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Janssen's IMBRUVICA®▼(ibrutinib) Approved by European Commission for Patients with Newly Diagnosed Chronic Lymphocytic Leukaemia

Approval based on data from Phase 3 RESONATE™-2 trial showing once-daily, oral ibrutinib significantly improved overall and progression-free survival versus chemotherapy

Beerse/Belgium, 31 May, 2016 – Janssen-Cilag International NV (Janssen) announced today that the European Commission (EC) has approved IMBRUVICA® (ibrutinib) for the treatment of adult patients with previously untreated chronic lymphocytic leukaemia (CLL).[1] This broadens the indication beyond the initial CLL approval by the EC in October 2014. Ibrutinib is now approved for all patients with CLL, expanding the number of patients who may benefit from this treatment.

The expanded ibrutinib indication is based on data from the Phase 3, randomised, open-label RESONATE™-2 trial, as published in *The New England Journal of Medicine (NEJM)* in 2015.

"Ibrutinib has shown remarkable improvements in overall survival, progression-free survival and response rates compared with chlorambucil," said Professor Paolo Ghia, Associate Professor of Internal Medicine at Università Vita-Salute San Raffaele in Milan, Italy. "The RESONATE™-2 data indicate that ibrutinib can provide a much-needed first line treatment alternative for many patients."

Results from the RESONATE™-2 study showed that ibrutinib significantly prolonged overall survival (OS) (HR=0.16, 95 percent CI 0.05 to 0.56; P=0.001), with 98 percent of patients still alive after two years, compared to 85 percent for patients randomised to the chlorambucil arm.[2] The median progression-free survival (PFS) was not reached for patients receiving

ibrutinib versus 18.9 months for those in the chlorambucil arm, representing a statistically significant 84 percent reduction in the risk of death or progression in the ibrutinib arm (HR=0.16, 95 percent CI 0.09 to 0.28; P<0.001).[2] The overall safety of ibrutinib in the treatment-naïve CLL patient population was consistent with previously reported studies.[3] The most common adverse reactions (ARs) (≥20 percent) of any Grade in the RESONATE-2 trial for ibrutinib were diarrhoea (42 percent), fatigue (30 percent), cough (22 percent) and nausea (22 percent).[2]

"The availability of a targeted therapy as an initial treatment is a tremendous step forward for people affected by CLL and has been long-awaited by the CLL community," said Nick York, patient advocate, CLL Advocates Network (CLLAN). "Many patients are considered unsuitable for the current first line standard of care so there is a real need for new, effective treatment options for these patients."

Despite the availability of effective first line chemo-immunotherapy regimens for CLL, many patients, especially the elderly, cannot tolerate their adverse effects.[3] CLL is generally a slow-growing blood cancer of the white blood cells.[4] The prevalence rate of CLL in Europe among men and women is approximately 5.87 and 4.01 cases per 100,000 persons per year, respectively.[5,6] CLL is predominantly a disease of the elderly, with a median age of 72 at diagnosis.[7]

"The body of clinical and real-world evidence in support of ibrutinib's patient benefits continues to grow, and with this first line approval we are so pleased to be able to alter the treatment landscape and options for CLL patients," said Jane Griffiths, Company Group Chairman, Janssen Europe, Middle East and Africa. "We now look forward to working with health authorities across the region to make ibrutinib available to patients in this indication as soon as possible."

This latest EC approval follows the decision by the U.S. Food and Drug Administration on 04 March 2016 to approve the expanded use of ibrutinib capsules for treatment-naïve patients with CLL.

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 co-market it. Janssen and Pharmacyclics continue to support an extensive clinical development program for ibrutinib, including Phase 3 study commitments in multiple patient populations.

#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 treatment of adult patients with relapsed or refractory mantle cell lymphoma (MCL); for previously untreated adult patients with chronic lymphocytic leukaemia (CLL) or those who have received at least one prior therapy; and in 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.[10] Additional uses are under clinical investigation but have not yet been granted regulatory approval.

Please see the ibrutinib summary of product characteristics for further information.

About CLL

CLL is a chronic disease; median overall survival ranges between 18 months and more than 10 years, according to the stage of disease.[11] The disease eventually progresses in the majority of patients, and patients are faced with fewer treatment options each time. Patients are often prescribed multiple lines of therapy as they relapse or become resistant to treatments.

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. Follow us on www.twitter.com/janssenEMEA for our latest news.

Cilag GmbH International; 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 [a newly approved product/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 [OPCO] and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to: 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 03 January 2016, 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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