

# NAIT Newsletter

**NEW  
AGENTS &  
INNOVATIVE  
THERAPY  
PROGRAM**

The vision of the New Agents and Innovative Therapy Program (NAIT) supports The Garron Cancer Centre and SickKids' commitment to innovation and providing Canadian children and their families living with cancer with greater access to the best and newest treatment that will assist to improve clinical care and quality of life.

**KTE-C19 CAR-T  
Cell study is now  
open!**



Current Trials	CNS	Leukemia/ Lymphoma	Solid Tumours
<p><b><u>1200.120 – Afatinib</u></b> Phase I open label, dose escalation trial to determine the MTD, safety, PK and efficacy of afatinib monotherapy in children with recurrent/refractory neuroectodermal tumours, rhabdomyosarcoma and/or other solid tumours with known ErbB pathway deregulation regardless of tumour histology.</p>	●		●
<p><b><u>ADVL1412</u></b> 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 (Temporarily closed for accrual)</p>		●	●
<p><b><u>BRF116013</u></b> Phase I/IIa, 2-Part, Multi-Center, Single-Arm, Open-Label Study to Determine the Safety, Tolerability and Pharmacokinetics of Oral Dabrafenib in Pediatric Subjects Aged 12 Month to &lt;18 Years with Advanced BRAF V600-Mutation Positive Solid Tumours.</p>	●	●	●
<p><b><u>CLDK378X2103</u></b> A Phase I open label dose escalation study of LDK378 in pediatric patients with malignancies that have genetic alteration in anaplastic lymphoma kinase (ALK)</p>	●	●	●
<p><b><u>CFZ008</u></b> Phase 1b/2 Study of Carfilzomib in Combination with Dexamethasone, Mitoxantrone, PEG-asparaginase, and vincristine in Children with Relapsed or Refractory Acute Lymphoblastic Leukemia (Temporarily closed for accrual)</p>		●	
<p><b><u>EZH102</u></b> A Phase I Study of the EZH2 Inhibitor Tazemetostat in Pediatric Subjects with Relapsed or Refractory INI1-Negative Tumors or Synovial Sarcoma</p>	●		●
<p><b><u>MEK116540</u></b> An Open-Label, Dose-Escalation, Phase I/II Study to Investigate the Safety, Pharmacokinetics, Pharmacodynamics and Clinical Activity of the MEK Inhibitor Trametinib in Children and Adolescents Subjects with Cancer or Plexiform Neurofibromas and Trametinib in Combination with Dabrafenib in Children and Adolescents with Cancers Harboring V600 mutations</p>	●		●
<p><b><u>MEL-P1</u></b> Phase 1 Dose Finding Study For Melatonin in Pediatric Oncology Patients with Relapsed Solid Tumors</p>			●
<p><b><u>N2011-04</u></b> A Phase I Study of Lenalidomide and Anti-GD2 Mab Ch14.18 +/- Isotretinoin in Patients with Refractory/Recurrent Neuroblastoma</p>			●
<p><b><u>N2011-01</u></b> Randomized Phase II Study of 131I-MIBG vs. 131I-MIBG with Vincristine and Irinotecan vs. 131I-MIBG with Vorinostat for Resistant/Relapsed Neuroblastoma (temporarily closed for accrual)</p>			●

### HELPING FAMILIES NAVIGATE

To assist patients and families with their transition, our **Patient Navigator Program** will collaborate with your team and the family to provide assistance with issues related to travel, accommodation, and navigating their way around the hospital and in the city. Furthermore, for patients living outside of Ontario, our **Patient Navigator** will assist physicians in completing an **Out-of-Province Prior Approval Application** to the Provincial Ministry of Health. Please contact us for more information.

**SickKids is one of only two centres in Canada offering MIBG therapy.**

For more information, please visit

<http://www.sickkids.ca/gfcc/mibg/index.html>

or contact us by email at

[mibg.info@sickkids.ca](mailto:mibg.info@sickkids.ca)

# SickKids

The Hospital for Sick Children  
555 University Ave  
Toronto, ON  
Canada M5G 1X8

## Current Trials

	CNS	Leukemia/ Lymphoma	Solid Tumours
<b><u>N2012-01</u></b> Phase 1 study of difluoromethylornithine (DFMO) and celecoxib with cyclophosphamide/topotecan for patients with relapsed or refractory neuroblastoma			●
<b><u>TOPAZ</u></b> A Phase I and Enrichment Study of Low-Dose Metronomic Topotecan and Pazopanib in Pediatric Patients with Recurrent or Refractory Solid Tumours Including CNS Tumours (temporarily closed for accrual)	●		●
<b><u>KTE-C19</u></b> A Phase 1/2 Multi-Center Study Evaluating the Safety and Efficacy of KTE-C19 in Pediatric and Adolescent Subjects with Relapsed/Refractory B-precursor Acute Lymphoblastic Leukemia		●	
<b><u>T2014-001</u></b> A Phase 1 Trial of Temozolomide in combination with etoposide and cyclophosphamide in children with relapsed acute ALL with non-Hodgkins lymphoma		●	

## Upcoming Trials

	CNS	Leukemia/ Lymphoma	Solid Tumours
<b><u>N2015-02</u></b> Phase 1/2 study of PF-06463922, an oral small molecule inhibitor of ALK/ROS1, for patients with ALK-driven relapsed or refractory neuroblastoma			●
<b><u>CCTL019B2001X</u></b> Expanded treatment protocol for relapsed/refractory pediatric/young adult acute lymphoblastic leukemia patients to be treated with CTL019		●	
<b><u>CA 209-908</u></b> Phase Ib/II Clinical Trial of Nivolumab Monotherapy and Nivolumab in Combination with Ipilimumab in Pediatric Subjects with High Grade Primary CNS Malignancies	●		
<b><u>OZM-077</u></b> Phase I/Ib trial of combined 5'azacitidine and carboplatin for recurrent/refractory pediatric brain and solid tumors and recurrent or refractory ependymoma	●		●
<b><u>M13-833</u></b> A Phase 1 Study of the Safety and Pharmacokinetics of Venetoclax in Pediatric Patients with Select Relapsed or Refractory Malignancies		●	●

For more information on current and upcoming trials, please visit [www.sickkids.ca/centres/gfcc/nait/index.html](http://www.sickkids.ca/centres/gfcc/nait/index.html)

or send an email directly to

**Solid Tumour:** Dr. Daniel Morgenstern [daniel.morgenstern@sickkids.ca](mailto:daniel.morgenstern@sickkids.ca)

**Leukemia/Lymphoma:** Dr. Jim Whitlock [jim.whitlock@sickkids.ca](mailto:jim.whitlock@sickkids.ca)

**CNS:** Dr. Eric Bouffet [eric.bouffet@sickkids.ca](mailto:eric.bouffet@sickkids.ca)

**Patient Navigator:** Karen Fung [karen.fung@sickkids.ca](mailto:karen.fung@sickkids.ca)

**General Inquiries:** [nait.info@sickkids.ca](mailto:nait.info@sickkids.ca)