CLINICAL TRIALS FOR RELAPSED OR RESISTANT CANCERS

Updated September 2018

For information about participating in a Phase 1 Clinical Research Trial, speak with your Michigan Medicine physician or call 734-647-3529.

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 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 ≥ 1 and ≤ 30 years of age at time of enrollment

*Only available at Michigan Medicine*

Principle Investigator(s): Carl Koschmann, 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 cancer patients ≤ 21 years of age at the time of enrollment

*Only available at Michigan Medicine*

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 cancer patients ≤ 10 years of age at the time of enrollment, must be < 4 years of age at diagnosis
Only available at Michigan Medicine
Principle Investigator(s): Carl Koschmann, MD

Gemcitabine in Newly-Diagnosed Diffuse Intrinsic Pontine Glioma
Open to newly diagnosed, recurrent or progressive cancer patients ≥ 3 and < 18 years of age at time of enrollment
Only available at Michigan Medicine
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 cancer patients ≥ 2 and ≤ 18 years of age at time of enrollment
Only available at Michigan Medicine
Principle Investigator(s): Carl Koschmann, MD

LEUKEMIA STUDIES

ALL Studies

A Pilot Study of Vincristine Sulfate Liposome Injection (Marqibo®) in Combination with UK ALL R3 Induction Chemotherapy for Children, Adolescents, and Young Adults with Relapse of Acute Lymphoblastic Leukemia IND 128316
Open to relapsed cancer patients ≥ 1 and ≤ 21 years of age at the time of enrollment
Principle Investigator(s): Rajen Mody, MD

Phase 1b Study of Carfilzomib in Combination with Induction Chemotherapy in Children with Relapsed or Refractory Acute Lymphoblastic Leukemia
Open to relapsed or refractory patients age ≤ 21 years at the time of initial ALL diagnosis and age > 1 year at the time of study treatment initiation
Principle Investigator(s): Rajen Mody, MD

AML Studies

A Phase 1/2 Study of CPX-351 (NSC# 775341; IND #129443) Alone Followed by Fludarabine, Cytarabine, and G-CSF (FLAG) for Children with Relapsed Acute Myeloid Leukemia (AML)
Open to relapsed patients ≥ 1 year and ≤ 21 years of age at the time of enrollment
**Temporarily Closed to Accrual**
Principle Investigator(s): Rajen Mody, MD

A Phase 2 study of the MEK inhibitor Trametinib (IND# 119346, NSC# 763093) in Children with Relapsed or Refractory Juvenile Myelomonocytic Leukemia
Open to relapsed or refractory patients ≥ 2 years and < 22 years of age at the time of study entry
Principle Investigator(s): Rajen Mody, MD
Epigenetic Reprogramming in Relapse AML: A Phase 1 Study of Decitabine and Vorinostat Followed by Fludarabine, Cytarabine and G-CSF (FLAG) in Children and Young Adults with Relapsed/Refractory AML
Open to relapse or refractory patients ≥ 1 and ≤25 years of age
Principle Investigator(s): Rajen Mody, MD

**Lymphoma Studies**

A Phase I Trial of Temsirolimus (CCI-779, Pfizer, Inc.) in Combination with Etoposide and Cyclophosphamide in Children with Relapsed Acute Lymphoblastic Leukemia and Non-Hodgkins Lymphoma
Open to relapsed patients ≥ 12 months and ≤ 21 years of age at the time of study enrollment
Principle Investigator(s): Rajen Mody, MD

**Cancer Control & Supportive Care Studies**

A Comprehensive Approach to Improve Medication Adherence in Pediatric ALL
Open to remission patients with diagnosis of ALL at ≥ 1 year and ≤ 21 years of age, in first remission.
Enrollment on a COG therapeutic study for ALL is not required
Principle Investigator(s): Rajen Mody, MD

Apixaban for Thromboembolism Prevention versus No Systemic Anticoagulant Prophylaxis during Induction Chemotherapy in Children with Newly Diagnosed Acute Lymphoblastic Leukemia (ALL) or Lymphoma (T or B cell) Treated with Pegylated Asparaginase
Open to patients before first dose of PEG, aged 2 to < 18 years of age
Principle Investigator(s): Steven Pipe, MD

**Umbrella Long term Follow Up Protocol**
Open to patients within 6 months of completion of transplant, no specific age requirement
Principle Investigator(s): Rajen Mody, MD

