



## EMA Approves Update to Velcade® (bortezomib) Label to Include Survival Benefit in Previously Untreated Patients with Multiple Myeloma

### Additional data demonstrating efficacy of Velcade presented at the 15th Congress of the European Hematology Association

**BEERSE, BELGIUM, 15 June 2010** Janssen-Cilag today welcomes the approval by the European Commission of the update to the Summary of Product Characteristics (SmPC) for Velcade® (bortezomib) for the treatment of patients with multiple myeloma. The update includes data on overall survival rates. The decision follows a positive recommendation by the Committee for Medicinal Products for Human Use (CHMP), the scientific committee of the European Medicines Agency (EMA).

The CHMP reviewed clinical evidence from a prospectively defined survival update of the phase III international VISTA (Velcade as Initial Standard Therapy in Multiple Myeloma) study, which shows a significantly improved overall survival of 68.5% for patients treated with Velcade plus melphalan and prednisone (Vc+M+P), compared to 54% (p=0.0008) for patients on melphalan and prednisone (M+P) alone after three years of treatment. The study also showed a significantly higher complete response rate of 30% for Vc+M+P versus 4% for M+P alone.<sup>1</sup>

The Pharmacological Properties section of the SmPC for Velcade now includes these updated efficacy results following the pre-planned survival follow-up analysis in the VISTA study.<sup>2</sup>

In addition, data from more than ten studies demonstrating the efficacy of Velcade in a number of different treatment settings was presented this weekend at the 15th Congress of the European Hematology Association in Barcelona.

The data presented highlights the evidence supporting the use of Velcade as induction, first line and second line therapy and includes; a phase II study of Velcade (Ludwig *et al.*) as induction therapy showing positive complete response rates<sup>3</sup>; data from RETRIEVE (Petrucci *et al.*), a large international phase II study on retreatment with Velcade in patients who had previously responded, demonstrating the efficacy of Velcade as a retreatment option<sup>4</sup>; and a phase II trial (Dimopoulos *et al.*) of Velcade as a second line treatment in patients with relapsed or refractory multiple myeloma - which showed an overall response rate of 83.7%.<sup>5</sup>

Multiple myeloma, a cancer of the blood, is the second most common haematologic malignancy. Traditionally, multiple myeloma was associated with a poor prognosis with a median survival of 3-5 years from diagnosis.

Although the disease remains incurable with conventional therapy, the outlook for patients has improved in the last few years due to advances in novel therapies, such as Velcade, which is increasingly being incorporated into present-day treatment practices.

**ENDS**

#### For further information please contact:

Jennifer Tear  
Director  
Communications and Public Affairs  
Tel: +32 14 60 26 38  
Mobile: + 32 473 55 94 60  
Email: [JTear1@its.jnj.com](mailto:JTear1@its.jnj.com)

#### Notes to editors

**About Velcade (bortezomib)** 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 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. It is licensed 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.

## About Janssen-Cilag

Janssen-Cilag is one of the world's leading research-based pharmaceutical companies, with operations throughout the world.

The company is committed to discovering and delivering innovative medicines for diseases of high unmet medical need and has introduced a range of treatments that make an important difference to the lives of patients with serious health conditions.

Key areas of activity include; psychiatry; neurology; oncology; immunology, HIV; antibiotics; pain management; fungal diseases/dermatology; gastroenterology and women's health.

Key products include Risperdal® (schizophrenia, bipolar disorder), Risperdal® Consta® (schizophrenia) Concerta® XL (ADHD), Velcade® (oncology), Prezista® & Intelence® (HIV), Stelara (psoriasis), Topamax® (epilepsy, migraine), Doribax® (antibiotics), Daktarin® (anti-fungal), Sporanox (anti-fungal), Durogesic® DTrans® (pain management), Pariet® (gastroenterology), Cilest® and Evorel® (women's health).

Medicines developed by Janssen-Cilag are used to treat around 1,500 million patients worldwide every year.

Janssen-Cilag is part of the Johnson & Johnson family of companies, which comprises around 250 operating companies throughout the world and employ approximately 120,000 people in 57 countries. Johnson & Johnson is the world's most comprehensive and broadly based manufacturer of health care products and related services. More information can be found at [www.janssen-cilag.co.uk](http://www.janssen-cilag.co.uk)

## References

---

<sup>1</sup>Maria-Victoria Mateos et al. Bortezomib plus melphalan-prednisone compared with Melphalan and Prednisone in previously untreated Multiple Myeloma: Updated follow-up and impact of subsequent therapy in phase 111 VISTA trial. *J Clin Oncol* 2010;28 (13): 2259-66

<sup>2</sup>Janssen-Cilag International NV. Velcade 1 mg powder for solution for injection. Summary of Product Characteristics, June 2010.

<sup>3</sup>Ludwig H, Viterbo L, Greil R, et al. Phase II study of Bortezomib, thalidomide, and dexamethasone +/- cyclophosphamide as induction therapy in previously untreated multiple myeloma (MM): safety and activity including evaluation of MRD; 15th Congress of the European Hematology Association 2010; Jun 10-13; Barcelona, Spain. Abstr 0371

<sup>4</sup>Petrucci T, Blau I, Corradini P et al. Efficacy and safety of retreatment with bortezomib in patients with multiple myeloma: interim results from retrieve, a prospective international phase 2 study; 15th Congress of the European Hematology Association 2010; Jun 10-13; Barcelona, Spain. Abstr. 0377

<sup>5</sup>Dimopoulos M, Roddie H, Beksac M, et al. Randomized phase 2 trial of bortezomib-dexamethasone (VD) versus VD plus cyclophosphamide or lenalidomide in myeloma patients achieving stable disease after 4 cycles of VD as second-line treatment; 15th Congress of the European Hematology Association 2010; Jun 10-13; Barcelona, Spain. Abstr 0366