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PRESS RELEASE

AbbVie Receives Health Canada Approval for the Combination of VENCLEXTA® (venetoclax) with Obinutuzumab for Patients with Previously Untreated Chronic Lymphocytic Leukemia

- VENCLEXTA® (venetoclax) plus obinutuzumab is the first chemotherapy-free, fixed-duration combination regimen approved by Health Canada for patients with previously untreated chronic lymphocytic leukemia (CLL).
- Approval is based on data from the Phase 3 CLL14 trial, which showed that patients treated with obinutuzumab plus one year of treatment with VENCLEXTA had clinically meaningful and statistically significant progression-free survival (PFS) and higher rates of undetectable minimal residual disease compared to patients receiving a standard of care chemoimmunotherapy regimen of obinutuzumab and chlorambucil.[1]

Montreal, QC, May 5, 2020 – AbbVie (NYSE: ABBV), a research-based global biopharmaceutical company, announced today that Health Canada has approved VENCLEXTA® (venetoclax) in combination with obinutuzumab for the treatment of adult patients with previously untreated chronic lymphocytic leukemia (CLL). The regimen combines six 28-day cycles of obinutuzumab with 12 cycles of VENCLEXTA.

“Venetoclax in combination with obinutuzumab is an effective treatment with a finite treatment duration. The approval by Health Canada is good news, especially for patients that prefer not to remain on therapy indefinitely,” explains Dr. Sue Robinson, MD, FRCPC, Professor, Division of Hematology, Department of Medicine, Dalhousie University, Halifax, Nova Scotia. “Based on my experience on the CLL14 clinical trial, I am looking forward to prescribing this combination regimen for older patients with previously untreated CLL and/or those who have concomitant medical problems”.

This is the third indication for VENCLEXTA, a first-in-class B-cell lymphoma-2 (BCL-2) inhibitor. BCL-2 is a protein that prevents cancer cells from undergoing apoptosis, the process that leads to the natural death or self-destruction of cancer cells. VENCLEXTA is also approved in combination with rituximab for the treatment of adult patients with CLL who have received at least one prior therapy, and as a monotherapy for the treatment of CLL in the presence or absence of 17p deletion in adult patients who have received at least one prior therapy and for whom there are no other available treatment options.[1]

“Lymphoma Canada is pleased with the approval of VENCLEXTA in combination with obinutuzumab by Health Canada for the treatment of chronic lymphocytic leukemia. Due to the nature of the disease and its high relapse rate, it is important 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 Antonella Rizza, Chief Executive Officer, Lymphoma Canada.

This most recent approval is based on the primary analysis (median follow up of 28 months) of the Phase 3 CLL14 clinical trial, which demonstrated clinically meaningful and statistically significant progression-free survival (PFS; the time during and after treatment without disease progression, relapse, or death) as assessed by investigators in patients treated with VENCLEXTA plus obinutuzumab compared

to patients who received a standard of care chemotherapy regimen of chlorambucil plus obinutuzumab (hazard ratio 0.35; 95% CI (0.23,0.53), p<0.0001, medians not yet reached).[1]

“We are extremely proud of the Health Canada approval of VENCLEXTA in combination with obinutuzumab,” said Denis Hello, General Manager, AbbVie Canada. “This third approval for VENCLEXTA underscores our commitment to develop blood cancer treatments.”

CLL, which is typically a slow-progressing cancer of the bone marrow and blood[2], is one of the most common types of leukemia in adults. In Canada, CLL accounts for approximately 1,745 newly diagnosed cases of leukemia each year and is responsible for more than 600 deaths a year.[3]

VENCLEXTA 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 CLL14 Trial
The randomized, multicenter, open-label, actively controlled Phase 3 CLL14 trial, which was conducted in close collaboration with the German CLL Study Group (DCLLSG), evaluated the efficacy and safety of a combined regimen of VENCLEXTA and obinutuzumab (n=216) versus obinutuzumab and chlorambucil (n=216) in patients with previously-untreated CLL and coexisting medical conditions (total Cumulative Illness Rating Scale [CIRS] score >6 or creatinine clearance <70 mL/min). The therapies were administered for a fixed duration of 12 cycles for VENCLEXTA in combination with six cycles of obinutuzumab. Cycles were comprised of 28 days. The trial enrolled 432 patients, all of whom were diagnosed according to the International Workshop on Chronic Lymphocytic Leukemia (iwCLL) criteria and were previously untreated. The primary efficacy outcome was PFS as assessed by the investigator.[4] Key secondary endpoints included MRD-negativity in peripheral blood and bone marrow, and overall and complete response rates.[4,5]

About AbbVie Care
Canadians prescribed VENCLEXTA can 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. For more information, please visit www.abbviecare.ca.

About AbbVie in Oncology
At AbbVie, we strive to discover and develop medicines that deliver transformational improvements in cancer treatment by uniquely combining our deep knowledge in core areas of biology with cutting-edge technologies, and by working together with our partners – scientists, clinical experts, industry peers, advocates, and patients. We remain focused on delivering these transformative advances in treatment across some of the most debilitating and widespread cancers. We are also committed to exploring solutions to help patients obtain access to our cancer medicines. AbbVie's oncology portfolio now consists of marketed medicines and a pipeline containing multiple new molecules being evaluated worldwide in more than 300 clinical trials and more than 20 different tumor types.

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 and www.abbvie.com. Follow @abbvieCanada and @abbvie on Twitter or view careers on our Facebook or LinkedIn page.

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[2] Lymphoma Canada. Chronic lymphocytic leukemia. www.lymphoma.ca/lymphoma/lymphoma-101/types-lymphoma/cll. Accessed May 2020.
[3] Canadian Cancer Statistics. Chronic lymphocytic leukemia statistics. www.cancer.ca/en/cancer-information/cancer-type/leukemia-chronic-lymphocytic-cll/statistics/?region=on. Accessed May 2020.
[4] Fischer K, et al. Effect of fixed-duration venetoclax plus obinutuzumab (VenG) on progression-free survival (PFS), and rates and duration of minimal residual disease negativity (MRD–) in previously untreated patients (pts) with chronic lymphocytic leukemia (CLL) and comorbidities. Presented at the 2019 American Society of Clinical Oncology Annual Meeting: June 4, 2019; Chicago.
[5] N Engl J Med 2019;380:2225-36. DOI: 10.1056/NEJMoa1815281