

## NEWS RELEASE

### ABBVIE RECEIVES APPROVAL FROM HEALTH CANADA FOR THE COMBINATION OF VENCLEXTA® WITH RITUXIMAB AS A TREATMENT FOR PATIENTS WITH CHRONIC LYMPHOCYTIC LEUKEMIA

- In the MURANO Phase 3 clinical trial, the VENCLEXTA® (venetoclax) plus rituximab combination showed a significant improvement in progression-free survival (PFS, the time on treatment without disease progression or death) for relapsed/refractory (R/R) chronic lymphocytic leukemia (CLL) patients,
- The combination of VENCLEXTA plus rituximab reduced the risk of disease progression or death by 81 percent when compared to a standard of care chemoimmunotherapy regimen, bendamustine plus rituximab.<sup>i</sup>
- Patients receiving VENCLEXTA plus rituximab achieved a high overall response rate (ORR) of 92 percent.<sup>i</sup>
- With this approval, VENCLEXTA plus rituximab is the first chemotherapy-free combination with a 24-month treatment duration for CLL.
- Approximately 2,400 cases of chronic lymphocytic leukemia (CLL) are diagnosed every year in Canada.<sup>ii</sup>

**Montreal, QC, September 25, 2018** –AbbVie (NYSE: ABBV), a global research and development-based biopharmaceutical company, today announced Health Canada has issued a Notice of Compliance for VENCLEXTA® (venetoclax) in combination with rituximab for the treatment of adult patients with chronic lymphocytic leukemia (CLL) who have received at least one prior therapy.<sup>i</sup>

“Having another effective therapy for relapsed/refractory CLL is a great benefit to patients. It is also valuable to have this new therapy be of fixed duration because most patients prefer not to have to remain on therapy indefinitely” explains Dr. Carolyn Owen, MD, MDres(UK), FRCPC, a Hematologist and associate professor at the University of Calgary. “With venetoclax plus rituximab, I can now offer my patients an effective treatment with a clear end-date, allowing patients to plan for the future and enjoy time off therapy.”

The approval is based on the MURANO Phase 3 clinical trial data which demonstrated a significant improvement in progression-free survival (PFS, the time on treatment without disease progression or death) for relapsed/refractory (R/R) CLL patients, reducing the risk of disease progression or death by 81 percent when compared to bendamustine in combination with rituximab, a standard of care chemoimmunotherapy regimen.<sup>i</sup>

“Lymphoma Canada is pleased with the approval of VENCLEXTA in combination with rituximab for the treatment of chronic lymphocytic leukemia. Due to the nature of the disease and its high relapse rate, it is imperative to offer patients effective treatment options so that they can face their cancer journey with the comfort of knowing that there are always alternatives,” says Elizabeth Lye, Scientific Advisor, Lymphoma Canada.

Clinical trial patients who received VENCLEXTA plus rituximab achieved an overall response rate (ORR) of 92 percent and those who received the bendamustine plus rituximab regimen achieved an ORR of

72 percent.<sup>i</sup> The most common adverse reactions (ARs), greater than or equal to 20 percent, with a 5 percent higher frequency reported with VENCLEXTA in combination with rituximab were neutropenia, diarrhea and upper respiratory tract infection.<sup>i</sup>

“When my CLL relapsed for the second time, I was fortunate to have access to VENCLEXTA in combination with rituximab,” explains Mark Silverstein of Aurora, ON. “Today, I am able to enjoy an improved quality of life, and do what brings a great deal of meaning to my life: to help others navigate through their cancer journey with confidence and dignity by encouraging them to advocate for themselves within the health care system, reflect on the potential benefits in understanding their cancer and treatment landscape, to assist in managing the emotional and spiritual effects of a diagnosis, and finally to help them find what is meaningful in their own lives.”

In Canada, CLL accounts for approximately 2,400 newly diagnosed cases of leukemia each year and is responsible for more than 600 deaths a year.<sup>ii</sup> The goal of treatment is to delay progression of the disease and improve quality of life.

“VENCLEXTA plus rituximab is the first chemotherapy-free combination in CLL that allows patients a 24-month treatment duration,” says Stéphane Lassignardie, General Manager of Abbvie Canada. “The approval of this regimen will bring a much needed treatment option to Canadians living with CLL.”

VENCLEXTA continues to be investigated in CLL and other hematological diseases.

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

#### **About the MURANO Study**

A total of 389 patients with R/R CLL who had received at least one prior therapy were enrolled in the international, multicenter, open-label, randomized (1:1) MURANO study (NCT02005471). The study was designed to evaluate the efficacy and safety of VENCLEXTA in combination with rituximab (194 patients) compared with bendamustine in combination with rituximab (195 patients). The median age of patients in the trial was 65 years (range 22-85).<sup>i</sup>

#### **About AbbVie Care**

Canadians prescribed VENCLEXTA will have the opportunity to be enrolled in AbbVie Care, AbbVie's signature care program. The program is designed to provide a wide range of customized services including reimbursement and financial support, pharmacy services, lab work reminders and coordination, personalized education and ongoing disease management support throughout the treatment and beyond. For more information, please visit [www.abbviecare.ca](http://www.abbviecare.ca).

#### **About AbbVie**

Abbvie is a global, research and development-driven biopharmaceutical company committed to developing innovative advanced therapies for some of the world's most complex and critical conditions. The company's mission is to use its expertise, dedicated people and unique approach to innovation to markedly improve treatments across four primary therapeutic areas: immunology, oncology, virology and neuroscience. In more than 75 countries, AbbVie employees are working every day to advance health solutions for people around the world. For more information about AbbVie, please visit us at [www.abbvie.ca](http://www.abbvie.ca) and [www.abbvie.com](http://www.abbvie.com). Follow [@abbvieCanada](https://twitter.com/abbvieCanada) and [@abbvie](https://twitter.com/abbvie) on Twitter or view careers on our [Facebook](https://www.facebook.com/abbvie) or [LinkedIn](https://www.linkedin.com/company/abbvie) page.

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<sup>i</sup> VENCLEXTA product monograph, AbbVie Corporation, September 21, 2018

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