



Arnie Charbonneau Cancer Institute The Riddell Centre for Cancer Immunotherapy





PROJECT SUMMARY

Clinical Research & Translation

Dr. Kevin Hay, a clinician-scientist recruited to UCalgary in 2023, is advancing the development of novel CAR T-cell therapies for blood cancers. In collaboration with Dr. Natasha Kekre (Ottawa Hospital), Dr. Hay co-led Canada's first clinical trial of in-house manufactured CAR T-cells — CLIC-1901 — targeting CD19, a protein found on relapsed or refractory acute lymphoblastic leukemia and non-Hodgkin's lymphoma. This trial demonstrated that fresh, made-in-Canada CAR T-cell products can be delivered safely and effectively, offering a scalable model for resource-constrained health-care systems.

Building on this foundation, Dr. Hay is now leading a Phase I clinical trial of a made-in-Canada CAR T-cell therapy — CLIC-2201 — targeting CD22, a protein associated with B-cell malignancies. Sponsored by the BC Cancer Agency and supported by CIHR funding, the trial is being conducted in partnership with the National Research Council and the Canadian-Led Immunotherapies in Cancer (CLIC) program (a national research program co-led by Dr. Hay dedicated to building Canadian expertise and

capacity for promising cell immunotherapies for cancer). The first patient was treated at Vancouver General Hospital in early 2025, with additional recruitment underway across Canada, including in Calgary.

CLIC-2201 is a first-in-human, dose-finding trial evaluating the safety, feasibility and anti-tumour activity of patient-derived, made-in-Canada CD22-targeted CAR T-cells in both adult and paediatric patients. Participants first undergo leukapheresis — a procedure to collect white blood cells — which are then shipped to the Conconi Family Immunotherapy Laboratory in Victoria, B.C., for CAR T-cell manufacturing. Prior to infusion, participants receive conditioning chemotherapy to deplete existing immune cells, creating space for the infused CAR T-cells to expand and function effectively. The trial follows a standard dose-escalation design to determine the maximum tolerated dose.

Extensive followup includes safety monitoring, immune profiling, biomarker analysis and quality-of-life assessments over a 15-year period.

OVERALL IMPACT

The launch of the CLIC-2201 trial marks a critical advancement in the development of Canadian-made CAR T-cell therapies. By targeting CD22 and enrolling both adult and paediatric patients, this trial addresses an urgent need for new treatment options in relapsed B-cell malignancies. The trial also strengthens national infrastructure for cell therapy manufacturing and clinical delivery, setting the stage for broader implementation of sustainable, locally produced immunotherapies.