



Novartis receives Health Canada approval of its CAR-T cell therapy, Kymriah™ (tisagenlecleucel) Français

NEWS PROVIDED BY

Novartis Pharmaceuticals Canada Inc.

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- *Kymriah, the first chimeric antigen receptor T cell (CAR-T) therapy approved in Canada, is manufactured individually for each patient*
- *Novartis is working with qualified treatment centres to prepare for the delivery of this treatment for relapsed/refractory (r/r) pediatric and young adult B-cell ALL and adult r/r DLBCL indications*

DORVAL, QC, Sept. 6, 2018 /CNW/ - Novartis is pleased to announce that following a Priority Review, Health Canada has approved Kymriah™ (tisagenlecleucel/ CTL019) the first chimeric antigen receptor T cell (CAR-T) therapy to receive regulatory approval in Canada.



The Lahti family on Cameron's CAR-T experience



Kymriah, a CD19-directed genetically modified autologous T-cell immunocellular therapy, is approved to treat two life-threatening cancers that have limited treatment options and historically poor outcomes, demonstrating the critical need for new therapies for these patients.

Health Canada has approved Kymriah for use in pediatric and young adult patients 3 to 25 years of age with B-cell acute lymphoblastic leukemia (ALL) who are refractory, have relapsed after allogeneic stem cell transplant (SCT) or are otherwise ineligible for SCT, or have experienced second or later relapse; and for the treatment of adult patients with relapsed or refractory (r/r) large B-cell lymphoma after two or more lines of systemic therapy including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, high grade B-cell lymphoma and DLBCL arising from follicular lymphoma¹.

Kymriah is a one-time treatment that uses a patient's own T cells to fight and kill cancer cells. Bringing this innovative therapy to Canadian patients requires collaboration among many health system stakeholders. Regulatory approval is an important first step; certification and training at key qualified treatment centres for the appropriate indications are underway to facilitate safe and seamless delivery to patients. Novartis also continues to enhance manufacturing capacity to meet patient needs in both indications.

"This first approval of a CAR-T cell therapy in Canada heralds the start of what promises to be a new age in the way cancer is treated. Novartis is working collaboratively with a number of treatment centres to build a delivery system that did not previously exist," said Daniel Hébert Medical Director, Novartis Pharmaceuticals Canada Inc. "Kymriah is a concrete demonstration of our commitment to reimagine medicine and to develop new practice-changing technologies."

Pioneering Technology

CAR-T cell therapy represents a significant step forward in treating these cancers and is the embodiment of personalized medicine. Kymriah is manufactured individually for each patient using their own cells. It is not a pill or traditional chemotherapy but instead is produced via pioneering technology and a sophisticated manufacturing process. The one-time therapy uses the patient's T cells, a type of white blood cell, which are harvested from a patient's blood, frozen and then transported to the Novartis manufacturing facility. They are then modified to create T cells that are genetically coded to recognize, fight and kill cancer cells and other B-cells expressing a specific antigen. The resulting therapy is returned to the treatment centre and administered to the patient via infusion in one session.

"This is an exciting step forward. We have been looking forward to the approval of CAR-T cell therapy, so we can offer an important and promising new treatment option to young patients we see with refractory or relapsed B-cell acute lymphoblastic leukemia who have exhausted other treatment options," said Dr. Henrique Bittencourt, hematologist at the Centre hospitalier universitaire Sainte-Justine (CHU Sainte-Justine) in Montreal and assistant clinical professor, Department of Pediatrics, University of Montreal. "This is a new era of cell therapy that offers an opportunity to these very sick children and youth."

"This innovation in cancer treatment opens the door to a new care approach for individuals for whom traditional therapies such as chemotherapy, radiation and surgery are not an option," said Dr. Ronan Foley, Site Principal Investigator, JULIET Clinical Trial, Juravinski Hospital and Cancer Centre, Hamilton Health Sciences and McMaster University; Professor, Department of Pathology and Molecular Medicine, Faculty of Health Sciences, McMaster University; and Director, Stem Cell Laboratory, Hamilton Health Sciences. "CAR-T cell therapy uniquely harnesses the potential of the individual's own immune system to target and destroy cancer cells. It is a major advancement in the emergence of immune-based strategies and shows great promise as a potentially life-saving treatment in cancer care."

