Subcutaneous Velcade® Approved In The EU For The Treatment Of Multiple Myeloma

Simpler, easier route of administration offers improved safety and convenience, with maintained efficacy

Beerse, Belgium, [28th September, 2012] Janssen-Cilag International NV (Janssen) today announced that the European Commission has granted marketing authorisation for the subcutaneous (under the skin) administration of VELCADE® (bortezomib) in the European Union. Bortezomib is indicated for the treatment of multiple myeloma, a type of blood cancer.1 The authorisation is based on data from a Phase III study demonstrating that subcutaneous administration of bortezomib is equally effective as intravenous (into the vein) bortezomib but is associated with a significant reduction in the frequency and severity of side effects. It also offers greater convenience for patients and physicians.2

“The trial results and approval of subcutaneous bortezomib builds on a wealth of existing data and experience with intravenous bortezomib, which already plays a vital role in managing multiple myeloma,” said Professor Philippe Moreau, lead investigator on the trial and Head of Haematology at University Hospital Hôtel-Dieu. Nantes, France. “The new administration route will make treatment easier. This, combined with reduced levels of side effects, which can impact hugely on the lives of patients, will make subcutaneous bortezomib an important option moving forward.”

The marketing authorisation is based on the results of the MMY-3021 Phase III trial, published in The Lancet Oncology in 2011.2 The trial compared subcutaneous (SC) and intravenous (IV) administration of bortezomib in relapsed multiple myeloma patients. Results from the trial showed that the efficacy of SC bortezomib was similar to that of IV bortezomib, but that the frequency and severity of side effects were significantly reduced in the SC, compared to the IV group. The incidence of grade 3 or higher adverse events was significantly lower in SC compared to IV administration. Of particular note is that peripheral neuropathy (pain and tingling in the extremities) was observed in 38% of patients who received SC bortezomib compared with 53% receiving IV bortezomib and grade 3 or higher peripheral neuropathy events were reduced from 16% with IV to 6% with SC.2

SC bortezomib is therefore an important new option for multiple myeloma patients, particularly those who may not be eligible, or suitable, for IV treatment.

“We strive to develop innovative therapeutic options that meet the unmet needs of patients suffering from devastating diseases such as multiple myeloma,” said Jane Griffiths, Company Group Chairman, Janssen Europe, Middle-East, Africa. “We are delighted to now be able to offer an alternative treatment option that could result in both improved convenience and outcomes for patients across Europe, and the professionals that treat them.”

NOTES TO EDITORS

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.3 It is the second most frequent form of malignant bone marrow diseases. It is a relatively rare form of cancer, accounting for around 1% of all cancers and 2% of all deaths from cancer. In Europe, approximately 60,000 people are estimated to be living with the disease and there are over 21,400 new cases and 15,000 deaths each year.4

About the MMY-3021 Phase III trial2
The European Commission’s marketing authorisation for bortezomib is based on results of the MMY-3021 Phase III trial published in The Lancet Oncology in 2011. MMY-3021 is an open-label, randomised, Phase III non-inferiority trial conducted in 222 patients with relapsed multiple myeloma randomly assigned to receive SC or IV bortezomib. The trial found that patients receiving bortezomib subcutaneously achieved a four-cycle objective response rate (ORR) of 42% and a complete response (CR) rate of 7%, while patients receiving bortezomib intravenously achieved an ORR of 42% and a CR rate of 8%. The overall safety profile was similar between the two arms. However, the incidence of grade 3 or higher treatment-related adverse events was significantly lower in SC compared to IV administration (39% in SC vs. 55% in IV). Also of note was that, in the SC arm, 38% of patients experienced peripheral neuropathy (PN) of all grades, compared with 53% of patients in the IV arm. The incidence of grade 3 or higher PN events was reduced from 16% with IV to 6% with SC. SC administration of bortezomib was also shown to reduce discontinuation and dose reduction rates compared to IV.

About VELCADE® (bortezomib)
VELCADE® (bortezomib) is a medicine used to treat the blood-based cancer known as multiple myeloma. It contains an active
A substance called bortezomib and was the first in 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.\(^5\)

It is licensed in the EU for use in combination with melphalan and prednisone in previously untreated patients with multiple myeloma (i.e. the front-line setting) who are ineligible for high-dose chemotherapy and bone marrow 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 bone marrow transplantation.

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.\(^2\)

VELCADE® is the market leader in treating relapsed multiple myeloma with over 300,000 patients treated worldwide. VELCADE® is co-developed by Millennium Pharmaceuticals and Janssen Pharmaceutical Companies of Johnson & Johnson. Millennium is responsible for commercialization of VELCADE® in the U.S., Janssen Pharmaceutical Companies of Johnson & Johnson 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.

Subcutaneous bortezomib was approved in the USA by the Food and Drug Administration (FDA) for the treatment of multiple myeloma and relapsed mantle cell lymphoma in January 2012, and by Health Canada for the treatment of multiple myeloma in March 2012.

**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, we develop innovative products, services and healthcare solutions to help people throughout the world.

More information can be found at [www.janssen-emea.com](http://www.janssen-emea.com)

**References**