Media Contact:
Janssen Inc.
Jennifer McCormack
Office: (416) 382-5121

Investor Contact:
Lesley Fishman
Office: (732) 524-3922

Janssen Announces Health Canada Approval of IMBRUVICA® (ibrutinib) in Combination with Obinutuzumab for Treatment-Naïve Patients with Chronic Lymphocytic Leukemia

Patients experienced a 77 per cent reduction in risk of disease progression or death compared to chlorambucil plus obinutuzumab

IMBRUVICA® Product Monograph now includes additional monotherapy long-term follow-up data

Toronto, ON, November 8, 2019 – The Janssen Pharmaceutical Companies of Johnson & Johnson announces the Health Canada approval of IMBRUVICA® (ibrutinib) in combination with obinutuzumab for treatment-naïve patients with active chronic lymphocytic leukemia (CLL), one of the most common types of leukemia in adults.[1,2] This is the ninth indication for IMBRUVICA® in Canada since its first approval in November 2014, and the first approval for a non-chemotherapy combination regimen for treatment-naïve patients with CLL.

"In just five years, IMBRUVICA® has become an important option for CLL treatment," says Dr. Loree Larratt, Professor in the Division of Hematology in the Faculty of Medicine and Dentistry at the University of Alberta in Edmonton. "Whether as monotherapy, or now in combination with obinutuzumab, IMBRUVICA® is proven to be an effective alternative to chemoimmunotherapy."

Concurrently, the IMBRUVICA® Product Monograph has been updated to include additional long-term efficacy data for IMBRUVICA® use as a monotherapy in CLL, with five years of follow-up from the Phase 3 RESONATE (PCYC-1112) clinical trial and four years of follow-up from the Phase 3 RESONATE-2 (PCYC-1115) trial. This data demonstrates that more than seven in 10 treatment-naïve patients were still progression free after four years on IMBRUVICA®.[3]

"More effective treatments are needed for Canadians living with CLL," said Antonella Rizza, CEO of Lymphoma Canada. "This combination therapy represents an important new advance for CLL patients. It is exciting to see that research is continuing to drive progress, providing patients with improved treatment options to consider, in consultation with their health care professionals, in the management of their disease."

About IMBRUVICA® in Combination with Obinutuzumab

The latest approval is based on data from the Phase 3 iLLUMINATE study (PCYC-1130), a head-to-head clinical trial comparing IMBRUVICA® plus obinutuzumab to chlorambucil (a chemotherapy agent) plus obinutuzumab. At a median follow-up of 31 months, IMBRUVICA® plus obinutuzumab showed a significant improvement in Independent Review Committee (IRC)-evaluated progression free survival compared with chlorambucil plus obinutuzumab (median not evaluable [NE] vs. 19 months; hazard ratio [HR] 0.23; 95 per cent confidence interval [CI]: 0.15-0.37; P<0.0001), with a 77 per cent reduction in risk of progression or death.[4] Patients with high-risk disease (17p deletion/TP53 mutation, 11q deletion, or unmutated IGHV) treated with IMBRUVICA® plus obinutuzumab experienced an 85 per cent reduction in risk of progression or death (HR 0.15; 95 per cent CI: 0.09-0.27).[5] The IRC-evaluated overall response rate was 89 per cent in the IMBRUVICA® plus obinutuzumab arm versus 73 per cent in the chlorambucil plus obinutuzumab arm.[6] The data were presented in an oral session at the 2018 American Society of Hematology (ASH) Annual Meeting and simultaneously published in *The Lancet Oncology*.

The most common adverse reactions (occurring in 20 per cent or more of patients) of all grades in patients treated with IMBRUVICA® plus obinutuzumab in the iLLUMINATE study were neutropenia (48 per cent), thrombocytopenia (36 per cent), rash (36 per cent), diarrhea (34 per cent), musculoskeletal pain (33 per cent), bruising (32 per cent), cough (27 per cent), infusion related reactions (25 per cent), hemorrhage (25 per cent), and arthralgia (22 per cent).[7]

About IMBRUVICA® Monotherapy Long-Term Follow-Up

With a median follow-up of 48 months (up to 55 months of follow-up) in RESONATE-2 (PCYC-1115-CA) and its extension study among treatment-naïve CLL patients, the median investigator-assessed PFS was not reached in the IMBRUVICA® arm and was 15 months [95 per cent CI (10.22, 19.35)] in the chlorambucil arm; (HR = 0.14 [95 per cent CI (0.090, 0.21)]).[8] The 4-year PFS estimates were 73.9 per cent and 15.5 per cent, respectively.[9] The Kaplan-Meier landmark estimate for overall survival (OS) at 48 months was 85.5% in the IMBRUVICA® arm and 75.6 per cent in the chlorambucil arm, irrespective of 54.9 per cent of patients who crossed over from the chlorambucil arm to receive ibrutinib treatment.[10]

