

PRESS RELEASE

ABBVIE'S NEW ORAL THERAPY VENCLEXTA™ NOW AVAILABLE FOR CANADIANS WITH A DIFFICULT-TO-TREAT BLOOD CANCER

- Nearly 2,200 cases of chronic lymphocytic leukemia (CLL) are diagnosed every year in Canada.¹
- Up to 50% of previously treated CLL patients have a genetic mutation, known as 17p deletion, which results in a faster moving disease and a life expectancy of only four years²
- In phase 2 clinical trials, CLL patients taking VENCLEXTA had an overall response rate of 79%³
- Health Canada's approval of VENCLEXTA reinforces AbbVie's growing position in hematologic oncology

Montreal, QC, October 5, 2016 –AbbVie, a global biopharmaceutical company, today announced Health Canada has issued a Notice of Compliance with Conditions (NOC/c) for VENCLEXTA™ (venetoclax). The therapy has been approved for previously treated chronic lymphocytic leukemia (CLL) patients, who have either a genetic mutation, known as 17p deletion, or no other available treatment options. Under NOC/c policy, AbbVie will provide Health Canada with data from additional studies to confirm the clinical benefit of VENCLEXTA.

VENCLEXTA is a first-in-class, oral, once-daily medicine that works differently than all other approved therapies. It selectively inhibits the BCL-2 protein, which is responsible for helping cancer cells survive in the blood. The BCL-2 protein blocks apoptosis (programmed cell death) of cells, including some cancer cells that can be overexpressed in CLL. In phase 2 clinical trials, patients taking VENCLEXTA had an overall response rate of 79%.⁴

"I've been battling CLL since 2008. A few months after diagnosis, I underwent chemotherapy. It worked fine until I relapsed in 2013," said Lewis Backler, a 74-year-old CLL patient in Montreal, QC. "I was so happy when my oncologist suggested I try a new targeted therapy. VENCLEXTA has been highly effective for me. Since I started the treatment two years ago, my white blood cell counts have improved to where they should be and my symptoms have all but disappeared. I feel great. I feel as good as anyone feels. I've been enjoying the usual summer activities with family and friends."

CLL is one of the most common types of leukemia in adults.

In Canada, CLL accounts for approximately 2,200 newly diagnosed cases of leukemia each year and is responsible for more than 600 deaths a year.⁵ The 17p deletion is a genetic mutation that is found in 3 to 10 percent of people with previously untreated CLL and up to 50 percent of relapsed or refractory cases.^{6,7} Patients with the deletion typically have a faster moving disease and a life expectancy of four years⁸. There is no cure for CLL. The goal of treatment is to delay progression of the disease and improve quality of life.

“Based on the efficacy and safety profile observed in clinical trials, VENCLEXTA is proving to be a highly valuable therapy for relapsed/refractory CLL patients, who have few, and in some cases, no treatment options available to them,” said Dr. April Shamy, hematologist at Montreal’s Jewish General Hospital, a McGill University teaching hospital, and participating physician in the VENCLEXTA clinical trial program. “Furthermore because VENCLEXTA is an oral medication, it is much more convenient for patients than intravenous therapies, which are often disruptive to patients’ lives.”

CLL is typically a slow-progressing cancer of the bone marrow and blood.⁹

In CLL, certain types of white blood cells, called lymphocytes, become cancerous and multiply abnormally. Symptoms include:

- Tiredness, weakness and shortness of breath resulting from anemia
- Weight loss
- Enlarged lymph nodes and spleen due to accumulation of CLL cells
- Weakened immune system, leading to serious infections (Infections account for 30% to 50% of disease related deaths)¹⁰

“BCL-2 inhibition is an exciting new mechanism of action,” said Stéphane Lassignardie, General Manager of Abbvie Canada. “The latest research underscores AbbVie’s growing hematology portfolio and our commitment to change the way blood cancer is treated with innovative new treatment options.”