Key Adverse Events After Childhood Cancer
Limited Strata Available
Principle Investigator(s): Rajen Mody, MD

Pharmacologic Reversal of Ventricular Remodeling in Childhood Cancer Survivors at Risk for Heat Failure (PREVENT-hf): A Phase 2B Randomized Placebo-Controlled (Carvedilol) Trial
Open to patients ≥ 2yrs after transplant, diagnosed < 21 years of age regardless of current age; Weight male > 55, female > 50 Kg
Principle Investigator(s): Rama Jasty, MD

Neuropsychological Testing for Children with Cancer
No specific age requirement, must be enrolled on a COG therapeutic study that examines neuro/behavioral functioning
Principle Investigator(s): Patricia Robertson, MD

A Randomized Web-based Physical Activity Intervention among Children and Adolescents with Acute Lymphoblastic Leukemia
Principle Investigator(s): Rajen Mody, MD
Effects of Modern Chemotherapy Regimens on Spermatogenesis and Steroidogenesis in Adolescent and Young Adult (AYA) Survivors of Osteosarcoma
Principle Investigator(s): Rajen Mody, MD

Home or Away, Neutropenia Quality of Life (HUM00122924)
Open to newly diagnosed patients <18 years old at initial diagnosis; able to read English or Spanish (if age 8 or over); enrolled as patient/caregiver dyad
Principle Investigator(s): Rajen Mody, MD

SOLID TUMOR STUDIES

Neuroblastoma Studies

A Phase 2 Randomized Trial of Irinotecan/Temozolomide with Temsirolimus (NSC# 683864, IND# 61010) or Chimeric 14.18 Antibody (ch14.18) (NSC# 623408, IND# 4308) in Children with Refractory, Relapsed or Progressive Neuroblastoma
Open to relapse or refractory patients **Temporarily Closed to Accrual**
Principle Investigator(s): Rajen Mody, MD

A Phase 2 Trial of Pazopanib NSC# 737754, IND# 65747 in Children with Refractory Solid Tumors
Open to refractory patients at least 1 year old and less than or equal to 18 years of age at the time of study entry
Principle Investigator(s): Rajen Mody, MD

A Phase 1/2 Study of Lenvatinib in Combination With Everolimus in Recurrent and Refractory Pediatric Solid Tumors, Including CNS Tumors
Open to recurrent/refractory patients ≥2 years and ≤21 years of age
Principle Investigator(s): Rajen Mody, MD

A Phase 1/2 Study of Lenvatinib in Combination With Everolimus in Recurrent and Refractory Pediatric Solid Tumors, Including CNS Tumors
Open to recurrent/refractory patients ≥12 years and ≤30 years of age
Principle Investigator(s): Gregory Yanik, MD

A Phase 1/2 Study of Lenvatinib in Combination With Everolimus in Recurrent and Refractory Pediatric Solid Tumors, Including CNS Tumors
Open to recurrent/refractory patients ≥12 months of age
Principle Investigator(s): Rajen Mody, MD

Ewing’s Sarcoma Studies

A Phase 2 Trial of Pazopanib NSC# 737754, IND# 65747 in Children with Refractory Solid Tumors
Open to refractory patients at least 1 year old and less than or equal to 18 years of age at the time of study entry
Principle Investigator(s): Rajen Mody, MD
Phase 2 Trial of XL184 (Cabozantinib) an Oral Small-Molecule Inhibitor of Multiple Kinases, in Children and Young Adults with Refractory Sarcomas, Wilms Tumor, and Other Rare Tumors
Open to refractory (or no know curative therapy) patients \( \geq 2 \) and \( \leq 30 \) years of age at the time of study entry for all strata except upper age limit of \( \leq 18 \) years of age for MTC, RCC and HCC
**Stratum 2 Temporarily Closed**
Principle Investigator(s): Rajen Mody, MD

A Phase 1/2 Study of Lenvatinib in Combination With Everolimus in Recurrent and Refractory Pediatric Solid Tumors, Including CNS Tumors
Open to recurrent and refractory patients \( \geq 2 \) years and \( \leq 21 \) years of age
Principle Investigator(s): Rajen Mody, MD

