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News Release

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Janssen Withdraws Application in European Union Seeking Approval of IMBRUVICA® (ibrutinib) for the Treatment of Patients with Untreated Mantle Cell Lymphoma

BEERSE, BELGIUM, 16 December 2022 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced that the company has withdrawn its application seeking a change to the marketing authorisation for IMBRUVICA® (ibrutinib). The application sought to add a new treatment option for ibrutinib in combination with bendamustine and rituximab (BR) for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL) who are unsuitable for autologous stem cell transplantation (ASCT). Janssen informed the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) of its decision based on feedback from an early evaluation that indicated the SHINE study (MCL3002) data are considered insufficient by the CHMP to support the approval for the use of ibrutinib in the proposed indication in the European Union (EU).

"We have elected to withdraw our application seeking approval of ibrutinib, in combination with bendamustine and rituximab in first-line mantle cell lymphoma, in the European Union following discussion with the EMA," said Craig Tendler, M.D., Vice President, Late Development and Global Medical Affairs, Janssen Research & Development, LLC. "While we are disappointed that this treatment combination will not be available for patients, we will continue our commitment to further understand the potential therapeutic benefit of ibrutinib in the treatment of patients living with mantle cell lymphoma and other haematological malignancies."

The withdrawal of the ibrutinib application in the EU has no direct impact on any ongoing regulatory applications based on the SHINE study worldwide and has no impact on any of the approved indications for ibrutinib, including single agent ibrutinib for patients with relapsed or refractory MCL. It also has no impact on ongoing company-sponsored studies, including SHINE.

#ENDS#

About Ibrutinib

Ibrutinib is a once-daily oral prescription medication that is jointly developed and commercialised by Janssen Biotech, Inc. and Pharmacyclics LLC, an AbbVie company.[1,3] 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.[2] By blocking BTK, ibrutinib may help move abnormal B-cells out of their nourishing environments and inhibits their proliferation.[3]

Ibrutinib is approved in more than 100 countries and has been used to treat more than 270,000 patients worldwide.[4] There are more than 50 company-sponsored clinical trials, including 18 Phase 3 studies, over 11 years evaluating the efficacy and safety of ibrutinib.[1,5] In October 2021, ibrutinib was added to WHO's Model Lists of Essential Medicines (EML), which refer to those medicines considered to be the most effective and safe to meet the most important needs in a health system.[6]

Ibrutinib was first approved by the European Commission (EC) in 2014, and approved indications to date include:[1]

- As a single agent or in combination with rituximab or obinutuzumab or venetoclax for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL)
- 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
- As a single agent for the treatment of adult patients with relapsed or refractory (RR) mantle cell lymphoma (MCL)
- As a single agent for the treatment of adult patients with Waldenström's macroglobulinaemia (WM) 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 with WM

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 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 & Retina; 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 Pharmaceutica NV, Janssen Research & Development, LLC 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 Pharmaceutica NV, Janssen Research & Development, LLC and 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 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 January 2, 2022, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," and in Johnson & Johnson's subsequent Quarterly Reports on Form 10-Q and other 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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References

[1] Imbruvica Summary of Product Characteristics, November 2022. Available at: https://www.ema.europa.eu/en/documents/product-information/imbruvica-epar-product-information_en.pdf Last accessed: November 2022.
[2] Turetsky A, et al. Single cell imaging of Bruton's tyrosine kinase using an irreversible inhibitor. Sci Rep. 2014 Apr 24;4:4782.
[3] 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.
[4] Janssen Data on File (RF-241102). Global number of cumulative patients treated with Ibrutinib since launch. June 2022.
[5] 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: March 2022.
[6] World Health Organisation. WHO prioritizes access to diabetes and cancer treatments in new Essential Medicines Lists. Available at: https://www.who.int/news/item/01-10-2021-who-prioritizes-access-to-diabetes-and-cancer-treatments-in-new-essential-medicines-lists. Last accessed: March 2022.