VENCLEXTA Clinical Trial Program

The safety and efficacy of VENCLEXTA was evaluated in an open-label, multicenter clinical trial of 106 previously-treated CLL patients with 17p deletion. The median time on treatment at the time of evaluation was 12.1 months (range: 0 to 21.5 months). The primary efficacy endpoint, overall response rate (ORR), was 79 percent. The median time to first response was 0.8 months (range: 0.1 to 8.1 months). Median duration of response (DOR) has not been reached with approximately 12 months of median follow-up. The DOR ranged from 2.9 to 19.0+ months. The safety of VENCLEXTA is based on pooled data from 240 patients with previously treated CLL from two phase 2 clinical trials and one phase 1 trial. The most common adverse reactions (≥20%) were neutropenia (low white blood cell count), diarrhea, nausea, and fatigue. The most frequent serious adverse reactions (≥2%) were pneumonia, low white blood cell count with fever (febrile neutropenia), and fever. Tumor lysis syndrome (TLS) is an important, identified risk when initiating VENCLEXTA. TLS is caused by the fast breakdown of cancer cells. In 66 CLL patients starting with a daily dose of 20 mg and increasing over five weeks to a daily dose of 400 mg, the rate of TLS was 6 percent. All events either met laboratory TLS criteria or were reported as TLS events by the physician. No TLS with clinical consequences was observed in these patients.¹¹

VENCLEXTA is being developed by AbbVie and Genentech, a member of the Roche Group. It is jointly commercialized by the companies in the U.S. and by AbbVie outside of the U.S.

About AbbVie Care

Abbvie Care is a support program designed for people taking VENCLEXTA who live with Chronic Lymphocytic Leukemia, as well as their caregivers. This program provides a wide range of customized

services throughout the treatment journey. AbbVie Care services complement the offering of the health care professional team. For more information, call 1-844-346-ONCO or consult www.abbviecare.ca. Please note that a compassionate program is available; criteria may apply – please inquire with your treating physician for eligibility.

About AbbVie in Oncology

AbbVie is striving to outsmart cancer by working with scientists, physicians, industry peers, patient advocacy groups and most importantly patients, to discover, develop and provide new therapies that will have a remarkable impact on the lives of people around the world affected by cancer. Our goal is to provide medicines that make a transformational improvement in cancer treatment and outcomes for cancer patients. By exploring and investing in new pathways, technologies and approaches, AbbVie is breaking ground in some of the most widespread and difficult-to-treat cancers. We are also exploring solutions to help patients obtain access to our cancer medicines. With the acquisition of Pharmacyclics in 2015 and Stemcentrx in 2016, and through several collaborations, AbbVie's oncology portfolio consists of marketed medicines and a pipeline containing multiple new molecules being evaluated worldwide in nearly two hundred clinical trials in 20 different tumor types. For more information about AbbVie Oncology, please visit <https://abbvieoncology.com>.

About AbbVie

AbbVie is a new global, research-based biopharmaceutical company formed in 2013 following separation from Abbott Laboratories. The company's mission is to use its expertise, dedicated people and unique approach to innovation to develop and market advanced therapies that address some of the world's most complex and serious diseases. Together with its wholly-owned subsidiary, Pharmacyclics, AbbVie employs more than 28,000 people worldwide and markets medicines in more than 170 countries. For further information on the company and its people, portfolio and commitments, please visit www.abbvie.ca and www.abbvie.com. Follow @abbvie and @abbviecanada on Twitter or view careers on our Facebook or LinkedIn page.

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¹ Canadian Cancer Statistics, 2015 <http://www.cancer.ca/en/cancer-information/cancer-type/leukemia-chronic-lymphocytic-cll/statistics/?region=on>

² Döhner H et al. N Engl J Med 2000;343:1910-1916

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- ³ VENCLEXTA product monograph, AbbVie Corporation, September 27, 2016
- ⁴ VENCLEXTA product monograph, AbbVie Corporation, September 27, 2016
- ⁵ Canadian Cancer Statistics, 2015 <http://www.cancer.ca/en/cancer-information/cancer-type/leukemia-chronic-lymphocytic-cl/statistics/?region=on>
- ⁶ Schnaiter A. et al. 17p deletion in chronic lymphocytic leukemia: risk stratification and therapeutic approach. *Hematol Oncol Clin N Am.* 2013;27:289–301.
- ⁷ American Cancer Society (2015). Leukemia – Chronic Lymphocytic. <http://www.cancer.org/acs/groups/cid/documents/webcontent/003111-pdf.pdf>
- ⁸ Döhner H et al. *N Engl J Med* 2000;343:1910-1916
- ⁹ Lymphoma Canada. Chronic lymphocytic leukemia. Available at <http://www.lymphoma.ca/lymphoma/lymphoma-101/types-lymphoma/cl>
- ¹⁰ Leukemia & Lymphoma Society of Canada. Chronic lymphocytic leukemia. Available at <http://www.llscanada.org/leukemia/chronic-lymphocytic-leukemia?src1=20032&src2=>
- ¹¹ VENCLEXTA product monograph, AbbVie Corporation, September 27, 2016