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PRESS RELEASE

AbbVie Receives a Positive Reimbursement Recommendation from the Canadian Agencies for Drugs and Technology in Health (CADTH) pan-Canadian Oncology Drug Review Expert Review Committee (pERC) for VENCLEXTA® (venetoclax) in Combination with azacitidine for Acute Myeloid Leukemia (AML) patients

- pERC recommends reimbursement of VENCLEXTA® (venetoclax) in combination with azacitidine for the treatment of newly diagnosed acute myeloid leukemia (AML) who are ineligible for intensive induction chemotherapy.
- The VIALE-A trial demonstrated a statistically significant increase in overall survival with VENCLEXTA® in combination with azacitidine compared to placebo in combination with azacitidine alone.[1]
- AML is one of the most difficult-to-treat blood cancers with a very low survival rate.[2,4]

Montreal, QC, August 26, 2021 – AbbVie (NYSE: ABBV), a research-based global biopharmaceutical company, announced today that the CADTH pCODR Expert Review Committee (pERC) recommends that VENCLEXTA® (venetoclax) in combination with azacitidine should be reimbursed for the treatment of patients with newly diagnosed acute myeloid leukemia (AML) who are 75 years or older, or who have comorbidities that preclude use of intensive induction chemotherapy, only if the conditions listed are met.[3] AML is an aggressive and difficult-to-treat blood cancer with a low survival rate.[2,4] In Canada, the five-year net survival rate is approximately 21% for people diagnosed with AML in the general population.[4]

“AML is one of the most common types of leukemia in adults. This cancer progresses rapidly and has a significantly lower survival rate compared to other cancers,” said Dr. Joseph Brandwein, Hematology Division Director and Professor in the Department of Medicine at the University of Alberta. “The average age is nearly 70, and most older AML patients are not candidates for intensive chemotherapy and stem cell transplantation. For those patients, treatments to date have not been very effective. This new regimen has demonstrated improved outcomes.”

Overall, pERC concluded that venetoclax plus azacitidine provides a treatment option for older patients and patients with comorbidities that has an impact on the disease and improves survival.[3]

“I was diagnosed in November 2019 with AML and my treatment plan included VENCLEXTA. I am hopeful that newly diagnosed AML patients will soon have access to this treatment,” said William Levine of Courtice, Ontario.

In the VIALE-A trial, the median overall survival of patients who received VENCLEXTA plus azacitidine was 14.7 months (95% CI, 11.9, 18.7) vs 9.6 months (95% CI, 7.4, 12.7) in patients who received azacitidine in combination with placebo. In the VENCLEXTA plus azacitidine arm, the most frequent serious adverse reactions (≥ 5%) were febrile neutropenia (30%), pneumonia (23%), sepsis (16%) and hemorrhage (9%).[1]

“We have reached another important milestone. With this positive recommendation by the pCODR Expert Review Committee, we are one step closer to providing this treatment to all Canadians who need it. At AbbVie, we stand by our mission to transform the standard of care for people living with cancer,” said Tracey Ramsey, Vice President and General Manager, AbbVie Canada.

VENCLEXTA in combination with azacitidine was approved by Health Canada in December 2020. Health Canada’s approval was granted under Project Orbis, an FDA initiative which provides a framework for concurrent submission and review of oncology products among international partners.

Venetoclax 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 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 consists of marketed medicines and a robust pipeline containing multiple new molecules being evaluated worldwide in more than 300 clinical trials and more than 20 different tumor types.

About AbbVie
AbbVie’s mission is to discover and deliver innovative medicines that solve serious health issues today and address the medical challenges of tomorrow. We strive to have a remarkable impact on people’s lives across several key therapeutic areas: immunology, oncology, neuroscience, eye care, virology, women’s health and gastroenterology, in addition to products and services across its Allergan Aesthetics portfolio. For more information about AbbVie, please visit us at www.abbvie.ca. Follow @abbviecanada on Twitter or find us on Facebook, Instagram, YouTube and LinkedIn.

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[1] AbbVie Corporation Venclexta(R) (venetoclax) Product Monograph. Date of Preparation: September 27, 2016. Date of Revision: January 21, 2021. https://www.abbvie.ca/content/dam/abbvie-dotcom/ca/en/documents/products/VENCLEXTA_PM_EN.pdf. Accessed August 26, 2021.
[2] Leukemia & Lymphoma Society of Canada. Acute myeloid leukemia (AML). https://www.llscanada.org/leukemia/acute-myeloid-leukemia. Accessed August 26, 2021.
[3] CADTH. https://www.cadth.ca/venetoclax. Accessed August 26, 2021.
[4] Canadian Cancer Society. Survival statistics for acute myelogenous leukemia. https://www.cancer.ca/en/cancer-information/cancer-type/leukemia-acute-myelogenous-aml/prognosis-and-survival/survival-statistics/?region=on. Accessed August 26, 2021.