					
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Choi	Sherin Mathew	Alliance A071601: Phase II Trial of BRAF/MEK Inhibitors in Papillary Craniopharyngiomas	BRAF/MEK inhibitors	Central pathology review with positive BRAF V600E mutation by IHC Measurable disease No prior treatment with BRAF or MEK inhibitors	only Arm B (recurrent disease) open to accrual
CNS Metastases					
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Choi	Mehir Tharani	Alliance A071701: Genetic Testing in Guiding Treatment for Patients with Brain Metastases	Targeted therapy; CDK, PI3K and NTRK/ROS1 inhibitors	Tissue available for biomarker testing- Participants must have histologically confirmed metastatic disease to the brain from any solid tumor (new or progressive) Tumor must have one of the following mutations: NTRK/ROS1/CDK/P13K pathway alterations	Open to Accrual
Kong	Mehir Tharani	CCTG CE7: A Phase III Trial of Stereotactic Radiosurgery Compared with Hippocampal-Avoidant Whole Brain Radiotherapy (HA-WBRT) Plus Memantine for 5-15 Brain Metastases	SRS or HA-WBRT	5 or more brain mets Largest must be < 2.5 cm in maximal diameter Brain mets located ≤ 5 mm of optic chiasm or optic nerve Leptomeningial disease	Open to Accrual
Bota	TBD	UCI 18-55: A Randomized Open-Label, Multi-Center Pivotal Study of ANG1005 Compared with Physician s Best Choice in HER2-Negative Breast Cancer Patients with Newly Diagnosed Leptomeningeal Carcinomatosis and Previously Treated Brain Metastases	Paclitaxel-Angiopep-2 conjugate and HER2-Negative	Newly diagnosed leptomeningeal carcinomatosis and previously treated brain metastases; Leptomeningeal carcinomatosis treatment naïve; HER2-negative	PRMC approval; Pending Activation

ND and Maintenance therapy for Primary CNS Lymphoma					
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Bota	TDB	UCI 21-196: Maintenance Obinutuzumab for Primary Central Nervous System Lymphoma Complete or Partial Response	Type II anti-CD20 monoclonal antibody (mAb)	CR or PR after HD-MTX therapy w/ or w/o Brain XRT; start within 75 days of completion of first-line treatment; Clinical evidence of extra CNS (systemic) non-Hodgkin Lymphoma	PRMC approved, Pending activation
Recurrent Primary CNS Lymphoma					
Bota	Mehir Tharani	UCI 21-77: An Open-Label Phase II Study to Investigate the Efficacy, Safety, and Pharmacokinetics of Tirabrutinib in Patients with Primary Central Nervous System Lymphoma (PCNSL)	Bruton's Tyrosine Kinase Inhibitor	R/R PCNSL with atleast 1 prior HD-MTX therapy; No intraocular PCNSL without brain lesion, No systemic lymphoma, No non-B-cell PCNSL	Initial IRB approval, Pending activation
Rare Cancers and Basket Trials					
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Bota	Daniel Na	ECOG EAY131: Molecular Analysis for Therapy Choice (MATCH)	Treatment based on mutations	Positive for specific mutations	Open to Accrual (only some cohorts)
Bota	Mehir Tharani	SWOG S1609: Dual Anti-CTLA-4 and Anti-PD-1 Blockade in Rare Tumors	Immunotherapy	Recurrent disease - Rare cancer	Open to Accrual (only some cohorts)
Bota	Daniel Na	UCI 20-152: Ph II Immune Checkpoint Inhibitor Nivolumab in Patients with Recurrent Select Rare CNS Cancers	Immunotherapy	Recurrent Rare CNS disease	Open to Accrual
Bota	Mehir Tharani	UCI 20-180: Drug-drug Interaction Substudy to Assess the Effect of Repeated Doses of Erdafitinib on the Single-dose Pharmacokinetics of Midazolam and Metformin in Subjects with Advanced Solid Tumors that Harbor Target FGFR Mutations or FGFR Gene Fusions at Selected Sites	Assess the effect of repeated doses of erdafitinib on the single-dose pharmacokinetics (PK) of midazolam and metformin	Unresectable, locally advanced, or metastatic solid tumor malignancy; FGFR mutation; documented disease progression	Initial IRB approval; Pending Activation

Supportive Care/Diagnostic/Correlative					
PI	CRC	Protocol #/Title	Mechanism	Primary In/Ex Criteria	Status
Chang	Mazaya Soundara	UCI 18-73: Deep Learning Convolutional Neural Networks Reliably Monitor and Accurately Identifies Predictors of Response to Novo-TTF	Imaging trial	Newly diagnosed GBM Undergoing Optune TTF Age >21; KPS ≥70	Open to Accrual
Bota	Mehir Tharani	UCI 18-83: Pilot Study of Mirtazapine for the Dual Treatment of Depression and Temozolomide-Induced Nausea and Vomiting (CINV) in Newly-Diagnosed High-Grade Glioma Patients on Temozolomide Therapy	Antidepressant	Histologically confirmed diagnosis of glioma -No prior treatment with temozolomide TMZ -Patient will receive temozolomide TMZ therapy as part of their standard treatment.	Open to Accrual
Bota	TBD	UCI 20-56: Tissue Correlates of Outcome in Rare CNS Tumors and Pregnancy Sub Study in Primary Brain Tumors	Data, specimen collection	Available tumor tissue, no needle biopsy allowed, Deceased or lost to follow-up patients only	PRMC approval; Pending Activation
Kong	TBD	UCI 21-197: A Retrospective Observational Study for H3 K27M-mutant Glioma	Data collection	Pathology-proven diffuse glioma with a known H3 K27M mutation and/or tumor in midline structure; initial diagnosis in 2012 or later	PRMC approval; Pending Activation
Others					