

## **KITE'S YESCARTA® (AXICABTAGENE CILOLEUCEL) REIMBURSED IN ONTARIO FOR THE TREATMENT OF CERTAIN TYPES OF AGGRESSIVE NON-HODGKIN**

*– YESCARTA is a Chimeric Antigen Receptor T-Cell (CAR T) Therapy –*

*– CAR T Therapy is a Hematologic Cancer Treatment in Which a Patient's Own T Cells are Engineered to Seek and Destroy Cancer Cells –*

*– CAR T Therapy is Manufactured Specifically for Each Individual Patient –*

**MISSISSAUGA, ON, Dec. 10, 2020** – Gilead Sciences Canada, Inc. (Gilead Canada) announced today that YESCARTA® (axicabtagene ciloleucel) is now available in Ontario as a treatment for adult patients with relapsed or refractory large B-cell lymphoma after two or more lines of systemic therapy, including diffuse large B-cell lymphoma (DLBCL) not otherwise specified, primary mediastinal large B-cell lymphoma (PMBCL), high grade B-cell lymphoma, and DLBCL arising from follicular lymphoma.<sup>i</sup> YESCARTA will be manufactured by Kite, a Gilead Company (Kite) at its commercial manufacturing facility in El Segundo, California.

YESCARTA is a chimeric antigen receptor T-cell (CAR T) therapy, an individualized method of treatment that harnesses the power of the body's own immune system to target cancer cells. In CAR T therapy, T cells (a type of white blood cell) are removed from a patient (a process called apheresis) and modified so they can recognize and respond to a specific antigen, which is identified on cancer cells and signals cell death.<sup>ii</sup> This cell therapy can induce a complete response (no detectable cancer) in a proportion of patients with relapsed or refractory DLBCL and PMBCL, which are aggressive forms of non-Hodgkin lymphoma (NHL).<sup>iii</sup> Eligible patients in Ontario now have the option to be treated with YESCARTA at Princess Margaret Cancer Centre and The Ottawa Hospital.

"Today's announcement means that patients now have a much-needed new treatment option, which offers an exciting and innovative way to treat these types of blood cancer," said Melissa Koomey, Vice President and General Manager, Gilead Canada. "Gilead will continue to work to provide final site certification to a number of specialized centres across Canada enabling them to make YESCARTA available to appropriate patients."

DLBCL is the most common form of NHL (a group of cancers that originate primarily in types of white blood cells)<sup>iv</sup> and accounts for approximately 30 per cent of newly diagnosed cases.<sup>v</sup> Based on previous rates of diagnosis, in Canada it is estimated that up to 4,000 new cases of DLBCL were diagnosed in 2019.<sup>vi, vii</sup> The prognosis for relapsed or refractory adult patients is very poor, with a median survival of just six months.<sup>viii</sup> Gilead Canada received approval for YESCARTA in Canada in February, 2019.

"CAR T therapy is a personalized treatment option that could offer a significant benefit to patients with certain rare and aggressive forms of relapsed or refractory non-Hodgkin lymphoma," said Dr. John Kuruvilla, MD, FRCPC, ZUMA-1 Investigator and Hematologist in the Division of Medical Oncology and Hematology at the Princess Margaret Cancer Centre. "For these patients, the prognosis is very poor, even a year or less. With access to YESCARTA, they have a new and potentially life changing opportunity."

The approval of YESCARTA was based on one-year follow-up data (median of 15.4 months) from the pivotal ZUMA-1 trial of axicabtagene ciloleucel in adult patients with refractory large B-cell lymphoma. Data from the two-year (median of 27.1 months) follow-up of ZUMA-1 showed that 74 per cent (n=75/101) of adult patients with relapsed or refractory large B-cell lymphoma treated with a single infusion of YESCARTA responded to therapy, with 54 per cent achieving a complete response.ix

In the ZUMA-1 trial the most common Grade 3 or higher adverse reactions include encephalopathy (30%), unspecified pathogen infection (19%), hypotension (15%), fever (14%), cytokine release syndrome (12%), hypoxia (10%), bacterial infection (8%), aphasia (7%), arrhythmia (6%), viral infection (6%), delirium (6%), and hypertension (6%).x Grade 3 or higher prolonged cytopenias (still present at Day 30 or with an onset at Day 30 or beyond) included neutropenia (31%), thrombocytopenia (27%), and anemia (17%).xi

"Today's announcement offers new hope for patients with certain types of relapsed and refractory lymphomas, who previously faced a dire prognosis," said Antonella Rizza, CEO at Lymphoma Canada. "By taking this step, the Ontario government is ensuring Canadians in this province have access to this new and potentially transformative treatment option."

In the ZUMA-1 pivotal trial, Kite demonstrated a 99 per cent manufacturing success rate with a median manufacturing turnaround time of 17 daysxii.

### **Important Safety Information**

The YESCARTA Product Monograph has a **SERIOUS WARNINGS AND PRECAUTIONS BOX** regarding the risks of:

Cytokine Release Syndrome (CRS), including fatal or life-threatening reactions, occurred in patients receiving YESCARTA. Delay YESCARTA treatment if a patient has active uncontrolled infection or inflammatory disorders, active graft-versus-host disease (GVHD) or unresolved serious adverse reactions from prior therapies. Monitor for CRS after treatment with YESCARTA. Provide supportive care, tocilizumab, or tocilizumab and corticosteroids, as needed.xiii

Neurologic adverse reactions, including fatal or life-threatening reactions, occurred in patients receiving YESCARTA, including concurrently with CRS or independently of CRS. Monitor for neurologic adverse reactions after treatment with YESCARTA. Provide supportive care, tocilizumab (if with concurrent CRS), or corticosteroids, as needed.xiv

YESCARTA should be administered by experienced health professionals at specialized treatment centres.xv

For all important safety information for YESCARTA, including contraindications, warnings and precautions, adverse reactions and drug interactions, please see the Canadian Product Monograph at [www.gilead.ca](http://www.gilead.ca).



