



University of Michigan  
Comprehensive Cancer Center

THE MICHIGAN DIFFERENCE®

For appointments,  
consultation or  
to speak to an  
oncology nurse  
about eligibility

M-LINE

800-962-3555

**Executive Officers of the  
University of Michigan Health System**

Robert P. Kelch, Executive  
Vice President for Medical Affairs

James O. Woolliscroft, Dean  
U-M Medical School

Douglas Strong, Chief Executive Officer  
U-M Hospitals and Health Centers

Kathleen Potempa, Dean  
School of Nursing

**The Regents of the  
University of Michigan**

Julia Donovan Darlow  
Laurence B. Deitch  
Denise Ilitch  
Olivia P. Maynard  
Andrea Fischer Newman  
Andrew C. Richner  
S. Martin Taylor  
Katherine E. White  
Mary Sue Coleman (ex-officio)

The University of Michigan, is a non-  
discriminatory affirmative action employer.

© 2009  
The Regents of the University of Michigan

University of Michigan Health System  
Public Relations and Marketing Communications  
2901 Hubbard, Ste. 2600  
Ann Arbor, MI 48109-2435

Non Profit Org  
US Postage  
PAID  
Permit #144  
Ann Arbor, MI

CANCER RESEARCH



A clinical trials update  
for physicians and health  
care professionals

# Colleagues in care

ISSUE 2 | SPRING 2009

## U-M COMPREHENSIVE CANCER CENTER OFFERS FULL SPECTRUM OF CLINICAL TRIALS TO CHILDHOOD CANCER PATIENTS

### CHILDHOOD CANCER *continued from page one*

including Children's Oncology Group, Therapeutic Advances in Childhood Leukemia, New Approaches to Neuroblastoma Therapy, as well as with its own laboratory researchers to develop the newest potential therapies for childhood cancer.

At the opposite end of the research spectrum, the U-M Comprehensive Cancer Center is also a leader in assessing the long-term effects of childhood cancer and its treatments. As a member of the Childhood Cancer Survivors Study, the U-M has contributed to 95 publications during the past 15 years about long-term quality of life for pediatric cancer survivors.

The study, which includes 26,000 cancer survivors across the United States, uses siblings as a control to better understand the impact of childhood cancer. This is important, as studies have shown that pediatric cancer survivors are at higher risk of developing other cancers later in life; cognitive difficulties that may impact their ability to succeed in school and pursue careers as adults; and a range of other long-term side effects.

"Once we identify the problems that survivors may face, we can work with families to help lessen the impact," Mody said. "We understand that quality of life is as important as quantity of life. By advancing research, our goal is to help these children excel throughout their lives."

### engage

The engage web portal is a searchable database of hundreds of studies, including eligibility criteria and contact information.

[www.med.umich.edu/engage](http://www.med.umich.edu/engage)



Rajen Mody, M.D.

### Great advances

have been made in treating pediatric cancer during the past 30 years, but one-third of childhood cancer patients will experience a relapse. For many of these patients, early-stage clinical trials - Phase I/II clinical trials—offer hope when other treatment options have run out.

The University of Michigan Comprehensive Cancer Center is making strides to ensure that every childhood cancer patient has the best shot at a healthy life. Whether it's offering patients new hope when other therapies have failed or providing early intervention for survivors who may be at risk for long-term effects of treatment, the U-M Comprehensive Cancer Center supports a full range of clinical trials.

"We are trying to bridge the gap between basic research and clinical medicine," said Rajen Mody, M.D., assistant professor of pediatrics and principal investigator of the

U-M's Children's Oncology Group Phase I consortium. "The trials provide another choice for our patients. As many of our families tell us, it provides them, most importantly, with hope."

Phase I trials are designed to determine the safety and tolerability of a drug that has not yet been used in humans. Phase II trials are designed to test the effectiveness of a new therapy and further evaluate

its safety. Physician researchers also monitor the drug's effectiveness in providing symptomatic relief, prolonging survival and improving quality of life.

The U-M Comprehensive Cancer Center is by far the largest institution of Phase I clinical trials in Michigan for childhood cancer. The Cancer Center collaborates with several multi-institutional clinical trial consortiums

*continued on back*

"The trials provide another choice for our patients. As many of our families tell us, it provides them, most importantly, with hope."

