

## CLINICAL TRIALS FOR NEWLY DIAGNOSED CANCERS

*Updated October 2019*

For information about participating in a Phase II and III Clinical Research Trial, speak with your Michigan Medicine physician or call 734-647-3529 or email [PedsOncCRA@med.umich.edu](mailto:PedsOncCRA@med.umich.edu).

### STUDIES ONLY AVAILABLE AT MICHIGAN MEDICINE

#### Pediatric Oncology Research Studies

##### **Personalized Medicine based on Molecular Profiling of Pediatric and Young Adult Patients with Cancer**

Open to patients at any phase of treatment, up to age 25

*Only available at Michigan Medicine*

Principle Investigator(s): Rajen Mody, MD

##### **Evaluation of Urine and Blood Biomarkers as Noninvasive Tools for Cancer Monitoring in Children and Young Adults**

Open to newly diagnosed, relapsed or refractory patients up to age 25

*Only available at Michigan Medicine*

Principle Investigator(s): Rajen Mody, MD

##### **Sample Repository for Pediatric Hematology/Oncology**

Open to patients at any phase of treatment, up to age up to age 26

*Only available at Michigan Medicine*

Principle Investigator(s): Rajen Mody, MD

#### Brain Tumor Studies

##### **A Phase II Study of Dasatinib in Combination with Everolimus for Children with Gliomas Harboring PDGFR/FGFR Alterations**

Open to newly diagnosed, recurrent or progressive cancer patients  $\geq 1$  and  $\leq 30$  years of age at time of enrollment

*Only available at Michigan Medicine*

Principle Investigator(s): Carl Koschmann, MD



## LEUKEMIA STUDIES

### ALL Studies

**A Phase 3 Trial Investigating Blinatumomab (IND# 117467, NSC# 765986) in Combination with Chemotherapy in Patients with Newly Diagnosed NCI Standard Risk or Down Syndrome B-Lymphoblastic Leukemia (B-ALL) and the Treatment of Patients with Localized B-Lymphoblastic Lymphoma (B-LLy)**

Open to newly diagnosed patients

B-ALL Diagnosis: without Down Syndrome age 1 - <10 & WBC < 50,000 $\mu$ L

B-ALL Diagnosis: with Down Syndrome age 1 -  $\leq$ 31

B-LLy Diagnosis: with or without Down Syndrome ages  $\geq$ 1 -  $\leq$ 31, Murphy stage I or II

Principle Investigator(s): Rajen Mody, MD

**A Groupwise Pilot Study to Test the Tolerability and Biologic Activity of the Addition of Azacitidine to Chemotherapy in Infants with Acute Lymphoblastic Leukemia (ALL) and KMT2A (MLL) Gene Rearrangement**

Open to newly diagnosed infant patients less than 1 year of age on the date of diagnosis are eligible; infants must be > 36 weeks gestational age at the time of enrollment

**\*\*Temporarily Closed to Accrual**

Principle Investigator(s): Rajen Mody, MD

**International Phase 3 Trial in Philadelphia Chromosome-Positive Acute Lymphoblastic Leukemia Ph+ ALL Testing Imatinib in Combination with Two Different Cytotoxic Chemotherapy Backbones**

Open to newly diagnosed patients > 1 year and  $\leq$  21 years at ALL diagnosis

Principle Investigator(s): Rajen Mody, MD

**Phase II JAK1/JAK2 Inhibitor Ruxolitinib for De Novo ALL**

Consolidation

Principle Investigator(s): Rajen Mody, MD

### AML Studies

**Risk-stratified Therapy for Acute Myeloid Leukemia in Down Syndrome**

Open to newly diagnosed patients with Down syndrome aged 3 mos to 4 yrs

Principle Investigator(s): Rajen Mody, MD



## Lymphoma Studies

### **Bortezomib - on a Modified Augmented BFM (ABFM) Backbone in Newly Diagnosed T-Lymphoblastic Leukemia (T-ALL) and T-Lymphoblastic Lymphoma (T-LLy)**

Open to newly diagnosed patients > 1 and < 31 years of age

**\*\*Temporarily Closed to Accrual**

Principle Investigator(s): Rajen Mody, MD

### **Pilot study testing rituximab and immune cells from donors to treat PTLD in people after SOT**

Open to patients after transplant <30, have SOT, CD20 positive, EBV positive, w/evaluable disease

Principle Investigator(s): Rajen Mody, MD

## SOLID TUMOR STUDIES

### Neuroblastoma Studies

#### **Utilizing Response and Biology Based Risk Factors to Guide Therapy in Patients with Non-High Risk NBL**

Open to newly diagnosed patients < 12 months of age at diagnosis with INRG Stage L1 or < 18 months of age at diagnosis with INRG Stage L2 or Stage Ms NBL/Ganglioneuroblastoma

Principle Investigator(s): Rajen Mody, MD

#### **A Phase 3 Study of 131I-Metaiodobenzylguanidine (131I-MIBG) or Crizotinib Added to Intensive Therapy for Children with Newly Diagnosed High-Risk Neuroblastoma (NBL) (IND# 134379)**

Open to newly diagnosed patients  $\geq 365$  days and  $\leq 30$  years of age at diagnosis; Dx of NBL or Ganglio-NBL

Principle Investigator(s): Rajen Mody, MD



## Wilm's Tumor Studies

### Renal Tumors Classification, Biology, and Banking Study

Open to newly diagnosed patients < 30 years old at the time of diagnosis

**\*\*temp closed to accrual**

Principle Investigator(s): Rajen Mody, MD

### A Randomized Phase 2 Trial of Axitinib/Nivolumab Combination Therapy vs. Single Agent Axitinib or Nivolumab for the Treatment of TFE/rRCC Across All Age Groups

Open to newly diagnosed patients or those who have received prior cancer therapy with histologically confirmed unresectable or metastatic translocation morphology renal cell carcinoma. Must have measurable disease.