A Phase 2, multicenter, open-label study to assess safety and preliminary activity of eribulin mesylate in pediatric subjects with relapsed/refractory rhabdomyosarcoma (RMS), non-rhabdomyosarcoma soft tissue sarcoma (NRSTS) and Ewing sarcoma (EWS)
Open to relapsed and refractory patients \( \geq 12 \) months and \( \leq 18 \) years of age
Principle Investigator(s): Rajen Mody, MD

Osteosarcoma Studies

Phase 2 Study of Denosumab (IND#127430, NSC# 744010, a RANK Ligand Antibody, for Recurrent or Refractory Osteosarcoma
Open to recurrent or refractory patients **Temporarily Closed due to Drug Shortage**
Principle Investigator(s): Rama Jasty, MD

A Phase 2 Study of Human-Mouse Chimeric Anti-Disialoganglioside (Dinutuximab, NSC# 764038, IND# 4308) in Combination with Sargramostim (GM-CSF) in Patients with Recurrent Osteosarcoma
Open to recurrent patients less than 30 years of age
Principle Investigator(s): Rama Jasty, MD

A Phase 2 Trial of Pazopanib NSC# 737754, IND# 65747 in Children with Refractory Solid Tumors
Open to recurrent or refractory patients at least 1 year of age and less than or equal to 18 years of age at the time of study entry
Principle Investigator(s): Rajen Mody, MD

Phase 2 Trial of XL184 (Cabozantinib) an Oral Small-Molecule Inhibitor of Multiple Kinases, in Children and Young Adults with Refractory Sarcomas, Wilms Tumor, and Other Rare Tumors
Open to recurrent or refractory patients (or no know curative therapy) \( \geq 2 \) and \( \leq 30 \) years of age at the time of study entry for all strata except upper age limit of \( \leq 18 \) years of age for MTC, RCC and HCC
**Stratum 2 Temporarily Closed**
Principle Investigator(s): Rajen Mody, MD

A Phase 1/2 Study of Lenvatinib in Combination With Everolimus in Recurrent and Refractory Pediatric Solid Tumors, Including CNS Tumors
Open to recurrent or refractory patients \( \geq 2 \) years and \( \leq 21 \) years of age
Principle Investigator(s): Rajen Mody, MD
**Wilm’s Tumor Studies**

Phase 2 Trial of XL184 (Cabozantinib) an Oral Small-Molecule Inhibitor of Multiple Kinases, in Children and Young Adults with Refractory Sarcomas, Wilms Tumor, and Other Rare Tumors
Open to recurrent or refractory patients (or no known curative therapy) ≥ 2 and ≤ 30 years of age at the time of study entry for all strata except upper age limit of ≤ 18 years of age for MTC, RCC and HCC
**Stratum 2 Temporarily Closed**
Principle Investigator(s): Rajen Mody, MD

A Phase 1/2 Study of Lenvatinib in Combination With Everolimus in Recurrent and Refractory Pediatric Solid Tumors, Including CNS Tumors
Open to Recurrent/Refractory, Subjects must be ≥2 years and ≤21 years of age
Principle Investigator(s): Rajen Mody, MD

**Neuroblastoma/Hepatocellular Carcinoma Studies**

A Phase 2 Trial of Pazopanib NSC# 737754, IND# 65747 in Children with Refractory Solid Tumors
Open to refractory patients at least 1 year of age and less than or equal to 18 years of age at the time of study entry
Principle Investigator(s): Rajen Mody, MD

Phase 2 Trial of XL184 (Cabozantinib) an Oral Small-Molecule Inhibitor of Multiple Kinases, in Children and Young Adults with Refractory Sarcomas, Wilms Tumor, and Other Rare Tumors
Open to recurrent or refractory patients (or no known curative therapy) ≥ 2 and ≤ 30 years of age at the time of study entry for all strata except upper age limit of ≤ 18 years of age for MTC, RCC and HCC
**Stratum 2 Temporarily Closed**
Principle Investigator(s): Rajen Mody, MD

**Rhabdomyosarcoma / NRSTS Studies**

Phase 2 Trial of XL184 (Cabozantinib) an Oral Small-Molecule Inhibitor of Multiple Kinases, in Children and Young Adults with Refractory Sarcomas, Wilms Tumor, and Other Rare Tumors
Open to recurrent or refractory patients (or no known curative therapy) ≥ 2 and ≤ 30 years of age at the time of study entry for all strata except upper age limit of ≤ 18 years of age for MTC, RCC and HCC
**Stratum 2 Temporarily Closed**
Principle Investigator(s): Rajen Mody, MD

