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IMBRUVICA® (ibrutinib) Combination Regimen to Treat Waldenström's Macroglobulinemia Approved Through Health Canada Priority Review

IMBRUVICA plus rituximab showed significant improvement in progression-free survival versus rituximab monotherapy in Waldenström's macroglobulinemia, a rare blood cancer

Toronto, ON, March 8, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced the Health Canada approval of IMBRUVICA® (ibrutinib) in combination with rituximab for the treatment of Waldenström's macroglobulinemia (WM).[1] The approval expands the indication of IMBRUVICA in WM, which in 2016 became the first Bruton's tyrosine kinase (BTK) inhibitor approved for this rare blood cancer. This approval, which was expedited through a Priority Review designation by Health Canada, is for the eighth indication for IMBRUVICA in Canada. IMBRUVICA is jointly developed and commercialized by Janssen Biotech, Inc. and Pharmacyclics LLC, an AbbVie company. Janssen Inc. markets ibrutinib in Canada.

Waldenström's macroglobulinemia is a slow-growing and incurable form of non-Hodgkin lymphoma (NHL); its cause is unknown.[2] Typically, patients with WM are diagnosed after developing symptoms such as anemia, fatigue and night sweats.[3]

"WM is a rare form of blood cancer for which treatment options are limited," said Chaim Shustik, M.D., FRCP(C), Professor of Medicine, McGill University, Division of Hematology, Royal Victoria Hospital. "The latest clinical data show significant improvement in progression-free survival with IMBRUVICA in combination with rituximab, compared to rituximab alone, for both first line and later lines of treatment. IMBRUVICA offers an

important new option for physicians to consider in the treatment of Canadians living with this challenging disease."

The approval is based on results from the randomized, double-blind, placebo-controlled iNNOVATE study (PCYC-1127), the largest Phase 3 study of a non-chemotherapy combination in patients living with WM. The iNNOVATE study evaluated IMBRUVICA in combination with rituximab versus placebo plus rituximab in 150 patients with either relapsed/refractory (r/r) disease or previously untreated WM.[4] At a median follow-up of 26.5 months, a significant improvement in the Independent Review Committee (IRC)-assessed primary endpoint of progression-free survival (PFS) was seen with IMBRUVICA plus rituximab when compared with placebo plus rituximab.[5] Patients in the IMBRUVICA plus rituximab treatment arm experienced an 80 per cent reduction in relative risk of disease progression or death compared with patients treated with placebo plus rituximab (hazard ratio=0.20; confidence interval, 0.11-0.38, p<0.0001).[6] The median progression-free survival was 20.3 months (95 per cent confidence interval, 13.7 to 27.6 months) in the placebo plus rituximab arm, and was not reached in the IMBRUVICA plus rituximab arm (95 per cent confidence interval, 35.0 months to not estimable).[7] The data was presented in an oral session at the 2018 American Society of Clinical Oncology (ASCO) Annual Meeting, selected for Best of ASCO 2018 Meetings, and simultaneously published in *The New England Journal of Medicine*.

The adverse reactions reported in the Phase 3 iNNOVATE study reflect treatment with IMBRUVICA plus rituximab for a median duration of 25.8 months.[8] The most common adverse reactions (occurring in 20 per cent or more of patients with an incidence of at least 5 per cent greater than the placebo plus rituximab arm) of all grades in patients treated with IMBRUVICA plus rituximab in the iNNOVATE study were bruising (37 per cent), musculoskeletal pain (35 per cent), hemorrhage (32 per cent), diarrhea (28 per cent), rash (24 per cent), arthralgia (24 per cent), nausea (21 per cent), and hypertension (20 per cent).[9] Grade 3 or 4 infusion-related reactions were observed in 1 per cent of patients treated with IMBRUVICA plus rituximab.[10] The most common Grade 3/4 adverse reactions (occurring in 5 per cent or more of patients with either an all-grade incidence of at least 5 per cent greater than the placebo plus rituximab arm or a serious adverse event incidence of at least 2 per cent greater than the placebo plus rituximab arm) with IMBRUVICA plus rituximab in the iNNOVATE study were hypertension (13 per cent),

pneumonia (13 per cent), atrial fibrillation (12 per cent), neutropenia (12 per cent), and anemia (11 per cent).[11]

About Waldenström's Macroglobulinemia (WM)

WM is a rare, slow-growing and incurable form of non-Hodgkin lymphoma (NHL), which comprises 1-2 per cent of all blood cancers. [12] WM typically affects older adults and is primarily found in the bone marrow, although lymph nodes and the spleen may also be affected.[13] Diagnosis of WM generally depends on a blood and urine test with a bone marrow biopsy to confirm.[14] In Canada, there are an estimated 140 new cases of WM each year.[15, 16]

