Johnson&Johnson

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For Immediate Release

Johnson & Johnson submits application to the European Medicines Agency seeking approval of a new indication for IMBRUVICA® (ibrutinib) in adult patients with previously untreated mantle cell lymphoma (MCL) who are eligible for autologous stem cell transplant

The European MCL Network Phase 3 TRIANGLE study, evaluated ibrutinib in combination with induction immunochemotherapy, both with and without an autologous stem cell transplant, followed by 24 months fixed-duration ibrutinib therapy[1]

Both ibrutinib-based regimens, transplant-free and with transplant, delivered clinically meaningful improvement in efficacy compared to the current standard of care of induction immunochemotherapy followed by transplant[2]

BEERSE, BELGIUM (18 December 2024) – Janssen-Cilag International NV, a Johnson & Johnson company, today announced the submission of a Type II variation application to the European Medicines Agency (EMA). The submission seeks approval for an indication extension of IMBRUVICA® (ibrutinib) in combination with rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisolone (R-CHOP) for the treatment of adult patients with previously untreated mantle cell lymphoma (MCL), who are eligible for autologous stem cell transplant (transplant). This regulatory submission is supported by data from the TRIANGLE study, conducted by the European MCL Network.

“Mantle cell lymphoma remains an incurable and challenging disease to treat, particularly in younger patients in need of durable frontline options,” said Edmond Chan, MBChB, M.D. (Res), EMEA Therapeutic Area Lead Haematology, Johnson & Johnson Innovative Medicine. “The TRIANGLE study demonstrates ibrutinib's potential to replace or compliment a transplant-based regimen, offering eligible patients a more effective path to long term remission and representing the first major step forward in frontline mantle cell lymphoma treatment in years.”

The proposed indication is supported by results from the Phase 3 TRIANGLE study (NCT02858258) which investigated 870 patients across three treatment arms: standard induction immunochemotherapy followed by transplant, induction immunochemotherapy plus ibrutinib followed by transplant and 2-year fixed-duration ibrutinib therapy, and induction immunochemotherapy plus ibrutinib without transplant, followed by 2-year fixed-duration ibrutinib therapy.[2,3]

Prolonged efficacy and safety data from the TRIANGLE study were recently presented by the principal investigator Prof. Dr. Martin Dreyling, Ludwig Maximilian University of Munich, as an oral presentation at the 2024 American Society of Hematology (ASH) Annual Meeting.[3]

“At Johnson & Johnson, we are committed to investing in innovation that transforms clinical outcomes for those living with complex blood cancers, including mantle cell lymphoma,” said Jessica Vermeulen, Vice President, Oncology Late Development, Johnson & Johnson Innovative Medicine. “Today’s submission to the EMA could represent a pivotal step in moving beyond transplant as the frontline standard of care for younger patients with mantle cell lymphoma.”

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.[4] Ibrutinib blocks the BTK protein, which is needed by normal and abnormal B-cells, including specific cancer cells, to multiply and spread.[5] By blocking BTK, ibrutinib may help move abnormal B-cells out of their nourishing environments and inhibits their proliferation.[6]

Ibrutinib is approved in more than 100 countries and has been used to treat more than 300,000 patients worldwide.[7] There are more than 50 company-sponsored clinical trials, including 18 Phase 3 studies, over 11 years evaluating the efficacy and safety of ibrutinib.[4,8] In October 2021, ibrutinib was added to the World Health Organization's Model Lists of Essential Medicines (EML), which refers to medicines that address global health priorities and which should be available and affordable for all.[9]

Ibrutinib was first approved by the European Commission (EC) in 2014, and approved indications to date include:[4]

- 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 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. In combination with rituximab for the treatment of adult patients with WM

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

About Mantle Cell Lymphoma (MCL)

MCL is an aggressive type of blood cancer that originates from the B lymphocytes, a functional component of the human immune system.[10] The overall incidence of MCL globally is approximately 1-2 cases per 100,000 persons per year and it has a higher prevalence in men than women.[11] MCL typically affects individuals at 65-years of age at diagnosis.[11] While patient outcomes have dramatically improved over the latest few decades, MCL remains a difficult disease to treat with many patients relapsing or becoming resistant to therapy.[11]

About Johnson & Johnson

At Johnson & Johnson, we believe health is everything. Our strength in healthcare innovation empowers us to build a world where complex diseases are prevented, treated, and cured, where treatments are smarter and less invasive, and solutions are personal. Through our expertise in Innovative Medicine and MedTech, we are uniquely positioned to innovate across the full spectrum of healthcare solutions today to deliver the breakthroughs of tomorrow, and profoundly impact health for humanity.

Learn more at www.innovativemedicine.jnj.com/emea. Follow us at www.linkedin.com/company/jnj-innovative-medicine-emea. Janssen-Cilag International NV, Janssen Pharmaceutica NV, Janssen-Cilag Limited, Janssen Biotech, Inc., Janssen Biologics B.V. and Janssen Research & Development, LLC are Johnson & Johnson companies.

Cautions Concerning Forward-Looking Statements

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development and the potential benefits and treatment impact of ibrutinib. 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 materialise, actual results could vary materially from the expectations and projections of Janssen-Cilag International NV, Janssen Pharmaceutica NV, Janssen-Cilag Limited, Janssen Biotech, Inc., Janssen Research & Development, LLC, Janssen Biologics B.V. 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; competition, including technological advances, new products and patents attained by competitors; challenges to patents; 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 December 31, 2023, 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 http://www.sec.gov/, http://www.jnj.com/ or on request from Johnson & Johnson. None of Janssen-Cilag International NV, Janssen Pharmaceutica NV, Janssen-Cilag Limited, Janssen Biotech, Inc., Janssen Research & Development, LLC, Janssen Biologics B.V. 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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