**UPDATES**

- **ADVL1412 (nivolumab/ipilimumab)** has now reopened for patients with Ewing sarcoma and rhabdomyosarcoma. Patients should have available archival tissue but are not required to demonstrate PDL1 expression for enrolment.

### Study Details

<table>
<thead>
<tr>
<th>Study</th>
<th>Funding for travel, etc.</th>
<th>Key eligibility criteria</th>
<th>Current status</th>
<th>Solid tumours</th>
<th>CNS</th>
<th>Leukemia/lymphoma</th>
</tr>
</thead>
</table>
| **M13-833 venetoclax**  
A Phase I study of the safety and pharmacokinetics of venetoclax in pediatric and young adult patients with relapsed or refractory malignancies  
NCT03236857 | - | BCL2 inhibitor given in combination with chemotherapy  
Patients with CNS disease excluded  
Open for AML, ALL and NHL | Open  
(solid tumour cohort reopening shortly) |  |  |  |
| **Larotrectinib**  
A Phase 1/2 Study of the Oral TRK Inhibitor LOXO-101 [larotrectinib] in Pediatric Patients with Advanced Solid or Primary Central Nervous System Tumors  
NCT02637687 | - | NTRK-fusion tumours only | Open |  |  |  |
| **Avelumab**  
Open-label, Phase I/II study to evaluate pharmacokinetics, pharmacodynamics, safety and anticancer activity of avelumab in pediatric subjects from birth to less than 18 years of age with refractory or relapsed solid tumours and lymphoma  
NCT03451825 | - | Must have available tissue from within last 6 months (up to 12 months may be accepted); no other selective biomarker | Open  
(very limited slot availability) |  |  |  |
| **ADVL1412: nivolumab/ipilimumab**  
A Phase I/II study of nivolumab in children, adolescents and young adults with recurrent or refractory solid tumors as a single agent and in combination with ipilimumab  
NCT02304458 | - | - | Ewing/rhabdo |  |  |  |
| **Afatinib**  
Phase I/II open label, dose escalation trial of afatinib monotherapy in children aged ≥1 year to >18 years with recurrent/refractory neuroectodermal tumours, rhabdomyosarcoma and/or other solid tumours with known ErbB pathway deregulation regardless of tumour histology  
NCT02372006 | - | Need pre-screening to confirm ErbB/EGFR pathway activation | Open |  |  |  |
| **Tazemetostat**  
Phase I study of the EZH2 inhibitor tazemetostat in pediatric subjects with relapsed or refractory INI-1 negative tumours or synovial sarcoma  
NCT02601937 | - | Cohort for patients with ATRT is now closed | Open |  |  |  |
| **Trametinib/dabrafenib**  
An open-label, phase I/II study to investigate the safety, pharmacokinetics, pharmacodynamics and clinical activity of the MEK inhibitor trametinib... and trametinib in combination with dabrafenib  
NCT02124772 | - | - | Open for LCH and neuroblastoma only |  |  |  |
<table>
<thead>
<tr>
<th>Study ID</th>
<th>Title</th>
<th>Description</th>
<th>Eligibility</th>
<th>Status</th>
</tr>
</thead>
<tbody>
<tr>
<td>OZM-077</td>
<td>5’azacitidine/carboplatin</td>
<td>Phase 1/1b trial of combined 5’azacitidine and carboplatin for recurrent/refractory pediatric brain and solid tumors</td>
<td>No selective biomarker</td>
<td>Open</td>
</tr>
<tr>
<td>OZM-075</td>
<td>Nivolumab</td>
<td>Pilot study of nivolumab in pediatric patients with hypermutant cancers</td>
<td>Hypermutant cancers (mismatch repair or TMB &gt;5mut/Mb)</td>
<td>Open</td>
</tr>
<tr>
<td>NANT 2015-02</td>
<td>Lorlatinib</td>
<td>Phase 1 study of lorlatinib, an oral small molecule inhibitor of ALK/ROS1, for patients with ALK-driven relapsed or refractory neuroblastoma</td>
<td>ALK mutation required</td>
<td>Neuroblastoma only</td>
</tr>
<tr>
<td>NANT 2011-01</td>
<td>¹³¹I-mIBG +/- chemotherapy</td>
<td>Randomized phase II study of ¹³¹I-mIBG vs ¹³¹I-mIBG with vincristine and irinotecan vs ¹³¹I-mIBG with vorinostat for resistant/relapsed neuroblastoma</td>
<td>Neuroblastoma only</td>
<td>Open</td>
</tr>
<tr>
<td>ymAbs201 hu3F8 (naxitamab)</td>
<td>A Pivotal Phase 2 trial of antibody hu3F8 and GM-CSF in high-risk neuroblastoma patients with primary or secondary refractory osteomedullary disease</td>
<td>Neuroblastoma only</td>
<td>Osteomedullary disease only</td>
<td>For residual disease rather than at initial recurrence</td>
</tr>
</tbody>
</table>

For more information, please email: nait.info@sickkids.ca

Additional contacts:

- **Solid tumour**
  - Dr Daniel Morgenstern: daniel.morgenstern@sickkids.ca
  - Dr Eric Bouffet: eric.bouffet@sickkids.ca
  - Dr Jim Whitlock: jim.whitlock@sickkids.ca

- **Patient navigator**
  - Karen Fung: karen.fung@sickkids.ca

Please note that study status can change frequently and information above may become out of date. Please contact us to discuss currently availability for potential patients.

**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. Studies for which funding is likely to be available from the trial itself are indicated in the table above.