## **About Kite**

Kite, a Gilead Company, is a biopharmaceutical company based in Santa Monica, California. Kite is engaged in the development of innovative cancer immunotherapies. The company is focused on chimeric antigen receptor and T cell receptor engineered cell therapies. For more information on Kite, please visit [www.kitepharma.com](http://www.kitepharma.com).

## **About Gilead Sciences**

Gilead Sciences, Inc. is a research-based biopharmaceutical company that discovers, develops and commercializes innovative medicines in areas of unmet medical need. The company strives to transform and simplify care for people with life-threatening illnesses around the world. Gilead has operations in more than 35 countries worldwide, with headquarters in Foster City, California. Gilead Sciences Canada, Inc. is the Canadian affiliate of Gilead Sciences, Inc., and was established in Mississauga, Ontario, in 2006. For more information on Gilead Sciences, please visit the company's website at [www.gilead.com](http://www.gilead.com).

## **Forward-Looking Statement**

This press release includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 that are subject to risks, uncertainties and other factors, including the risk that physicians and patients may not see the benefits of YESCARTA as a treatment option for the indications for which it is approved; the ability to provide final site certification to specialized centres across Canada enabling them to make YESCARTA available to appropriate patients in the anticipated timelines or at all; the ability of Kite to continue to manufacture YESCARTA at the success rates experienced during clinical trials; and the possibility of unfavorable results from ongoing and additional clinical trials involving YESCARTA. All statements other than statements of historical fact are statements that could be deemed forward-looking statements. These risks, uncertainties and other factors could cause actual results to differ materially from those referred to in the forward-looking statements. The reader is cautioned not to rely on these forward-looking statements. These and other risks are described in detail in Gilead's Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 as filed with the U.S. Securities and Exchange Commission. All forward-looking statements are based on information currently available to Gilead, and Gilead assumes no obligation to update any such forward-looking statements.

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Learn more about Gilead at [www.gilead.com](http://www.gilead.com), follow Gilead on Twitter (@GileadSciences) or call Gilead Public Affairs at 1-800-GILEAD-5 or 1-650-574-3000. For more information on Kite, please visit the company's website at [www.kitepharma.com](http://www.kitepharma.com). Follow Kite on social media on Twitter (@KitePharma) and LinkedIn.

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- i YESCARTA® product monograph, February 13, 2019, revised March 18, 2020 ([www.gilead.ca](http://www.gilead.ca))
- ii Leukemia & Lymphoma Society (LLS). Chimeric antigen receptor (CAR) T-cell therapy. 2019. Available at: <https://www.lls.org/treatment/types-of-treatment/immunotherapy/chimeric-antigen-receptor-car-t-cell-therapy>. Accessed March 2020.
- iii Locke F. et al. Long-term safety and activity of axicabtagene ciloleucel in refractory large B-cell lymphoma (ZUMA-1): a single-arm, multicentre, phase 1-2 trial. *The Lancet Oncol.* 2019 Jan; 20(1):31-42.
- iv Lymphoma Research Foundation (LRF). Diffuse Large B-Cell Lymphoma (DLBCL). 2018. Available at: [https://lymphoma.org/wp-content/uploads/2018/05/LRF\\_FACTSHEET\\_DIFFUSE\\_LRG\\_BCELL\\_LYMPHOMA\\_DLBC.pdf](https://lymphoma.org/wp-content/uploads/2018/05/LRF_FACTSHEET_DIFFUSE_LRG_BCELL_LYMPHOMA_DLBC.pdf). Accessed March 2020.
- v Menon M. et al. The Histological and Biological Spectrum of Diffuse Large B-cell Lymphoma in the WHO Classification. *Cancer J.* 2012 Sept;18(5):411–420.
- vi Menon M. et al. The Histological and Biological Spectrum of Diffuse Large B-cell Lymphoma in the WHO Classification. *Cancer J.* 2012 Sept;18(5):411–420.
- vii Canadian Cancer Society: Non-Hodgkin Lymphoma statistics. Available at: <https://www.cancer.ca/en/cancer-information/cancer-type/non-hodgkin-lymphoma/statistics/?region=on> Accessed March 2020
- viii Crump M. et al, Outcomes in refractory diffuse large B-cell lymphoma: results from the international SCHOLAR-1 study. *Blood.* 2017 Oct. 130(16): 1800–1808.
- ix YESCARTA® product monograph, February 13, 2019, revised March 18, 2020 ([www.gilead.ca](http://www.gilead.ca)).
- x IBID
- xi IBID
- xii Neelapu, SS, Locke, FL, Bartlett, NL, et al. *New England Journal of Medicine.* "Axicabtagene Ciloleucel CAR T-Cell Therapy in Refractory Large B-Cell Lymphoma." Available at: <http://www.bloodjournal.org/content/130/16/1800>  
<https://www.nejm.org/doi/full/10.1056/NEJMoa1707447/>. Accessed: May 14, 2020.
- xiii YESCARTA® product monograph, February 13, 2019, revised March 18, 2020 ([www.gilead.ca](http://www.gilead.ca)).
- xiv IBID
- xv IBID
- SOURCE Gilead Sciences Canada, Inc.