Principle Investigator(s): Rajen Mody, MD

## Hepatoblastoma/Hepatocellular Carcinoma Studies

### Pediatric Hepatic Malignancy International Therapeutic Trial (PHITT) A Phase 2/3 Study

Open to newly diagnosed patients with histologically-proven primary pediatric hepatic malignancies including hepatoblastoma or hepatocellular carcinomas. Patients must be ≤30 years of age at the time of dx.

Principle Investigator(s): Rajen Mody, MD

## Rhabdomyosarcoma/NRSTS Studies

### A Randomized Phase 3 Study of Vincristine, Dactinomycin, Cyclophosphamide (VAC) Alternating with Vincristine and Irinotecan (VI) Versus VAC/VI Plus Temsirolimus (TORI, Torisel, NSC# 683864, IND# 122782) in Patients with Intermediate Risk (IR) Rhabdomyosar

Open to newly diagnosed patients ≤ 40 years of age at the time of enrollment

Principle Investigator(s): Rajen Mody, MD



## Germ Cell Tumors Studies

### **A Phase 3 Study of Active Surveillance for Low Risk and a Randomized Trial of Carboplatin vs. Cisplatin for Standard Risk Pediatric and Adult Patients with Germ Cell Tumors**

Open to newly diagnosed patients

Low Risk Stratum: Patients must be < 50 years of age at enrollment

Standard Risk 1: Patient must be < 11 years of age at enrollment

Standard Risk 2: Patients must be  $\geq 11$  and < 25 years of age at enrollment

Principle Investigator(s): Rajen Mody, MD

### **Phase 3 Accelerated BEP Trial: A randomised phase 3 trial of accelerated versus standard BEP chemotherapy for patients with intermediate and poor-risk metastatic germ cell tumours**

Open to newly diagnosed patients or those who have received prior cancer therapy between 11 years and 45 years with metastatic germ cell tumours of intermediate or poor prognostic category

Principle Investigator(s): Rajen Mody, MD

## Biology & Translational Studies

### **Project: EveryChild A Registry, Eligibility Screening, Biology and Outcome Study**

Open to patients within 6 mos of diagnosis  $\leq 25$  years of age at time of original diagnosis, except for patients who are being screened specifically for eligibility onto a COG therapeutic study, for which there is a higher upper age limit.

Principle Investigator(s): Rajen Mody, MD

### **COG Neuroblastoma Biology**

Open to newly diagnosed patients

Principle Investigator(s): Rajen Mody, MD

## Brain Tumor Studies

### **A Phase 2 Study of Reduced Therapy for Newly Diagnosed Average-Risk WNT-Driven Medulloblastoma Patients**

Open to newly diagnosed patients between 3 years and < 22 years at the time of enrollment

Principle Investigator(s): Rajen Mody, MD



**A Phase 2 Study of Veliparib (ABT-888, ING #139199) and Local Irradiation, Followed by Maintenance Veliparib and Temozolomide, in Patients with Newly Diagnosed High-Grade Glioma (HGG\_ without H3 K27M or BRAFV600E Mutations)**

Open to newly diagnosed patients; Stratum 1 (IDH wild-type)  $\geq 3$  years and  $\leq 21$ ; Stratum 2 (IDH mutant)  $\geq 3$  years and  $\leq 25$ ; Diffuse astrocytoma (G2), Oligodendrogliomas (any G), PXA, any grade); Eligibility must be confirmed centrally

Principle Investigator(s): Rajen Mody, MD

**A Study Comparing Two Carboplatin Containing Regimens for Children and Young Adults With Previously Untreated Low Grade Glioma**

Open to newly diagnosed, recurrent or progressive patients  $\leq 21$  years of age at the time of enrollment.

Principle Investigator(s): Carl Koschmann, MD

**Combination Chemotherapy With or Without Etoposide Followed By an Autologous Stem Cell Transplant in Treating Young Patients With Previously Untreated Malignant Brain Tumors**

Open to newly diagnosed, recurrent or progressive patients  $\leq 10$  years of age at the time of enrollment, must be  $< 4$  years of age at diagnosis.

Principle Investigator(s): Carl Koschmann, MD

**Gemcitabine in Newly-Diagnosed Diffuse Intrinsic Pontine Glioma**

Open to newly diagnosed, recurrent or progressive patients  $\geq 3$  and  $< 18$  years of age at time of enrollment.

Principle Investigator(s): Carl Koschmann, MD

**ONC201 in Newly Diagnosed Diffuse Intrinsic Pontine Glioma and Recurrent/Refractory Pediatric H3 K27M Gliomas**

Open to newly diagnosed, recurrent or progressive patients  $\geq 2$  and  $\leq 18$  years of age at time of enrollment.

Principle Investigator(s): Carl Koschmann, MD