AALL2131: An International Pilot Study of Chemotherapy and Tyrosine Kinase Inhibitor with Blinatumomab in Patients with Newly-Diagnosed Philadelphia Chromosome-Positive or ABL-class Philadelphia Chromosome-Like B-cell Acute Lymphoblastic Leukemia

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Goal:

- To improve the outcomes of newly-diagnosed children, adolescents and young adults with newly-diagnosed Philadelphia chromosome-positive (Ph+) or ABL-class Philadelphia chromosome-like (Ph-like) B-cell acute lymphoblastic leukemia (B-ALL)

Objectives:

- To estimate the three (3)-year event-free survival (EFS) of children, adolescents and young adults < 25 years old with newly-diagnosed Ph+ B-ALL who are treated with a modified Berlin-Frankfurt-Munster (mBFM) chemotherapy backbone that incorporates three cycles of blinatumomab without traditional consolidation chemotherapy in combination with continuous dasatinib
- To estimate the three (3)-year EFS of children, adolescents and young adults < 25 years old with newly-diagnosed ABL-class Ph-like B-ALL who are treated with a modified Berlin-Frankfurt-Munster (mBFM) chemotherapy backbone that incorporates three cycles of blinatumomab without traditional consolidation chemotherapy in combination with continuous imatinib for those with *PDGFRB* gene fusions or dasatinib for those without *PDGFRB* gene fusions
- To describe the safety and toxicity profile for patients with Ph+ or ABL-class Ph-like B-ALL treated on this novel chemo-immunotherapy backbone with continuous tyrosine kinase inhibitor (TKI)

Study Method:

- US National Cancer Institute (NCI)-sponsored, Children's Oncology Group (COG)-led international pilot study investigating a novel chemo-immunotherapy backbone that incorporates three (3) cycles of blinatumomab without traditional consolidation chemotherapy in combination with TKI for children, adolescents and young adults with newly-diagnosed Ph+ or ABL-class Ph-like B-ALL
- Target accrual :
  - Ph+ B-ALL cohort : 100 patients
  - ABL-class Ph-like B-ALL (*PDGFRB*-rearranged vs. non-*PDGFRB*-rearranged) cohort: 100 patients
- Statistics :
  - A sample size of 100 eligible, evaluable patients will allow estimation of three (3)-year EFS on the study treatment arm with a maximum standard error 4.8% or 95% confidence interval with a maximum margin of error of ± 9.4%

Results:

- AALL2131 was activated for enrollment on May 23, 2025
- As of February 5, 2026:
  - 117 COG member institutions across the United States, Canada, Australia and New Zealand have opened the study
  - This study is open at eight (8) Canadian centres:
    - ***Quebec:*** CHU Sainte-Justine, Montreal Children's Hospital, CHU de Quebec, CHU de Sherbrooke
    - ***Ontario:*** Hospital for Sick Children, McMaster Children's Hospital
    - ***British Columbia:*** BC Children's Hospital
    - ***Nova Scotia:*** IWK Health Centre
  - 38 patients enrolled – one (1) patient from the Hospital for Sick Children, Toronto, Canada
  - 60 peripheral blood and 23 cerebrospinal fluid samples received at the CHU Sainte-Justine's Clinical Pharmacology Laboratory for TKI therapeutic drug monitoring

Impact/Outcomes:

- Investigating a novel therapeutic approach incorporating blinatumomab plus TKI while removing traditional consolidation chemotherapy to improve the outcomes of children, adolescents and young adults with *de novo* Ph+ or ABL-class Ph-like B-ALL
- International trial including 17 countries including United States, Canada, Australia, New Zealand and 13 EU countries
- Providing access to next-generation sequencing minimal residual disease assays to Canadian patients enrolled on AALL2131
- Several planned correlative studies to study the biology of the disease and determinants of treatment response/resistance to inform future trial designs

Project Timelines:

- Study activation in the EsPhALL network (13 EU countries) in March 2026
- Estimated accrual completion by Fall 2027