



VELCADE® (bortezomib) Approved For Previously Untreated Multiple Myeloma

VELCADE approved across all disease stages for broad spectrum of patients

High Wycombe, England (September 8, 2008) Janssen-Cilag / Ortho Biotech, the biopharmaceutical division of Janssen-Cilag, today announced the European Commission's approval of VELCADE in combination with melphalan and prednisone for the treatment of patients with previously untreated multiple myeloma (MM) who are not eligible for high-dose chemotherapy with bone marrow transplant.

In more than 87 countries worldwide, VELCADE monotherapy had already been approved for the treatment of relapsed and / or refractory MM in patients who have received at least one prior therapy.

"VELCADE has already made an important contribution for patients with multiple myeloma at first relapse," said Professor Jesus San Miguel, M.D., University of Salamanca, Spain, the principal investigator for the VISTA trial. "The marketing authorisation from the EMEA is encouraging as it suggests that more patients may benefit from earlier treatment."

The frontline approval is based on phase III results from the VISTA trial, recently published in the *New England Journal of Medicine*, which demonstrated statistically superior results across all efficacy endpoints compared to melphalan and prednisone. In particular, complete response (CR) rates were similar to those achieved that have been achieved in the transplant setting.

Notes to Editors:

- Multiple myeloma (MM) is the second most common blood cancer, representing approximately one percent of all cancers and two percent of all cancer deathsⁱ
- In 2002, there were approximately 85,700 cases of MM worldwideⁱⁱ.
- Only 30 percent of MM patients survive longer than five yearsⁱⁱⁱ, with more than 18,000 people in the European Union dying each year from the disease^{iv}.

About the VISTA study

VISTA stands for: **VELCADE as Initial Standard Therapy in Multiple Myeloma: Assessment with melphalan and prednisone (VISTA) results.** More information is available upon request.

About VELCADE®

VELCADE is the first proteasome inhibitor to receive worldwide regulatory approval for the treatment of multiple myeloma (MM). In 2005, VELCADE was approved in the European Union for MM after first relapse and has now received approval from the European Commission in combination with melphalan and prednisone for the treatment of patients with previously untreated MM who are not eligible for high-dose chemotherapy with bone marrow transplant.

Clinical trials are underway to investigate the potential of VELCADE in additional settings and in combination with other anti-cancer drugs to enhance treatment effects or reverse resistance^v.

VELCADE has a well-defined 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, which is reversible in the majority of patients.

VELCADE is a market leader in treating relapsed multiple myeloma with over 100,000 patients treated worldwide. VELCADE is being co-developed by Johnson & Johnson Pharmaceutical Research & Development, L.L.C. (J&JPRD) and Millennium: The Takeda Oncology Company. Millennium is responsible for commercialisation of VELCADE in the U.S. Janssen-Cilag companies are responsible for commercialisation in Europe and the rest of the world. Janssen Pharmaceutical K.K. is responsible for commercialisation in Japan.

About Janssen-Cilag

The Janssen-Cilag companies have a long track record in developing and marketing treatments for central nervous system disorders, pain management, oncology, infectious diseases, reproductive health and gastrointestinal disorders. More information about Janssen-Cilag can be found at <http://www.janssen-cilag.com>.

- ⁱ <http://www.multiplemyeloma.org>.
- ⁱⁱ GLOBOCAN 2002, www-dep.iarc.fr.
- ⁱⁱⁱ Brenner H. Lancet 2002; 360:1131-1135.
- ^{iv} GLOBOCAN 2002, www-dep.iarc.fr.
- ^v Ciechanover A, Schwartz AL. The ubiquitin system: pathogenesis of human diseases and drug targeting. Biochim Biophys Acta 2004;1695(1-3):3-17.