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Janssen seeks expanded use of IMBRUVICA®▼ (ibrutinib) in two indications in Europe

Applications submitted to the European Medicines Agency (EMA) for new combinations in adult patients with chronic lymphocytic leukaemia (CLL) and Waldenström's macroglobulinemia (WM)

BEERSE, BELGIUM, 14 November 2018 – The Janssen Pharmaceutical Companies of Johnson & Johnson today announced the submission of two Type II variation applications to the European Medicines Agency (EMA) seeking approval for the expanded use of IMBRUVICA® (ibrutinib). One application seeks to include use of ibrutinib in combination with obinutuzumab in previously untreated adults with chronic lymphocytic leukaemia (CLL) and to add long-term follow-up data from the existing label studies RESONATE™ (PCYC-1112) and RESONATE™-2 (PCYC-1115). The second is for use of ibrutinib plus rituximab for the treatment of previously untreated and relapsed/refractory adults with Waldenström's macroglobulinemia (WM).

"Today's news brings us one step closer to potentially offering ibrutinib in new combinations for patients where unmet needs still persist," said Dr. Catherine Taylor, Haematology Therapy Area Lead, Europe, Middle East and Africa (EMEA), Janssen-Cilag Limited. "Ibrutinib continues to demonstrate clinical benefit over the long term for a broad group of patients living with blood cancer, and we look forward to working with relevant authorities to secure approval of these new combinations."

Ibrutinib, a first-in-class Bruton's tyrosine kinase (BTK) inhibitor, is jointly developed and commercialised by Janssen Biotech, Inc., and Pharmacyclics LLC, an AbbVie company.

The CLL submission is supported by positive results from the Phase 3 iLLUMINATE (PCYC-1130) study which investigated ibrutinib in combination with obinutuzumab versus chlorambucil plus obinutuzumab in patients with newly diagnosed CLL.[1] Study findings from iLLUMINATE will also be featured as an oral presentation (abstract #691), whilst further analysis of RESONATE™ and RESONATE™-2 results in comparison with real-world evidence databases (abstract #4427) will be included at the American Society of Hematology (ASH) Annual Meeting and Exposition, taking place in San Diego next month.[1,2] A supplemental New Drug Application (sNDA) which was also recently submitted to the U.S. Food and Drug Administration (FDA) received Priority Review.

In WM, the submission is supported by data from the Phase 3 iNNOVATE (PCYC-1127) study evaluating ibrutinib in combination with rituximab, versus rituximab with placebo, in patients with previously untreated and relapsed/refractory WM.[3] Follow-up efficacy and safety findings from the iNNOVATE study will also be presented at ASH 2018 (abstract #149).[4] In August 2018, the FDA approved ibrutinib in combination with rituximab for the treatment of WM based on the data from iNNOVATE.[5]

Additional information about both studies can be found at www.ClinicalTrials.gov (NCT02264574 and NCT02165397).[6,7]

#ENDS#

About ibrutinib

Ibrutinib is a first-in-class Bruton's tyrosine kinase (BTK) inhibitor, which works by forming a strong covalent bond with BTK to block the transmission of cell survival signals within the malignant B-cells.[8] By blocking this BTK protein, ibrutinib helps kill and reduce the number of cancer cells, thereby delaying progression of the cancer.[9]

Ibrutinib is currently approved in Europe for the following uses:[10]

- Chronic lymphocytic leukaemia (CLL): As a single agent 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): Adult patients with relapsed or refractory mantle cell MCL.
- Waldenström's macroglobulinemia (WM): Adult patients who have received at least one prior therapy or in first-line treatment for patients unsuitable for chemo-immunotherapy.

The most common adverse reactions seen with ibrutinib include diarrhoea, neutropenia, haemorrhage (e.g., bruising), musculoskeletal pain, nausea, rash, and pyrexia.[10]

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 CLL

CLL is typically a slow-growing blood cancer of the white blood cells.[11] The overall incidence of CLL in Europe is approximately 4.92 cases per 100,000 persons per year with rates amongst men and women approximately 5.87 and 4.01 cases per 100,000 persons per year, respectively.[12] CLL is predominantly a disease of the elderly, with a median age of 72 years at diagnosis.[13]

CLL is a chronic disease; median overall survival ranges between 18 months and more than 10 years, according to the stage of disease.[14] The disease eventually progresses in

the majority of patients, and patients are faced with fewer treatment options with each relapse. Patients are often prescribed multiple lines of therapy as they relapse or become resistant to treatments.

About Waldenström's macroglobulinemia

Waldenström's macroglobulinemia (WM) is a rare form of non-Hodgkin's lymphoma (NHL).[15] It causes overproduction of a protein called monoclonal immunoglobulin M (IgM) antibody, which causes a thickening of the blood.[16] Incidence rates among men and women in Europe are approximately 7.3 and 4.2 per million persons, respectively.[17] The causes of WM are unknown, with it typically affecting older adults and being slightly more common in men than women.[15,17]

About the Janssen Pharmaceutical Companies

At the Janssen Pharmaceutical Companies of Johnson & Johnson, we are working to create a world without disease. Transforming lives by finding new and better ways to prevent, intercept, treat and cure disease inspires us. We bring together the best minds and pursue the most promising science. We are Janssen. We collaborate with the world for the health of everyone in it. Learn more at www.janssen.com/emea. Follow us at www.twitter.com/janssenEMEA for our latest news.

Janssen Biotech, Inc., Janssen-Cilag International NV and Janssen-Cilag Limited 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 a recommendation to broaden the existing marketing authorisation for 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-Cilag Limited, 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 December 31, 2017, including in the sections captioned "Cautionary Note Regarding Forward-Looking Statements" and "Item 1A. Risk Factors," in the company's most recently filed Quarterly Reports 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. Neither 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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