MEDIA CONTACT: Satu Glawe
+49 172 294 6264
sglawe@its.jnj.com

INVESTOR RELATIONS: Stan Panasewicz
+1 732-524-2524
Louise Mehrotra
+1 732-524-6491

CHMP GIVES A POSITIVE OPINION FOR THE USE OF VELCADE® AS RETREATMENT AND FOR FRONTLINE INDUCTION THERAPY BEFORE STEM CELL TRANSPLANTATION

Label updates could lead to significantly improved outcomes for patients with multiple myeloma

Beerse, Belgium, 28 June 2013 Janssen-Cilag International NV (Janssen) announced today that *The Committee for Medical Products for Human Use* (CHMP) of *The European Medicines Agency* (EMA) has granted a positive opinion on two variations relating to the use of VELCADE®.[1] VELCADE® is indicated for the treatment of multiple myeloma, a type of blood cancer.

The first recommendation is for the use of VELCADE® (bortezomib) as retreatment in adult patients who have previously responded to treatment with the same medicine.[1] The positive opinion re-enforces the existing data supporting the use of VELCADE® in this wider relapsed patient population in the European Union. This is now included in the label and does not require an additional decision from the European Commission.

Concurrently, the CHMP also announced a positive opinion recommending the approval of VELCADE® as induction therapy in combination with dexamethasone (VD) or dexamethasone and thalidomide (VDT). This is for adult patients with previously untreated multiple myeloma who are eligible for high-dose chemotherapy with haematological stem cell transplantation.[1] This will now be referred for approval to the European Commission.

VELCADE® was previously indicated for use in combination with melphalan and prednisone for the treatment of multiple myeloma in adult patients that are previously untreated but ineligible for high-dose chemotherapy with haematological stem cell transplant, and alone in advanced multiple myeloma. These label updates could mean significantly improved outcomes for many patients with this disease.

VELCADE® (bortezomib) as retreatment therapy[2]

The submission for use of VELCADE® in adult patients who have previously been treated with the medicine but have since relapsed is supported by data from the Phase II RETRIEVE (MMY2036) study. The primary objective of this study was best confirmed response at retreatment. This study included heavily pre-treated VELCADE® patients, who had previously achieved a partial or greater response, and had at least six months since their previous VELCADE® dose.

VELCADE® as induction therapy prior to stem cell transplantation[3,4]

The submission for license extension was based on the analysis of data from two Phase III trials (IFM-2005-01, PETHEMA/GEM) which demonstrated that treatment with VELCADE®-based induction resulted in improvements in progression-free survival (PFS), and post-induction and post-transplant response rates.

The trials studied the use of VELCADE®-based regimens VD and VDT, compared to non-VELCADE®-based regimens of vincristine plus doxorubicin and dexamethasone, and thalidomide and dexamethasone, respectively, as induction therapy prior to autologous stem cell transplant in adult patients with previously-untreated multiple myeloma.

The CHMP

The CHMP is the committee responsible for the scientific assessment of products seeking centralised marketing authorisation throughout the European Union.

The positive opinion on retreatment re-enforces the existing data supporting the use of VELCADE® in the relapsed patient population who have previously responded to treatment with the same medicine. The positive opinion recommending VELCADE® as frontline induction therapy is now referred for approval to the European Commission (EC) who will decide on whether to follow its guidance and grant an extension to the current European license for VELCADE®. Janssen expects that a decision from the European Commission on this will be announced in September 2013.

About VELCADE®[5,6]

VELCADE® is a medicine used to treat the blood-based cancer known as multiple myeloma. It contains an active substance called bortezomib and is the first in a new 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 the other cells around them. Bortezomib reversibly interrupts the normal working of cell proteasomes causing myeloma cancer cells to stop growing and die.

Until now, it has been licensed in the EU for use in combination with melphalan and prednisone in previously untreated adult patients with multiple myeloma (i.e. the front line setting) who are ineligible for high-dose chemotherapy with haematological stem cell transplant, and as monotherapy for the treatment of progressive multiple myeloma in patients who have received at least one prior therapy and who have already undergone or are unsuitable for haematological stem cell transplant.

The European Commission recently granted marketing authorisation for the subcutaneous (under the skin) administration of VELCADE® (bortezomib) in the European Union. Subcutaneous bortezomib has fewer side effects and offers greater convenience for patients, with similar efficacy compared to intravenous bortezomib.

VELCADE® has a predictable safety profile and a favourable benefit–risk ratio. The most common side effects reported with VELCADE® include fatigue, gastrointestinal adverse events, transient thrombocytopenia and neuropathy.

VELCADE® is the market leader in the treatment of frontline non-transplant eligible multiple myeloma with over 400,000 patients treated worldwide. VELCADE® is co-developed by Millennium Pharmaceuticals and Janssen Pharmaceutical Companies. Millennium is responsible for commercialization of VELCADE® in the U.S., Janssen Pharmaceutical Companies are responsible for commercialization in Europe and the rest of the world. Takeda Pharmaceutical Company Limited and Janssen Pharmaceutical K.K. co-promote VELCADE in Japan.

About multiple myeloma (MM)

Multiple Myeloma is an incurable blood cancer that starts in the bone marrow and is characterised by an excess proliferation of abnormal plasma cells.[7]

MM is the second most frequent form of malignant bone marrow diseases. It is a relatively rare form of cancer that accounts for roughly one percent of all cancers and roughly two percent of all deaths from cancer. In Europe, around 60,000 people are living with the disease and there are 21,420 new cases and 15,000 deaths every year.[8]

About Janssen

Janssen-Cilag International NV (Janssen) is one of the Janssen Pharmaceutical Companies of Johnson & Johnson. We 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 at www.janssen-emea.com

This press release contains "forward-looking statements" as defined in the Private Securities Litigation Reform Act of 1995. 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 Janssen Pharmaceutical Companies and/or Johnson & Johnson. Risks and uncertainties include, but are not limited to, general industry conditions and competition; economic factors, such as interest rate and currency exchange rate fluctuations; technological advances, new products and patents attained by competitors; challenges inherent in new product development, including obtaining regulatory approvals; 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; 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 Exhibit 99 of Johnson & Johnson's Annual Report on Form 10-K for the fiscal year ended December 30, 2012. Copies of this Form 10-K, as well as subsequent filings, are available online at www.sec.gov, www.jnj.com or on request from Johnson & Johnson. None of the Janssen Pharmaceutical Companies nor Johnson & Johnson undertake to update any forward-looking statements as a result of new information or future events or developments.

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The original language of this press release is English. Translations into French, German, Italian and Spanish are provided by Businesswire as a courtesy.