About IMBRUVICA® (ibrutinib)

IMBRUVICA® contains the medicinal ingredient ibrutinib which is a targeted inhibitor of Bruton's tyrosine kinase (BTK). Ibrutinib blocks BTK activity, inhibiting cancer cell survival and spread.[17] The recommended dose of IMBRUVICA® for WM is 420 mg (three 140-mg capsules) orally once-daily until disease progression or unacceptable toxicity, as a single agent or in combination with rituximab.[18]

IMBRUVICA® was first approved in Canada in 2014 and now has eight indications. It is indicated for the treatment of patients with previously untreated active chronic lymphocytic leukemia (CLL), including those with 17p deletion; or patients with CLL who have received at least one prior therapy, including those with 17p deletion. It is also indicated in combination with bendamustine and rituximab for the treatment of patients with CLL who have received at least one prior therapy. For patients with Waldenström's macroglobulinemia (WM), IMBRUVICA® is indicated as a single agent or in combination with rituximab. Other indications are for the treatment of patients with relapsed or refractory mantle cell lymphoma (MCL); patients with marginal zone lymphoma (MZL) who require systemic therapy and have received at least one prior anti-CD20-based therapy; and for patients with steroid dependent or refractory chronic graft-versus-host disease (cGVHD).

IMBRUVICA® is co-developed by Cilag GmbH International (a member of the Janssen Pharmaceutical Companies) and Pharmacyclics LLC, an AbbVie company. Janssen Inc. markets IMBRUVICA® in Canada.

About the Janssen Pharmaceutical Companies of Johnson & Johnson

At Janssen, we're creating a future where disease is a thing of the past. We're the Pharmaceutical Companies of Johnson & Johnson, working tirelessly to make that future a reality for patients everywhere by fighting sickness with science, improving access with ingenuity, and healing hopelessness with heart. We focus on areas of medicine where we can make the biggest difference: Cardiovascular & Metabolism, Immunology, Infectious Diseases & Vaccines, Neuroscience, Oncology, and Pulmonary Hypertension. Learn more at www.janssen.com/canada. Follow us on Twitter at @JassenCanada. Janssen Inc. and Cilag GmbH International are members of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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**Dr. Shustik was not compensated for any media work. He has been compensated as a consultant.*

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding IMBRUVICA®. The reader is cautioned not to rely on these forward-looking statements. These statements are based on current expectations of future events. If underlying assumptions prove inaccurate or known or unknown risks or uncertainties materialize, actual results could vary materially from the expectations and projections of Janssen Research & Development, LLC, any of the other Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in product research and development, including the uncertainty of clinical success and of obtaining regulatory approvals; uncertainty of commercial success; manufacturing difficulties and delays; competition, including technological advances, new products and patents attained by competitors; challenges to patents; product efficacy or safety concerns resulting in product recalls or regulatory action; changes in behavior and spending patterns of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; and trends toward health care cost containment. A further list and descriptions of these risks, uncertainties and other factors can be found in Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2018, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in the company's most recently filed Quarterly Report on Form 10-Q, and the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.

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[1] IMBRUVICA® (Ibrutinib) Product Monograph, Janssen Inc. February 8, 2019.

[2] Leukemia & Lymphoma Society. "Waldenström Macroglobulinemia Facts." Available from: https://www.lls.org/sites/default/files/file_assets/FS20_Waldenstrom_2018_FINAL.pdf. Accessed January 2019.
[3] Leukemia & Lymphoma Society. "Waldenström Macroglobulinemia Facts." Available from: https://www.lls.org/sites/default/files/file_assets/FS20_Waldenstrom_2018_FINAL.pdf. Accessed January 2019.
[4] The New England Journal of Medicine. "Phase 3 Trial of Ibrutinib plus Rituximab in Waldenström's Macroglobulinemia." Available from: https://www.nejm.org/doi/full/10.1056/NEJMoa1802917. Accessed January 2019.
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[7] IMBRUVICA® (Ibrutinib) Product Monograph, Janssen Inc. February 8, 2019.
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[9] IMBRUVICA® (Ibrutinib) Product Monograph, Janssen Inc. February 8, 2019.
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[12] Leukemia & Lymphoma Society. "Waldenström Macroglobulinemia Facts." Available from: https://www.lls.org/sites/default/files/file_assets/FS20_Waldenstrom_2018_FINAL.pdf. Accessed January 2019.
[13] Leukemia & Lymphoma Society. "Waldenström Macroglobulinemia Facts." Available from: https://www.llscanada.org/sites/default/files/file_assets/FS20_Waldenstrom_M%20FINAL%206.15.pdf. Accessed January 2019.
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[18] IMBRUVICA® (Ibrutinib) Product Monograph, Janssen Inc. February 8, 2019.