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Application Submitted to the EMA to expand the therapeutic indication for IMBRUVICA® (ibrutinib) to include treatment of Waldenström's macroglobulinemia

A rare type of B-cell lymphoma for which there are limited treatment options available in Europe

Beerse/Belgium, December 01, 2014 – Janssen-Cilag International NV (Janssen) announced today the submission of a Type II variation application to the European Medicines Agency (EMA) to vary the marketing authorisation for IMBRUVICA® (ibrutinib), to include a new therapeutic indication, the treatment of adult patients with Waldenström's macroglobulinemia (WM). If approved, this latest regulatory submission will expand the indications for IMBRUVICA to a third type of blood cancer. WM is a rare type of B-cell lymphoma.

IMBRUVICA is a first-in-class, once-daily, oral Bruton's tyrosine kinase (BTK) inhibitor. IMBRUVICA is co-developed by Cilag GmbH International (a member of the Janssen Pharmaceutical Companies) and Pharmacyclics Switzerland GmbH. Janssen affiliates market IMBRUVICA in EMEA (Europe, Middle East and Africa) as well as the rest of the world, except for the United States, where both companies co-market it.

"At Janssen, we strive to develop innovative products that prolong and improve patients' lives," said Thomas Stark, Vice President Medical Affairs, Janssen EMEA. "This additional application for IMBRUVICA, for the treatment of Waldenström's macroglobulinemia, is an important milestone for patients suffering from the disease who currently have limited treatment options in Europe. If approved, IMBRUVICA has the potential to address a high unmet need among patients with this difficult to treat blood cancer."

WM (also known as IgM-excreting lymphoplasmacytic lymphoma) is a slow-growing and rare type of blood cancer[1,2] that originates from B cells, a type of white blood cell (lymphocyte) that develops in the bone marrow.[1,2] The median age at diagnosis is 63-68 years of age,[3,4] and incidence rates among men and women in Europe are approximately 7.3 and 4.2 per million persons, respectively.[4] WM remains an incurable disease.[1,2]

IMBRUVICA received European Commission approval in October 2014 for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL), and for adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy, or in first line in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy.[5] Janssen and Pharmacyclics are continuing an extensive clinical development programme for IMBRUVICA, including Phase 3 study commitments in multiple patient populations.

#ENDS#

About IMBRUVICA®

IMBRUVICA (ibrutinib) is a 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.[6] By blocking this BTK protein, IMBRUVICA helps kill and reduce the number of cancer cells. It also slows down the worsening of the cancer.[7]

IMBRUVICA received European Commission approval in October 2014 for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL), and adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy, or in first line in the presence of 17p deletion (del17p CLL) or TP53 mutation in patients with CLL who are unsuitable for chemo-immunotherapy.[5] This approval allows for the marketing of IMBRUVICA in all 28 countries of the European Union.

IMBRUVICA® received U.S. Food and Drug Administration (FDA) conditional approval for the treatment of patients with MCL who have received at least one prior therapy in November 2013[8] and conditional approval for the treatment of CLL in patients who have received at least one prior therapy in February 2014.[9] Full approval in patients with CLL who have received at least one prior therapy followed in July 2014, including approval as a first-line therapy in del17p CLL patients.[10] A supplemental New Drug Application (sNDA) for IMBRUVICA was filed with the FDA on October 20, 2014.[11] IMBRUVICA is also approved in Israel for the treatment of adult patients with MCL or CLL who have received at least one prior treatment, and in Switzerland for the treatment of adult patients with MCL, characterised by translocation t(11;14) and/or expression of cyclin D1, in whom no partial response was achieved with the prior therapy, or who exhibited progression after the previous therapy.

Investigational uses for ibrutinib, alone and in combination with other treatments, are underway in several blood cancers including CLL, MCL, Waldenström's macroglobulinemia (WM), diffuse large B-cell lymphoma (DLBCL), follicular lymphoma (FL) and multiple myeloma

(MM); IMBRUVICA is approved for the treatment of CLL and MCL[5]; regulatory approval for additional uses has not yet been granted.

About WM

WM (also known as IgM-excreting lymphoplasmacytic lymphoma) is a slow-growing, incurable, rare type of B-cell lymphoma for which no established standard of care, or EU-wide approved therapeutic, exists.[1,2] The median age at diagnosis is 63-68 years of age,[3,4] and incidence rates among men and women in Europe are approximately 7.3 and 4.2 per million persons, respectively.[4] WM begins with a malignant change to the B cell, a type of white blood cell (lymphocyte), during its maturation so that it continues to reproduce more malignant B cells. WM cells make large amounts of a certain type of antibody (immunoglobulin M, or IgM). Antibodies such as IgM normally help the body to fight infection. Excess IgM causes the blood to thicken and causes many of the symptoms of WM, including among others excess bleeding, problems with vision and nervous system problems.[1,2]

Janssen in Oncology

In oncology, our goal is to fundamentally improve the way cancer is understood, diagnosed, and managed, reinforcing our commitment to the patients who inspire us. In looking to find innovative ways to address the cancer challenge, our primary efforts focus on several treatment and prevention solutions. These include a focus on haematologic malignancies, prostate cancer and lung cancer; cancer interception with the goal of developing products that interrupt the carcinogenic process; biomarkers that may help guide targeted, individualised use of our therapies; as well as identification of early changes in the tumour microenvironment and safe and effective treatment.

About Janssen

Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving the most important unmet medical needs of our time, including oncology (e.g., multiple myeloma and prostate cancer), immunology (e.g., psoriasis), neuroscience (e.g., schizophrenia, dementia and pain), infectious disease (e.g., HIV/AIDS, hepatitis C and tuberculosis), and cardiovascular and metabolic diseases (e.g., diabetes). Driven by our commitment to patients, we develop sustainable, integrated healthcare solutions by working side-by-side with healthcare stakeholders, based on partnerships of trust and transparency. More information can be found on www.janssen-emea.com. Follow us on www.twitter.com/janssenEMEA for our latest news.

(This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995 regarding product development. 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-Cilag International NV, any of the other Janssen Pharmaceutical Companies, and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges inherent in new product development, including obtaining regulatory approvals; competition, including technological advances, new products and

patents attained by competitors; challenges to patents; changes in behaviour and spending patterns or financial distress of purchasers of health care products and services; changes to regulations and domestic and foreign health care reforms; and general industry conditions, including trends toward health care cost containment. A further list and description 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 29, 2013, including in Exhibit 99 thereto, 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 or Johnson & Johnson undertakes to update any forward-looking statement as a result of new information or future events or developments.)

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