



CLINICAL TRIALS FOR RELAPSED OR RESISTANT CANCERS

Updated October 2019

For information about participating in a Phase 1 Clinical Research Trial, speak with your Michigan Medicine physician or call 734-647-3529 or email 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 ≥ 1 and ≤ 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 2 Study of Inotuzumab Ozogamicin (NSC# 772518, IND# 133494) in Children and Young Adults with Relapsed or Refractory CD22+ B-Acute Lymphoblastic Leukemia (B-ALL)

Open to relapsed or refractory patients ≥ 1 and < 22 years of age at the time of enrollment

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

Principle Investigator(s): Rajen Mody, MD

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 patients ≥ 1 and ≤ 21 years of age at the time of enrollment

Principle Investigator(s): Rajen Mody, MD

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

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 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

SOLID TUMOR STUDIES

Neuroblastoma Studies

A Phase 2 Randomized Study of Irinotecan/Temozolomide/Dinutuximab with or without Eflornithine (DFMO) (IND# 141913) in Children with Relapsed, Refractory or Progressive Neuroblastoma

Open to relapsed, refractory or progressive patients ≥ 1 year 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 or refractory patients ≥ 2 years and ≤ 21 years of age

Principle Investigator(s): Rajen Mody, MD

A Phase 1/2 Study of the TRK Inhibitor LOXO-195 in Adult and Pediatric Subjects with Previously Treated NTRK Fusion Cancers

Open to patients with no other standard treatment available, solid tumor, previously treated NTRK fusion, life expectancy > 4 weeks, at least 1 month 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 or refractory patients ≥ 12 years and ≤ 30 years of age

Principle Investigator(s): Gregory Yanik, MD

Phase 1 Dose Escalation Study of Autologous Expanded NK Cells for Immunotherapy of Relapsed Refractory Neuroblastoma with Dinutuximab +/- Lenalidomide

Open to recurrent or refractory patients ≤ 30 years of age with w/o CNS disease

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 ≥ 12 months of age

Principle Investigator(s): Rajen Mody, MD

Phase 1 Study of 131 I-MIBG with Dinutuximab for Relapsed/Refractory Neuroblastoma

Open to recurrent or refractory patients ≥ 12 years and ≤ 30 years of age with MIBG avid disease

Principle Investigator(s): Rajen Mody, MD

Ewing's Sarcoma 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 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

****Only Rare Tumors and Osteosarcoma Open (≥ 9 years)****

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 relapsed or refractory patients ≥ 12 months and ≤ 18 years of age

Principle Investigator(s): Rajen Mody, MD



A Phase 1/2 Study of the TRK Inhibitor LOXO-195 in Adult and Pediatric Subjects with Previously Treated NTRK Fusion Cancers

Open to patients with no other standard treatment available, solid tumor, previously treated NTRK fusion, life expectancy >4 weeks. At least 1 month of age

Principle Investigator(s): Rajen Mody, MD

Osteosarcoma 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 refractory (or no know 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

****Only Rare Tumors and Osteosarcoma Open (≥ 9 years)****

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 1/2 Study of the TRK Inhibitor LOXO-195 in Adult and Pediatric Subjects with Previously Treated NTRK Fusion Cancers

Open to patients with no other standard treatment available, solid tumor, previously treated NTRK fusion, life expectancy >4 weeks. At least 1 month 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 refractory (or no know 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

****Only Rare Tumors and Osteosarcoma Open (≥ 9 years)****

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 1/2 Study of the TRK Inhibitor LOXO-195 in Adult and Pediatric Subjects with Previously Treated NTRK Fusion Cancers

Open to patients with no other standard treatment available, solid tumor, previously treated NTRK fusion, life expectancy >4 weeks. At least 1 month of age

Principle Investigator(s): Rajen Mody, MD

Hepatoblastoma/Hepatocellular Carcinoma 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 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

****Only Rare Tumors and Osteosarcoma Open (≥ 9 years)****

Principle Investigator(s): Rajen Mody, MD

A Phase 1/2 Study of the TRK Inhibitor LOXO-195 in Adult and Pediatric Subjects with Previously Treated NTRK Fusion Cancers

Open to patients with no other standard treatment available, solid tumor, previously treated NTRK fusion, life expectancy >4 weeks. At least 1 month of age

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 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

****Only Rare Tumors and Osteosarcoma Open (≥ 9 years)****

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 relapsed or refractory patients ≥ 12 months and ≤ 18 years of age

Principle Investigator(s): Rajen Mody, MD

A Phase 1/2 Study of the TRK Inhibitor LOXO-195 in Adult and Pediatric Subjects with Previously Treated NTRK Fusion Cancers

Open to patients with no other standard treatment available, solid tumor, previously treated NTRK fusion, life expectancy >4 weeks. At least 1 month of age

Principle Investigator(s): Rajen Mody, MD

Germ Cell Tumors 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

A Phase 1/2 Study of the TRK Inhibitor LOXO-195 in Adult and Pediatric Subjects with Previously Treated NTRK Fusion Cancers

Open to patients with no other standard treatment available, solid tumor, previously treated NTRK fusion, life expectancy >4 weeks. At least 1 month of age

Principle Investigator(s): Rajen Mody, MD

All Diagnosis 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 relapsed or refractory patients 12 months and less than 21 years of age on day of signing informed consent/assent

****Temporarily Closed to enrollment**

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 relapsed or refractory patients 12 months to 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 relapsed or refractory patients 12 months to 21 years

****Temporarily Closed to enrollment**

Principle Investigator(s): Rajen Mody, MD

A Phase 1 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 relapsed or refractory patients 12 months to 21 years

****Temporarily Closed to enrollment**

Principle Investigator(s): Rajen Mody, MD

A Phase I/II Study of VX/15/2503 in Children with Solid Tumors

Open to relapsed or refractory patients 12 months - 21 years; 22-30 years

****Temporarily Closed to enrollment**

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 relapsed or refractory patients 6 months - 21 years

Principle Investigator(s): Rajen Mody, MD

A Feasibility Trial of MLN4924 (Pevonedistat, TAK 924, IND#142772) Given in Combination with Azacitidine, Fludarabine, and Cytarabine, in Children, Adolescents, and Young Adults with Relapsed or Refractory Acute Myeloid Leukemia or Relapsed Myelodysplastic Syndrome

Open to recurrent or refractory patients \geq 1 month to \leq 21 years of age

****Temporarily Closed to enrollment**

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 MATCH - 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

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

****Temporarily Closed to enrollment**

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

Pediatric MATCH - BVD-523FB (ulixertinib) in Patients with Tumors Harboring Activating MAPK Pathway Mutations

Open to recurrent or refractory patients

****Temporarily Closed to enrollment**

Principle Investigator(s): Rajen Mody, MD

Biology & Translational Studies

NANT Neuroblastoma Biology Study

Open to refractory or recurrent patients, High Risk Only; ≥ 31 days old

Principle Investigator(s): Rajen Mody, MD

Neuroblastoma Precision Trial

Open to recurrent, refractory or persistent patients ≥ 1 year and ≤ 30 years of age at study registration

Principle Investigator(s): Rajen Mody, MD



Brain 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 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

****Only Rare Tumors and Osteosarcoma Open (≥ 9 years)****

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

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 ≤ 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 ≥ 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 ≥ 2 and ≤ 18 years of age at time of enrollment.

Principle Investigator(s): Carl Koschmann, MD