A Phase 1/2 Study of Lenvatinib in Combination With Everolimus in Recurrent and Refractory Pediatric Solid Tumors, Including CNS Tumors
Open to recurrent or refractory patients ≥2 years and ≤21 years of age
Principle Investigator(s): Rajen Mody, MD

A Phase 2, multicenter, open-label study to assess safety and preliminary activity of eribulin mesylate in pediatric subjects with relapsed/refractory rhabdomyosarcoma (RMS), non-rhabdomyosarcoma soft tissue sarcoma (NRSTS) and Ewing sarcoma (EWS)
Open to recurrent or refractory patients ≥12 months and ≤18 years of age
Principle Investigator(s): Rajen Mody, MD
**Germ Cell Tumor Studies**

A Phase 1/2 Study of Lenvatinib in Combination With Everolimus in Recurrent and Refractory Pediatric Solid Tumors, Including CNS Tumors  
Open to recurrent or refractory patients ≥2 years and ≤21 years of age  
Principle Investigator(s): Rajen Mody, MD

**All Diagnoses Studies**

A Phase 1/2 Study of MK-1775 (AZD1775, IND#121422) in Combination with Oral Irinotecan in Children, Adolescents, and Young Adults with Relapsed or Refractory Solid Tumors  
Open to recurrent or refractory patients, at least 12 months and less than 21 years of age on day of signing informed consent/assent  
Principle Investigator(s): Rajen Mody, MD

A Phase 1/2 Study of Nivolumab (IND#124729) in Children, Adolescents, and Young Adults with Recurrent or Refractory Solid Tumors as a Single Agent and in Combination with Ipilimumab  
Open to recurrent or refractory patients, age 12 months - 30 years  
Principle Investigator(s): Rajen Mody, MD

A Phase 1 Study of Selinexor (KPT-330, IND #125052), a Selective XPO1 Inhibitor, in Recurrent and Refractory Pediatric Solid Tumors, including CNS Tumors  
Open to Relapse or Refractory, 12 months - 21 years **Temporarily Closed to enrollment**  
Principle Investigator(s): Rajen Mody, MD

A Phase I Study of Ramucirumab, a Human Monoclonal Antibody Against the Vascular Endothelial Growth Factor-2 (VEGFR-2) Receptor in Children with Refractory Solid Tumors, including CNS Tumors  
Open to recurrent or refractory patients age 12 months - 21 years **Temporarily Closed to enrollment**  
Principle Investigator(s): Rajen Mody, MD

A Phase 1 Study of Entinostat, an Oral Histone Deacetylase Inhibitor, in Pediatric Patients with Recurrent or Refractory Solid Tumors, including CNS tumors and lymphoma  
Open to recurrent or refractory patients 12 months - 21 years of age **Temporarily Closed to enrollment**  
Principle Investigator(s): Rajen Mody, MD

A Phase I Study of ABI-009 (nab-rapamycin) in Pediatric Patients with Recurrent or Refractory Solid Tumors, including CNS Tumors as a Single Agent and in Combination with Temozolomide and Irinotecan  
Open to recurrent or refractory patients 12 months - 21 years of age  
Principle Investigator(s): Rajen Mody, MD

A Phase 1 Study of LY2606368, a CHK1/2 Inhibitor, in Pediatric Patients with Recurrent or Refractory Solid Tumors, including CNS Tumors  
Open to recurrent or refractory patients 12 months - 21 years of age  
Principle Investigator(s): Rajen Mody, MD
A Phase I/II Study of VX/15/2503 in Children with Solid Tumors
Open to recurrent or refractory patients 12 months - 21 years; 22-30 years
Principle Investigator(s): Rajen Mody, MD

A Phase 1 Study of Pevonedistat (MLN4924, IND# 136078), a NEDD8 Activating Enzyme (NAE) Inhibitor, in Combination with Temozolomide and Irinotecan in Pediatric Patients with Recurrent or Refractory Solid Tumors
Open to recurrent or refractory patients 6 months - 21 years of age
Principle Investigator(s): Rajen Mody, MD

Studies for Patients with Specific Genetic Abnormalities

Pediatric MATCH Screening Protocol
Open to recurrent or refractory patients ≥ 12 mos and ≤ 21 yrs; must have tumor sample from biopsy or surgery after tumor recurrence/progression
Principle Investigator(s): Rajen Mody, MD

