FOR EUROPEAN AND UK TRADE AND MEDICAL MEDIA ONLY

News Release

Media contact:
Noah Reymond
Mobile: +31 621 38 5718
Email: NReymond@ITS.JNJ.com

Investor Relations:
Jennifer McIntyre
Office: +1 732 524 3922

Janssen Seeks Approval of IMBRUVICA®(ibrutinib) in a Fixed-Duration Regimen for Patients with Untreated Chronic Lymphocytic Leukaemia (CLL)

Application based on Phase 3 GLOW and Phase 2 CAPTIVATE study results, which investigated the safety and efficacy of an all-oral fixed-duration ibrutinib plus venetoclax combination regimen in adult patients with previously untreated CLL[1,2]

BEERSE, BELGIUM, 30 November 2021 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced the submission of a Type II variation application to the European Medicines Agency (EMA) seeking approval of a new treatment option for IMBRUVICA® (ibrutinib) as a fixed-duration combination with venetoclax (I+V) for adult patients with previously untreated chronic lymphocytic leukaemia (CLL).

"Ibrutinib was the first approved Bruton's tyrosine kinase inhibitor and over the past seven years has become a key treatment for CLL and some other B-cell malignancies, treating more than 250,000 patients globally," said Edmond Chan MBChB MD (Res), EMEA Therapeutic Area Lead Haematology, Janssen-Cilag Ltd. "This latest submission is a testament to our unwavering commitment to meeting patient needs and a noteworthy step towards an innovative, non-chemotherapy treatment regimen in the first-line setting that will allow healthcare professionals the flexibility to use ibrutinib either in a fixed-duration combination treatment regimen or as continuous therapy, depending on patient needs."

The submission is supported by positive data from the pivotal Phase 3 GLOW study (NCT03462719) which investigated the efficacy and safety of first-line fixed-duration I+V versus chlorambucil plus obinutuzumab in elderly or unfit patients with CLL,[1] and the Phase 2 CAPTIVATE study (PCYC-1142) which evaluated I+V in previously untreated CLL patients

70 years or younger, including patients with high-risk disease.[2] Data from both studies were recently featured as oral presentations at the European Hematology Association (EHA) 2021 Congress (Abstract numbers #LB1902 and #S147) in June.

"Ibrutinib and venetoclax have demonstrated positive outcomes when used together for a fixed duration of treatment and this milestone highlights our commitment to developing more convenient treatment regimens for people living with complex blood cancers, such as CLL," said Craig Tendler, M.D., Global Head of Late Development, Diagnostics & Medical Affairs, Hematology & Oncology, Janssen Research & Development, LLC. "We now look forward to working in partnership with health authorities to bring this promising treatment option to patients who may benefit from it as soon as possible."

#ENDS#

About Ibrutinib

Ibrutinib is a once-daily oral medication that is jointly developed and commercialised by Janssen Biotech, Inc. and Pharmacyclics LLC, an AbbVie company.[3] Ibrutinib blocks the Bruton's tyrosine kinase (BTK) protein, which is needed by normal and abnormal B cells, including specific cancer cells, to multiply and spread.[4] By blocking BTK, ibrutinib may help move abnormal B cells out of their nourishing environments and inhibits their proliferation.[5]

Ibrutinib is approved in more than 100 countries and has been used to treat more than 250,000 patients worldwide.[6] There are more than 50 company-sponsored clinical trials, including 18 Phase 3 studies, over 11 years evaluating the efficacy and safety of ibrutinib.[3,7]

Ibrutinib was first approved by the European Commission (EC) in 2014, and approved indications to date include:[3]

- Chronic lymphocytic leukaemia (CLL): As a single agent or in combination with rituximab or obinutuzumab for the treatment of adult patients with previously untreated CLL, and as a single agent or in combination with bendamustine and rituximab (BR) for the treatment of adult patients with CLL who have received at least one prior therapy.
- Mantle cell lymphoma (MCL): As a single agent for the treatment of adult patients with relapsed or refractory MCL.
- Waldenström's macroglobulinemia (WM): As a single agent for the treatment of adult patients who have received at least one prior therapy or in first-line treatment for

patients unsuitable for chemo-immunotherapy, and in combination with rituximab for the treatment of adult patients.