M-LINE • For appointments, consultation or to speak to an oncology nurse about eligibility • 800-962-3555

## SELECTED CHILDHOOD CANCER CLINICAL TRIALS

### INVESTIGATOR INITIATED STUDIES AT UNIVERSITY OF MICHIGAN

#### UMCC 2006.084

Millennium Study—A Phase I Study of Irinotecan and Bortezomib in Children with Recurrent/Refractory High Risk Neuroblastoma

**Eligibility:** Patients are eligible 2 months after myeloablative therapy and autologous stem cell transplant if they meet all other entry criteria. Patients must be no greater than 25 years of age at time of diagnosis  
**PI:** Rajen Mody, M.D.

#### Children's Oncology Group (COG) Studies

#### UMCC 2008.009

Phase I—IMC-A12 (IGF-IR inhibitor) in Pediatric Patients with Relapsed/Refractory Solid Tumors

**Eligibility:** Eligible if stem cell transplant was  $\geq 2$  months ago and there is no evidence of graft vs. host disease. Patients with CNS tumors or lymphomas are excluded from participation. Patients must be  $\leq 21$  years of age at the time of enrollment.  
**PI:** Rajen Mody, M.D.

#### UMCC 2008.026

Phase I—VEGF Trap in Children with Refractory Solid Tumors

**Eligibility:** Eligible if stem cell transplant was  $\geq 2$  months ago and there is no evidence of graft vs. host disease. Patients with primary CNS tumors or known CNS metastasis are eligible. Patients must be  $\leq 21$  years of age at the time of enrollment.  
**PI:** Rajen Mody, M.D.

#### ADVL0812

Phase I—MLN 8237 (Small molecule inhibitor of Aurora

A Kinase) in Children with Relapsed/Refractory Solid Tumors in Leukemia

**Eligibility:** Eligible if stem cell transplant was  $\geq 3$  months ago and there is no evidence of graft vs. host disease. Patients must be  $\leq 21$  years of age at the time of enrollment. All patients must be evaluable for hematologic toxicities. Patients with primary CNS tumors or known CNS metastasis are not eligible.  
**PI:** Rajen Mody, M.D.

#### UMCC 2006.094

Phase I—Sorafenib in Pediatric Patients with Refractory Solid Tumors or Refractory Leukemias

**Eligibility:** Eligible if bone marrow/stem cell transplant was  $\geq 3$  months prior to study entry. Patients with brain tumors or known metastasis to the brain are excluded from trial participation. Patients must be  $\leq 21$  years of age at the time of enrollment. In leukemia cohort patients may have extramedullary disease.  
**PI:** Rajen Mody, M.D.

#### UMCC 2006.117

Phase I—Sunitinib in Pediatric Patients with Refractory Solid Tumors

**Eligibility:** Eligible if stem cell transplant was 3 months ago and there is no evidence of graft vs. host disease. Patients with primary CNS tumors or known CNS metastasis are excluded from participation. Patients must be  $\leq 21$  years of age at the time of enrollment.  
**PI:** Rajen Mody, M.D.

#### Therapeutic Advances in Childhood Leukemia (TACL) Studies

#### UMCC 2006.054

Phase I—Trial of ABT-751 Combined with

Dexamethasone, PEG-Asparaginase, and Doxorubicin in Relapsed Acute Lymphoblastic Leukemia

**Eligibility:** Patients are eligible 6 months after allogeneic stem cell transplant, as long as they are not being treated for graft-versus-host-disease. Patients with CNS involvement are NOT eligible. Patients must be  $< 21$  years of age at diagnosis.  
**PI:** Ray Hutchinson, M.D.

#### UMCC 2007.013

Study—Bortezomib with Chemotherapy for Relapsed/Refractory Acute Lymphoblastic Leukemia

**Eligibility:** Patients are eligible after allogeneic stem cell transplant (no specific time frame), as long as they are not being treated for graft-versus-host-disease. Patients with CNS involvement are eligible. Patients must be  $> 1$  and  $< 21$  years of age when enrolled on study.  
**PI:** Ray Hutchinson, M.D.

#### New Approaches to Neuroblastoma Therapy

#### UMCC 2008.001

Phase I—Study of Ultratrace for Relapsed Neuroblastoma

**Eligibility:** Patients are eligible 3 months after autologous stem cell transplant. Patients status post allogeneic stem cell transplant are excluded. All patients must meet adequate bone marrow function requirements post-myeloablative therapy. Patients must be  $> 1$  year of age and  $< 30$  years of age when registered on study.  
**PI:** Greg Yanik, M.D.

