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EUROPEAN COMMISSION APPROVES VELCADE® AS A FRONTLINE INDUCTION THERAPY BEFORE STEM CELL TRANSPLANTATION

Decision could significantly improve transplant outcomes for patients with multiple myeloma

Beerse, Belgium, 8th August 2013 - Janssen-Cilag International NV (Janssen) announced today that the European Commission (EC) has approved the use of VELCADE® (bortezomib) as induction therapy (a first therapeutic option) in combination with dexamethasone (VD) or thalidomide and dexamethasone (VTD).[1] This licence extension will apply to adult patients with previously-untreated multiple myeloma who are eligible for high-dose chemotherapy with haematological stem cell transplantation.

Until now, VELCADE's (bortezomib) indication has been limited to its use, in combination with melphalan and prednisone, in adult patients with multiple myeloma that are previously untreated and ineligible for stem cell transplant, and as a single agent in advanced multiple myeloma.[2] Multiple myeloma, a type of blood cancer, currently affects around 60,000 people in Europe.[3] This decision could mean significantly improved outcomes for many patients with this disease.

The approval by the EC was based on the analysis of data from two Phase III trials (IFM-2005-01, PETHEMA/GEM05) which demonstrated that treatment with VELCADE-based induction resulted in improvements in post-induction and post-transplant response rates and in progression-free survival (PFS); PFS and overall survival (OS) were secondary endpoints.

The trials studied the use of VELCADE-based regimens VD and VTD, compared to non-VELCADE-based regimens of vincristine plus doxorubicin and dexamethasone, or

thalidomide and dexamethasone, respectively, as induction therapy prior to autologous stem cell transplant in adult patients with previously-untreated multiple myeloma.[4,5]

 # ENDS #

Overview of the IFM-2005-01 and PETHEMA/GEM05 studies[4,5]

Study IFM-2005-01 evaluated VELCADE (bortezomib) in combination with dexamethasone (VD) compared to vincristine, plus doxorubicin and dexamethasone (VAD). The study included patients aged 65 or under with untreated symptomatic multiple myeloma, with measurable paraprotein in serum (over 10 g/L or urine over 0.2 g/24h).

Results demonstrated that complete response or near complete response rate was significantly improved in the VD group, with a 14.8 percent response rate compared to 6.4 percent [p = 0.004] in patients treated post induction therapy, and 35.0 percent compared to 18.4 percent [p <0.001] respectively in those treated post first transplantation.

PFS was 36.0 months in the VD group compared to 29.7 months [p = 0.064] in the VAD group. The OS rate at the 3 year follow up was 81.4 percent in those receiving VD compared to 77.4 percent [p = 0.508] in those treated with VAD.

Study PETHEMA/GEM05 evaluated VELCADE (bortezomib) in combination with thalidomide and dexamethasone (VTD) compared to thalidomide and dexamethasone (TD). It included patients with newly diagnosed and untreated symptomatic multiple myeloma who were 65 years of age or younger with measurable serum and/or urine M protein.

Results demonstrated an improvement in complete response rate, with 35 percent complete response in the VTD group compared to 14 percent [p = 0.0001] in the TD group, in patients post induction, and 46 percent compared to 24 percent in those post-transplant [OR: 2.34 (95 percent Cl: 1.42, 3.87); p = 0.004].

A statistically significant improvement in PFS of 56.2 months was achieved in the VTD group, compared to 28.2 months [p = 0.01] in the TD group. OS at the 4 year follow up was 74 percent in the VTD group compared to 65 percent in those treated with TD [p =NS].

About VELCADE (bortezomib)[2]

VELCADE (bortezomib) 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 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 the other cells around them. Bortezomib reversibly interrupts the normal working of cell proteasomes causing myeloma cancer cells to stop growing and die.

VELCADE (bortezomib) 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.

VELCADE (bortezomib) is the market leader in the treatment of frontline non-transplant eligible multiple myeloma, with more than 400,000 patients treated worldwide. VELCADE (bortezomib) is co-developed by Millennium Pharmaceuticals and Janssen Pharmaceutical Companies. Millennium is responsible for commercialisation of VELCADE (bortezomib) 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 (bortezomib) in Japan.

Recent advances: VELCADE SUBCUTANEOUS and RETREATMENT

In June 2013, an alteration to VELCADE's (bortezomib) label was approved by the *Committee for Medicinal Products for Human Use* (CHMP). This permitted wording to include the use of VELCADE (bortezomib) as retreatment in adult patients who have previously responded to treatment with the same medicine.[6]

In 2012, the European Commission 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.[7]

About multiple myeloma

Multiple myeloma is an incurable blood cancer that starts in the bone marrow and is characterised by an excess proliferation of abnormal plasma cells.[8]It is the second most frequent form of malignant bone marrow diseases and 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

The Janssen Pharmaceutical Companies of Johnson & Johnson are dedicated to addressing and solving the most important unmet medical needs of our time, including oncology, immunology, neuroscience, infectious disease, and cardiovascular and metabolic diseases. Driven by our commitment to patients, Janssen develops innovative products, services and healthcare solutions to help people throughout the world. 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.

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