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BEERSE, BELGIUM, 27 JUNE 2014 - Janssen-Cilag International NV today announced its submission of a type II variation to the European Medicines Agency (EMA) to expand the label for VELCADE® (bortezomib) to include its use, in combination with rituximab, cyclophosphamide, doxorubicin and prednisone, for the treatment of adult patients with previously untreated Mantle Cell Lymphoma (MCL). MCL is a rare and aggressive blood cancer that usually occurs in older adults.[1] VELCADE, in combination with other agents, is currently licensed to treat patients with Multiple Myeloma (MM) who have not yet had therapy or whose cancer has begun to progress after treatment.[2]

"We are committed to developing and delivering innovative therapeutic solutions to treat serious diseases," said Jane Griffiths, Company Group Chairman, Janssen Europe, the Middle East and Africa (EMEA). "The encouraging data we have seen on VELCADE when used as part of frontline treatment of Mantle Cell Lymphoma reinforce our belief that this therapy has the potential to be an important option in the treatment of this cancer."

Today's submission is based on data from the landmark LYM-3002 trial. In results from this study, presented at the 50th Annual Meeting of the American Society of Clinical Oncology (ASCO) and the 19th Annual Congress of the European Hematology Association (EHA), significant benefits were seen when treating newly diagnosed patients with MCL using a VELCADE-based combination, compared to a widely used standard of care. Patients in the study were previously untreated for their MCL and were either ineligible, or not considered, for a bone marrow transplant. Compared to the treatment combination R-CHOP†, the VELCADE-based regimen, VR-CAP* significantly improved progression-free survival (PFS) (the time patients live without their disease progressing) and showed improvements across a range of secondary endpoints.[3] An independent review committee reported the increase in median PFS to be 59 percent (24.7 vs. 14.4 months; HR 0.63; p<0.001), whereas the study investigators reported the increase in median PFS to be 96 percent (30.7 vs. 16.1 months; HR 0.51; p<0.001).3

VR-CAP was associated with additional, but manageable, toxicity as compared to R-CHOP.[3] Higher rates of thrombocytopenia and infection were observed with VR-CAP. However, there were no differences observed in bleeding events between the two treatment groups and rates of peripheral neuropathy were similar.[3] Overall, among patients receiving VR-CAP compared to R-CHOP in the LYM 3002 study, serious adverse events (AE) were reported in 38 percent vs. 30 percent of patients and grade ≥3 AEs were reported in 93 percent vs. 85 percent. Discontinuations of treatment due to AEs were nine percent (VR-CAP) vs. seven percent (R-CHOP) and on-treatment drug-related deaths were two percent vs. three percent.[3]

About VELCADE (bortezomib)

VELCADE (bortezomib) is a medicine currently licensed in the EU to treat the blood-based cancer, Multiple Myeloma (MM). VELCADE is currently indicated for use in the following groups:[2]

- Patients who have not been treated before and who are not suitable for high-dose chemotherapy (medicines to treat cancer) with a blood stem-cell transplant. In these patients, VELCADE is used in combination with melphalan and prednisone (other medicines for MM)
- Patients who have not been treated before and who are going to receive high-dose chemotherapy followed by a blood stem-cell transplant. In this group of patients, VELCADE is used in combination with dexamethasone, or with dexamethasone plus thalidomide
- Patients whose disease is progressive (getting worse) and who have failed to respond to at least one other treatment and have already had, or cannot undergo, a blood stem-cell transplant. VELCADE is either used on its own in these patients or in combination with CAELYX (pegylated liposomal doxorubicin) or dexamethasone

VELCADE contains an active substance called bortezomib and is the first in a specific class of medicines known as proteasome inhibitors. Proteasomes are present in all cells and play an important role in controlling cell function, growth and also how cells interact with other cells around them. Bortezomib reversibly interrupts the normal working of cell proteasomes, causing myeloma cancer cells to stop growing and die.[2]

VELCADE has a predictable safety profile and a favourable benefit-risk ratio. The most common side effects reported with VELCADE (bortezomib) include fatigue, gastrointestinal adverse events, transient thrombocytopenia and neuropathy.[2]

VELCADE is the market leader in the treatment of frontline, non-transplant eligible MM. It is co-developed by Millennium: The Takeda Oncology Company, a wholly owned subsidiary of Takeda Pharmaceutical Company Limited, and Janssen Pharmaceutical Companies. Millennium: The Takeda Oncology Company is responsible for commercialisation of VELCADE in the U.S.; Janssen Pharmaceutical Companies are responsible for commercialisation in Europe and the rest of the world. Takeda Pharmaceutical Company Limited and Janssen Pharmaceutical K.K. co-promote VELCADE in Japan. VELCADE is approved in more than 90 countries and has been used to treat more than 550,000 patients worldwide.

VELCADE (bortezomib) in Mantle Cell Lymphoma

In Europe, VELCADE is not currently licensed to treat Mantle Cell Lymphoma (MCL). The approved VELCADE indications can be viewed online at:[2]
http://www.ema.europa.eu/ema/index.jsp?curl=pages/medicines/human/medicines/000539/human_med_001130.jsp&mid=WC0b01ac058001d124

In 2006, the United States Food and Drug Administration (FDA) approved VELCADE for the treatment of patients with MCL who have received at least one prior therapy. VELCADE has subsequently been approved for the treatment of relapsed MCL in 53 additional countries, including Canada and

Switzerland.

About Mantle Cell Lymphoma
MCL is a rare and aggressive blood cancer that usually occurs in older adults, with the median age at diagnosis being 65 years. The disease typically begins in the lymph nodes, but can spread to other tissues such as bone marrow, liver and spleen. The incidence rates among men and women in Europe are approximately 0.64 and 0.27 cases per 100,000 persons per year, respectively. MCL patients generally have a poor prognosis. Median overall survival is typically three to four years, and only one to two years in patients following the first relapse.[4,5,6]

About Janssen
Janssen-Cilag International NV is one of the Janssen Pharmaceutical Companies. 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.

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 disease area strongholds that focus on haematologic malignancies and prostate 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; and safe and effective identification and treatment of early changes in the tumour microenvironment.

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 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 behavior and spending patterns or financial distress of purchasers of health care products and services; changes to governmental laws and regulations and domestic and foreign health care reforms; general industry conditions including trends toward health care cost containment; and increased scrutiny of the health care industry by government agencies. 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 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 statements as a result of new information or future events or developments.

† Rituximab, cyclophosphamide, doxorubicin, vinicristine and prednisone (R-CHOP)
*VELCADE, rituximab, cyclophosphamide, doxorubicin and prednisone (VR-CAP)

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Media Inquiries:
Satu Kaarina Glawe
Mobile: +49 (172) 294 6264

Investor Relations:
Stan Panasewicz
Phone: +1 732 524 2524

Louise Mehrotra
Phone: +1 732 524 6491