For a full list of side effects and information on dosage and administration, contraindications and other precautions when using ibrutinib please refer to the Summary of Product Characteristics for further information.

About Chronic Lymphocytic Leukaemia

Chronic lymphocytic leukaemia (CLL) is typically a slow-growing blood cancer of the white blood cells.[8] The overall incidence of CLL in Europe is approximately 4.92 cases per 100,000 persons per year and is about 1.5 times more common in men than in women.[9] CLL is predominantly a disease of the elderly, with a median age of 72 years at diagnosis.[10]

While patient outcomes have dramatically improved in the last few decades, the disease is still characterised by consecutive episodes of disease progression and the need for therapy.[11] Patients are often prescribed multiple lines of therapy as they relapse or become resistant to treatments.

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/EMEA. Follow us at www.twitter.com/janssenEMEA for our latest news. Janssen Research & Development, LLC, Janssen Pharmaceutica NV, Janssen-Cilag Ltd. and Janssen Biotech, Inc. are part of the Janssen Pharmaceutical Companies of Johnson & Johnson.

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, Janssen Pharmaceutica NV, Janssen-Cilag Ltd., Janssen Biotech, 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 behaviour 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 January 3, 2021, 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.

###

References

[1] Kater P, et al. Fixed-Duration Ibrutinib Plus Venetoclax (I+V) Versus Chlorambucil Plus Obinutuzumab (Clb+O) for First-Line Treatment of Chronic Lymphocytic Leukemia (CLL): Primary Analysis of the Phase 3 GLOW Study. 2021 European Hematology Association 2021 Virtual Congress. June 9-17, 2021.

[2] Ghia P et al. Fixed-Duration (FD) First-Line Treatment (tx) with Ibrutinib (I) Plus Venetoclax (V) For Chronic Lymphocytic Leukemia (CLL)/Small Lymphocytic Lymphoma (SLL): Primary Analysis of the FD Cohort of the Phase 2 CAPTIVATE Study. 2021 American Society of Clinical Oncology Annual Meeting. June 4-8, 2021.

[3] Imbruvica Summary of Product Characteristics, August 2021. Available at: https://www.ema.europa.eu/en/documents/product-information/imbruvica-epar-product-information_en.pdf. Last accessed: November 2021.

[4] Turetsky A, et al. Single cell imaging of Bruton's tyrosine kinase using an irreversible inhibitor. Sci Rep. 2014 Apr 24;4:4782.

[5] de Rooij MF, et al. The clinically active BTK inhibitor PCI-32765 targets B-cell receptor- and chemokine-controlled adhesion and migration in chronic lymphocytic leukemia. Blood. 2012;119(11):2590-2594.

[6] Janssen Data on File (RF-152098). Global number of cumulative patients treated with Ibrutinib since launch. October 2021.

[7] Pharmacyclics LLC. Safety of PCI-32765 in Chronic Lymphocytic Leukemia. ClinicalTrials.gov Identifier: NCT01105247. Available at: Safety of PCI-32765 in Chronic Lymphocytic Leukemia - Full Text View - ClinicalTrials.gov. Last accessed: November 2021.

[8] American Cancer Society. What is chronic lymphocytic leukemia? Available at: https://www.cancer.org/cancer/chronic-lymphocytic-leukemia/about/what-is-cll.html. Last accessed: November 2021.

[9] Sant M, et al. Incidence of hematologic malignancies in Europe by morphologic subtype: results of the HAEMACARE project. Blood. 2010; 116:3724–34.

[10] Eichhorst B, et al. Chronic lymphocytic leukaemia: ESMO Clinical Practice Guidelines for diagnosis, treatment and follow-up. Ann Oncol. 2015 Sep;26 Suppl 5:v78-84.

[11] Moreno C. Standard treatment approaches for relapsed/refractory chronic lymphocytic leukemia after frontline chemoimmunotherapy. Hematology Am Soc Hematol Educ Program. 2020;2020:33-40.