Pediatric MATCH - LOXO-101 in patients with tumors harboring actionable NTRK fusions.
Open to recurrent or refractory patients
Principle Investigator(s): Rajen Mody, MD

Pediatric - JNJ-42756493 (Erdafitinib) in patients with tumors harboring FGFR1/2/3/4 alterations.
Open to recurrent or refractory patients
Principle Investigator(s): Rajen Mody, MD

Pediatric MATCH - tazemetostat for patients with tumors harboring alterations in EZH2 or members of the SWI/SNF complex
Open to recurrent or refractory patients **Temporarily Closed due to Accrual**
Principle Investigator(s): Rajen Mody, MD

Pediatric MATCH - LY3023414 in Solid Tumors
Open to recurrent or refractory patients
Principle Investigator(s): Rajen Mody, MD

Pediatric MATCH - Selumetinib in patients with Tumors harboring activating MAPK pathway mutations
Open to recurrent or refractory patients
Principle Investigator(s): Rajen Mody, MD

Pediatric MATCH - Ensartinib in patients with tumors harboring ALK or ROS1 genomic alterations
Open to recurrent or refractory patients
Principle Investigator(s): Rajen Mody, MD

Pediatric MATCH - Vemurafenib in patients with tumors harboring actionable BRAF V600 mutations
Open to recurrent or refractory patients
Principle Investigator(s): Rajen Mody, MD

Pediatric MATCH - olaparib in patients with tumors harboring defects in DNA damage repair genes
Open to recurrent or refractory patients
Principle Investigator(s): Rajen Mody, MD
Pediatric MATCH - Palbociclib in Patients with Tumors Harboring Activating Alterations in Cell Cycle Genes
Open to recurrent or refractory patients
Principle Investigator(s): Rajen Mody, MD

**Biology & Translational Studies**

**NANT Neuroblastoma Biology Study**
Open to newly diagnosed, refractory, recurrent or high risk patients only; ≥ 31 days old
Principle Investigator(s): Rajen Mody, MD

**Neuroblastoma Precision Trial**
Open to Recurrent, Refractory or Persistent Disease, ≥ 1 year and ≤ 30 years of age at study registration
Principle Investigator(s): Rajen Mody, MD

**Cancer Control & Supportive Care Studies**

**Umbrella Long term Follow Up Protocol**
Open to patients within 6 months of completion of transplant, no specific age requirement
Principle Investigator(s): Rajen Mody, MD

**Key Adverse Events After Childhood Cancer**
Open to relapse, recurrent or refractory patients, Limited strata available
Principle Investigator(s): Rajen Mody, MD

**Pharmacologic Reversal of Ventricular Remodeling in Childhood Cancer Survivors at Risk for Heart Failure (PREVENT-hf): A Phase 2B Randomized Placebo-Controlled (Carvedilol) Trial**
Open to patients ≥ 2yrs after transplant, diagnosed < 21 years of age regardless of current age; Weight Male > 55, Female > 50 Kg
Principle Investigator(s): Rama Jasty, MD

**Neuropsychological Testing for Children with Cancer**
Open to after consolidation, no specific age requirement, must be enrolled on a COG therapeutic study that examines neuro/behavioral functioning
Principle Investigator(s): Patricia Robertson, MD

**BRAIN TUMOR STUDIES**

**A Phase I Study of MK-1775 (IND#116495) Concurrent With Local Radiation Therapy for the Treatment of Newly Diagnosed Children with Diffuse Intrinsic Pontine Gliomas**
Open to relapse or refractory patients **Temporarily Closed due to Accrual**
Principle Investigator(s): Rajen Mody, MD

**Phase 2 Trial of XL184 (Cabozantinib) an Oral Small-Molecule Inhibitor of Multiple Kinases, in Children and Young Adults with Refractory Sarcomas, Wilms Tumor, and Other Rare Tumors**
Open to refractory (or no known curative therapy) patients ≥ 2 and ≤ 30 years of age at the time of study entry for all strata except upper age limit of ≤ 18 years of age for MTC, RCC and HCC
Principle Investigator(s): Rajen Mody, MD
A Phase 1/2 Study of Lenvatinib in Combination With Everolimus in Recurrent and Refractory Pediatric Solid Tumors, Including CNS Tumors
Open to recurrent/refractory patients ≥2 years and ≤21 years of age
Principle Investigator(s): Rajen Mody, MD