NEWS RELEASE

Janssen's IMBRUVICA®▼(ibrutinib) Receives Additional European Commission Approval for the Treatment of Waldenström's Macroglobulinemia

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Beerse/Belgium, July 10 2015 - Janssen-Cilag International NV (Janssen) announced today that the European Commission (EC) has approved IMBRUVICA®▼ (ibrutinib) capsules as a treatment option for adult patients with Waldenström's macroglobulinemia (WM) who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy.[1] This approval represents a significant step forward for patients suffering from WM. There were previously no treatment options approved across Europe for this rare and slow-growing type of blood cancer.[2]

Ibrutinib is co-developed by Cilag GmbH International, a member of the Janssen Pharmaceutical Companies, and Pharmacyclics LLC, an AbbVie company. Janssen affiliates market ibrutinib in EMEA (Europe, Middle East and Africa) as well as the rest of the world, except for the United States, where Janssen Biotech, Inc. and Pharmacyclics LLC co-market it.

WM is the third type of blood cancer for which ibrutinib is indicated, having already been approved in Europe for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL), or 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.[3] Ibrutinib has also been recently approved for the treatment of WM by the U.S. FDA, which granted it Breakthrough Therapy Designation in 2013.

WM originates from B cells, a type of white blood cell (lymphocyte), and develops in the bone marrow.[4,5] The median age at diagnosis is 63-68 years and incidence rates among men and women in Europe are approximately 7.3 and 4.2 per million persons, respectively.[6,7]

"The clinical community now has at their disposal a treatment developed and assessed specifically for this rare B-cell lymphoma," says Professor Meletios-Athanassios Dimopoulos, Professor and Chairman of the Department of Clinical Therapeutics at the University Athens School of Medicine, Greece. "The clinical data for ibrutinib in Waldenström's macroglobulinemia showed that it was highly active for these previously-treated patients, giving

durable responses with an acceptable safety and tolerability profile."

Genome sequencing of patients with WM has revealed a common mutation in the MYD88 gene. This mutation triggers the activation of a number of targets, including Bruton's tyrosine kinase (BTK), which is a key component needed to regulate immune cell proliferation and cell survival which plays a part in B-cell malignancies, such as WM.[8] Ibrutinib forms a strong covalent bond with BTK, thereby inhibiting the enzyme and blocking the transmission of cell survival signals within the malignant B cells.[9]

"We are very pleased with the important progress the approval of ibrutinib represents for Waldenström's macroglobulinemia patients in Europe, since this authorisation marks the first EMA-approved treatment option for this rare form of cancer," said Jan Trapman, treasurer of the EWMnetwork, the umbrella organisation of Waldenström macroglobulinemia patient organisations in Europe. "This is certainly a significant milestone for patients and their families, whose interests have been at the centre of an international collaboration amongst scientists, patient groups and health authorities, focused on bringing this new treatment option to fruition."

The Phase 2 multi-centre study on which the European approval was based evaluated the efficacy and tolerability of ibrutinib 420 mg once daily in 63 patients with previously treated WM (median age of 63; range, 44-86 years old). Updated results from the study were published on 8 April 2015 in an online edition of The New England Journal of Medicine.[10] The overall response rate using criteria adopted from the International Workshop on WM was 90.5 percent, 57 out of 63 patients (95 percent CI 80.4-96.4). Eleven patients (17 percent) achieved a minor response, 36 patients (57 percent) achieved a partial response (PR) and 10 patients (16 percent) achieved a very good PR. The median times to at least minor and partial responses were four weeks and eight weeks respectively.[10]

Secondary endpoints of the registration trial included progression free survival (PFS) and the safety and tolerability of ibrutinib in symptomatic patients with previously treated WM. The estimated two-year PFS and overall survival rates among all patients were 69.1 percent (95 percent CI 53.2-80.5) and 95.2 percent (95 percent CI 86.0-98.4) respectively.[10] The most commonly occurring adverse reaction in the WM trial (14 patients, or 22 percent) was neutropenia (decreased amount of neutrophils in the blood). Thrombocytopenia (decrease in platelets in the blood) occurred in nine patients (14 percent), and other adverse events occurred in less than five patients (<10 percent) each. Four patients (six percent) in the WM trial receiving ibrutinib discontinued treatment due to neutropenia or thrombocytopenia. Additionally these two adverse events led to dose reduction in three patients (five percent).[10]

"Janssen welcomes this European Commission approval of ibrutinib for Waldenström's macroglobulinemia" said Jane Griffiths, Company Group Chairman, Janssen EMEA. "Waldenström's macroglobulinemia is a serious blood cancer and we at Janssen are pleased to lead the way in delivering innovative treatment options for those affected by rare blood cancers."

#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.[9] By blocking this BTK protein, ibrutinib helps kill and reduce the number of cancer cells. It also slows down the worsening of the cancer.[11]

Ibrutinib is approved in Europe for the treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL), or adult patients with chronic lymphocytic leukaemia (CLL) who have received at least one prior therapy, or in first line patients with CLL in the presence of 17p deletion or TP53 mutation in patients unsuitable for chemo-immunotherapy.[3] Ibrutinib has now also received approval in Europe for the treatment of adult patients with Waldenström's macroglobulinemia (WM) who have received at least one prior therapy, or in first line treatment for patients unsuitable for chemo-immunotherapy[1] - regulatory approval for additional uses has not yet been granted. Investigational uses for ibrutinib, alone and in combination with other treatments, are under way in several blood cancers including CLL, MCL, WM, diffuse large B-cell lymphoma (DLBCL), follicular lymphoma (FL), multiple myeloma (MM) and marginal zone lymphoma (MZL).

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About Waldenström's Macroglobulinemia

Waldenström's macroglobulinemia (WM) is a slow-growing, incurable, rare type of B-cell lymphoma for which no established standard of care, or EMA-approved therapeutic, exists.[2] 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 and problems with vision and the nervous system.[4,5]

Janssen in Oncology

In oncology, our goal is to fundamentally alter 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 safe and effective identification and treatment of early changes in the tumour microenvironment.

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 diseases (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.

Janssen Pharmaceuticals NV; Janssen Research & Development, LLC; Janssen Biotech, Inc.; and Janssen-Cilag International NV 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 the approval of a new indication. 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 any of the Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: challenges and uncertainties inherent in new product development, including uncertainty of clinical success and obtaining regulatory approvals; uncertainty of commercial success; 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 or financial distress of purchasers of health care products and services; changes to applicable laws and regulations, including global health care reforms; manufacturing difficulties and delays; and 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 28, 2014, 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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