In the RESONATE (PCYC-1112) trial among relapsed/refractory CLL patients, at a median follow-up of 55.9 months (up to 63 months of follow-up), the median investigator-assessed PFS was 44.1 months [95 per cent CI (38.54, 56.87)] in the IMBRUVICA® arm and 8.1 months [95 per cent CI (7.79, 8.25)] in the ofatumumab arm (HR=0.14; 95 per cent CI: 0.11, 0.19).[11] The Kaplan-Meier landmark estimate for OS at 60-months was 62.2 per cent in the IMBRUVICA® arm and 54.8 per cent in the ofatumumab arm, irrespective of 67.9 per cent of patients who crossed over from the ofatumumab arm to receive ibrutinib treatment.[12] The ORR (per investigator) was 87 per cent in the IMBRUVICA® arm versus 22.4 per cent in the ofatumumab arm.[13]

About Chronic Lymphocytic Leukemia (CLL)

CLL is a cancer that begins in blood stem cells, starting in abnormal lymphoid stem cells. It usually develops slowly over the course of months or years. In 95 per cent of cases, the abnormal lymphoid stem cells develop into cancerous, or malignant, B lymphocytes. CLL is one of the most common types of leukemia in adults.[14] Over 2,200 people in Canada are diagnosed with CLL each year.[15]

About IMBRUVICA®

IMBRUVICA® contains the medicinal ingredient ibrutinib which is a targeted inhibitor of Bruton's tyrosine kinase (BTK) and it is the only once-daily BTK inhibitor in Canada. Ibrutinib blocks BTK activity, inhibiting cancer cell survival and spread.[16]

IMBRUVICA® was first approved in Canada in 2014. 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 indicated in combination with bendamustine and rituximab for the treatment of patients with CLL who have received at least one prior therapy. It is also now indicated in combination with obinutuzumab for treatment-naïve patients with CLL. 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. commercializes 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 at @JanssenCanada. Janssen Inc. is one of the Janssen Pharmaceutical Companies of Johnson & Johnson.

- 30 -

**Dr. Larratt was not compensated for any media work. She has been compensated as a consultant.*

**Antonella Rizza, Lymphoma Canada, was not compensated for any media work. Lymphoma Canada has received funds for patient engagement.*

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 Inc., 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.

# # #

---

[1] IMBRUVICA® (Ibrutinib) Product Monograph, Janssen Inc. November 7, 2019.

[2] Canadian Cancer Society. What is Chronic Lymphocytic Leukemia? Available from https://www.cancer.ca/en/cancer-information/cancer-type/leukemia-chronic-lymphocytic-cll/chronic-lymphocytic-leukemia/?region=on. Accessed October 2019.

[3] IMBRUVICA® (Ibrutinib) Product Monograph, Janssen Inc. November 7, 2019.

[4] IMBRUVICA® (Ibrutinib) Product Monograph, Janssen Inc. November 7, 2019.

[5] IMBRUVICA® (Ibrutinib) Product Monograph, Janssen Inc. November 7, 2019.

[6] IMBRUVICA® (Ibrutinib) Product Monograph, Janssen Inc. November 7, 2019.

[7] IMBRUVICA® (Ibrutinib) Product Monograph, Janssen Inc. November 7, 2019.

[8] IMBRUVICA® (Ibrutinib) Product Monograph, Janssen Inc. November 7, 2019.

[9] IMBRUVICA® (Ibrutinib) Product Monograph, Janssen Inc. November 7, 2019.

[10] IMBRUVICA® (Ibrutinib) Product Monograph, Janssen Inc. November 7, 2019.

[11] IMBRUVICA® (Ibrutinib) Product Monograph, Janssen Inc. November 7, 2019.

[12] IMBRUVICA® (Ibrutinib) Product Monograph, Janssen Inc. November 7, 2019.

[13] IMBRUVICA® (Ibrutinib) Product Monograph, Janssen Inc. November 7, 2019.

[14] Canadian Cancer Society. What is Chronic Lymphocytic Leukemia? Available from https://www.cancer.ca/en/cancer-information/cancer-type/leukemia-chronic-lymphocytic-cll/chronic-lymphocytic-leukemia/?region=on. Accessed October 2019.

[15] Lymphoma Canada. "About CLL & SLL." Available from http://www.lymphoma.ca/lymphoma/cll-sll/about-cll-sll. Accessed October 2019

[16] IMBRUVICA® (Ibrutinib) Product Monograph, Janssen Inc. November 7, 2019.