The pediatric treatment centre in Ontario where tisagenlecleucel CAR-T cell therapy was delivered is The Hospital for Sick Children (SickKids) in Toronto.

About acute lymphoblastic leukemia (ALL)

Acute lymphoblastic leukemia (ALL) is a cancer of the lymphocytes, a type of white blood cell involved in the body's immune system. It is also called acute lymphoid leukemia or acute lymphocytic leukemia. In ALL, abnormal cells crowd out other types of cells in the bone marrow, preventing the production of other blood cellsⁱⁱ. In Canada, ALL accounts for approximately 75 per cent of leukemia cases diagnosed in children age 0 to 14ⁱⁱⁱ. Despite aggressive treatment, 15% to 20% of children with ALL relapse^{iv}.

About diffuse large B-cell lymphoma (DLBCL)

Lymphoma is the overall name for blood cancers that develop in the lymphatic system from lymphocytes^v, a type of white blood cell involved in the body's immune system^{vi}. There are two main types, Hodgkin lymphoma (HL) and non-Hodgkin lymphoma (NHL). In NHL, normal lymphocytes change and grow uncontrollably, displacing healthy white blood cells and weakening the body's ability to fight infection^{vii}. DLBCL is a cancer of the B-lymphocytes (B-cells). It is the most common subtype of NHL, accounting for up to 30-40 per cent of all cases in Canada^{viii}. Between 2,490 and 3,320 cases are diagnosed each year in Canada^{ix}. About two-thirds of patients achieve and maintain complete remission after first-line therapy^x, but about one-third relapse after treatment and 10 per cent have refractory disease (not responding to treatment)ⁱⁱ. Left untreated, refractory or relapsing DLBCL patients have a life expectancy of 3-4 monthsⁱⁱ. The risk of DLBCL increases with age, with the average age of diagnosis in the mid-60s^{ix}.

Kymriah™ (tisagenlecleucel) Important Safety Information

The full prescribing information for Kymriah™ can be found at: www.novartis.ca.

Novartis Leadership in Cell and Gene Therapy

Novartis is at the forefront of investigational immunocellular therapy and was the first pharmaceutical company to significantly invest in CAR-T research, work with pioneers in CAR-T and initiate global CAR-T trials. Kymriah™, the first approved CAR-T cell therapy in Canada, is the cornerstone of this strategy. Active research programs are underway targeting other hematologic malignancies and solid tumors, and include efforts focused on next generation CAR-Ts that involve simplified manufacturing schemes and gene edited cells.

About Novartis Pharmaceuticals Canada

Novartis Pharmaceuticals Canada Inc., a leader in the healthcare field, is committed to the discovery, development and marketing of innovative products to improve the well-being of all Canadians. In 2017, the company invested \$51 million in research and development in Canada. Located in Dorval, Quebec, Novartis Pharmaceuticals Canada Inc. employs approximately 750 people in Canada and is an affiliate of Novartis AG, which provides innovative healthcare solutions that address the evolving needs of patients and societies. For further information, please consult www.novartis.ca.

About Novartis

Novartis provides innovative healthcare solutions that address the evolving needs of patients and societies. Headquartered in Basel, Switzerland, Novartis offers a diversified portfolio to best meet these needs: innovative medicines, cost-saving generic and biosimilar pharmaceuticals and eye care. Novartis has leading positions globally in each of these areas. In 2017, the Group achieved net sales of USD 49.1 billion, while R&D throughout the Group amounted to approximately USD 9.0 billion. Novartis Group companies employ approximately 125,000 full-time-equivalent associates. Novartis products are sold in approximately 155 countries around the world. For more information, please visit <http://www.novartis.com>.

Kymriah is a trademark.

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Organization Profile



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