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PRESS RELEASE

Health Canada Approves VENCLEXTA® (venetoclax) in combination with azacitidine or low dose cytarabine for untreated Acute Myeloid Leukemia (AML)

- Health Canada's approval of VENCLEXTA for newly diagnosed AML patients who are ineligible for intensive chemotherapy is supported by data from two Phase 3 trials - VIALE-A (M15-656) and VIALE-C (M16-043)[1].
- The VIALE-A trial demonstrated a statistically significant increase in overall survival with VENCLEXTA in combination with azacitidine compared to azacitidine alone.[1]
- In the VIALE-C trial, clinical benefit was based on rate and duration of complete response.[1]
- AML is one of the most difficult-to-treat blood cancers with a very low survival rate.[2,3]

Montreal, QC, December 15, 2020 – AbbVie (NYSE: ABBV), a research-based global biopharmaceutical company, announced today that Health Canada has approved VENCLEXTA® (venetoclax) in combination with azacitidine or low-dose cytarabine (LDAC) for the treatment of newly-diagnosed acute myeloid leukemia (AML) in adults who are age 75 years or older, or who have comorbidities that preclude the use of intensive induction chemotherapy. AML is an aggressive and difficult-to-treat blood cancer with a low survival rate.[2,3] In Canada, the five-year survival rate for patients diagnosed with AML is approximately 21%.[3]

"AML is one of the most common types of leukemia in adults. AML progresses rapidly and has a significantly lower survival rate compared to other cancers. Having more effective treatment options for AML patients will improve treatment outcomes for Canadians and extend lives," said Dr. Brian Leber, Head of Leukemia Service at the Juravinski Hospital and Cancer Centre.

In the VIALE-A trial, the median overall survival of patients who received VENCLEXTA plus azacitidine was 14.7 months (11.9, 18.7) vs 9.6 months (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].

"With limited treatment options, it makes me very happy to know that VENCLEXTA has been approved to treat others, like me, who are diagnosed with AML," said William Levine of Courtice, Ontario.

In the VIALE-C trial, clinical benefit was based on the rate of complete responses (CR) and duration of CR, with supportive evidence of the rate of CR + CRi (complete remission with incomplete blood count recovery), duration of CR + CRi and the rate of conversion from transfusion dependence to transfusion independence. 27 % of patients achieved CR in the VENCLEXTA plus LDAC arm vs 7% of patients treated with Placebo+ LDAC. In the VENCLEXTA + LDAC arm, most frequent serious adverse (≥ 5%) were pneumonia (18%), febrile neutropenia (16%), sepsis (11%), hemorrhage (9%), and thrombocytopenia (5%)[1].

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"Every day, we aim to transform the standard of care for people living with cancer," said Denis Hello, Vice President and General Manager, AbbVie Canada. "Having effective and proven treatment options is vital for patients and their families impacted by AML."

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

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[1] AbbVie Corporation Venclexta(R) (venetoclax) Product Monograph. Date of Preparation: September 27, 2016. Date of Revision: December 3, 2020.
[2] Leukemia & Lymphoma Society of Canada. Acute myeloid leukemia (AML). https://www.llscanada.org/leukemia/acute-myeloid-leukemia. Accessed November 25, 2020.
[3] 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 November 25, 2020.