#### UMCC 2007.116

Phase I—Study of IV Fenretinide for Relapsed NBL

**Eligibility:** Patients status post myeloablative autologous

stem cell transplant are eligible 56 days from last day of infusion. Patients must be  $< 30$  years of age at time of registration.  
**PI:** Rajen Mody, M.D.

#### UMCC 2006.134

Phase I—Study of Irinotecan and VCR with MIBG Therapy for Relapsed Neuroblastoma

**Eligibility:** Patients are eligible three months after autologous stem cell transplant. Patients status post-allogeneic stem cell transplant are excluded. Must meet adequate bone marrow function definition post-myeloablative therapy. Patients must be  $> 1$  year and  $< 30$  years of age when registered on study.  
**PI:** Greg Yanik, M.D.

#### NANT 2001.02

131I-Metaiodobenzylguanidine (MIBG) with Intensive Chemotherapy and Autologous Stem Cell Rescue for High-Risk Neuroblastoma

**Eligibility:** Patients previously treated with previous MIBG therapy are excluded. Patients must be  $\geq 1$  year of age at the time of study entry and  $< 30$  years of age at the time of initial diagnosis. Patients who have undergone a prior myeloablative transplant will be excluded.  
**PI:** Greg Yanik, M.D.

#### UMCC 2003.069

Phase I—Study of CEP-701 for Refractory Neuroblastoma

**Eligibility:** Patients are eligible 3 months post stem cell transplant. Patients must be no greater than 21 at time of diagnosis.  
**PI:** Rajen Mody, M.D.

## M-LINE • 800-962-3555

### GROWING PAINS

#### CHILDHOOD CANCER SURVIVORS COPE WITH LONG-TERM EFFECTS OF TREATMENT

#### Laura Selecki doesn't remember

much about what it was like to have cancer. She was a little older than two when doctors told her family she had rhabdomyosarcoma. Now the University of Michigan Comprehensive Cancer Center is helping her learn about what she doesn't remember—and how it will affect her as she grows older.

As the University of Michigan Comprehensive Cancer Center's Pediatric Long-term Follow-Up Clinic celebrates its 10th anniversary this year, its work has become a model for survivorship care. The clinic evolved out of need and a commitment: Patients should fully understand their risks and how best to address them.

“Ten years ago when we first started seeing patients in the Long-term Follow-up Clinic, we saw too many 18-year-olds who were shocked to learn of the possibility of infertility because no one had told them that their treatment was likely to cause such problems,” said Marcia Leonard, R.N., P.N.P., co-director of the U-M Survivorship Program. “Even when we can't prevent these effects, we need to educate our patients about them.”

Families are referred to the Long-term Follow-up Clinic three to five years after cancer treatment ends. They meet with a multidisciplinary team of specialists, including Leonard; social worker Peg Woehrl, M.S.W.; child psychologist Catherine Peterson, Ph.D.; dietitian Nancy Burke, R.D.; and potentially an on-call physician.

These visits are important because they can ferret out problems that may not be obvious. Each family or young adult receives a treatment summary including all chemotherapy drugs and doses, radiation port and dose and surgical treatments. More importantly, a care plan specific to the needs of each child is developed. The plan takes into account the child's age, the known

risks associated with specific treatments the child received and the individual needs of the child and family.

Beyond possible medical complications, clinic staff members help educate families about the psycho-social impacts of cancer: the long-range effect on siblings; the difficulties in maintaining reasonably priced health insurance after a childhood cancer survivor turns 21; the impact of indulging a child's every wish—or of letting them slack off in school—because of a cancer diagnosis.

Academics are a focal point for the Long-term Follow-up Clinic, particularly if chemotherapy was administered directly into the spinal fluid or if cranial radiation was part of a child's treatment. School-age

children are evaluated to determine whether a child is having problems with cognitive functioning as a result of treatment. This will help parents work with school teachers to develop individualized education plans to help the child succeed in class.

#### REFERRALS

To refer a patient for an appointment in the Long-Term Follow-Up Clinic, contact M-LINE at 1-800-962-3555 to get the appointment process started.



Marcia Leonard, R.N., P.N.P.