



Velcade

-Preliminary phase II re-treatment results and two new analyses from phase III VISTA presented at ASH annual meeting-

Beerse, BELGIUM - (9 December, 2008) - Janssen-Cilag today announced preliminary results from a prospective, international, multicenter, open-label, phase II study showing re-treatment with VELCADE[®] (bortezomib) is an effective and well-tolerated treatment option for patients with relapsed multiple myeloma (MM) who had previously responded to VELCADE-based treatment. The patient response after re-treatment was similar when VELCADE was used alone or in combination with dexamethasone. These data were presented in San Francisco, CA at the 50th American Society of Hematology (ASH) Annual Meeting & Exposition.

The data demonstrate how VELCADE can play a role throughout the treatment sequence, which is especially important since relapsed MM patients often build a resistance to therapy. After a treatment-free interval, response to VELCADE is shown to be high and follows an established safety profile.

The primary objective of the study was to determine the best response to VELCADE re-treatment in patients with relapsed MM. Among the study patients, the best response to previous VELCADE treatment was complete response (CR) in 34 patients (27 percent) and partial response (PR) in 94 patients (73 percent). Re-treatment with VELCADE alone or in combination with dexamethasone resulted in 60 percent overall response rate (ORR) including 34 percent CR by single best urine M-protein analysis. The safety profile of VELCADE during re-treatment was consistent with that seen in phase II and III studies in patients with relapsed MM. , ,

In addition, results from two new follow-up analyses of the VISTA (VELCADE as Initial Standard Therapy in Multiple Myeloma: Assessment with Melphalan and Prednisone) Phase III clinical trial were presented at the ASH meeting. An analysis of the three-year survival rate (median follow up of 25.9 months) reinforces the statistically significant survival benefit for the VELCADE arm, which had been seen in earlier analyses. The VELCADE melphalan-prednisone (VMP) arm had at three-year survival rate of 72 percent versus 59 percent in the melphalan-prednisone (MP) arm. The other analysis demonstrates VELCADE efficacy in patients with renal impairment showing a reversal of renal impairment in a significant number of patients.

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 a positive opinion from the CHMP recommending approval for VELCADE 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.

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, which is reversible in the majority of patients.

VELCADE is the 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.

The Janssen-Cilag companies have a long and successful track record in developing and marketing treatments for a wide variety of conditions such as cancer, HIV, pain management, multiple myeloma, gastroenterological disorders, epilepsy, Alzheimer's disease, schizophrenia, acute bipolar mania, behavioural psychological symptoms of dementia, disruptive behaviour disorders and autism. More information can be found at www.janssen-cilag.com.

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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 deaths
- In 2002, there were approximately 85,700 cases of MM worldwide .

- Only 30% percent of MM patients survive longer than five years , with more than 18,000 people in the European Union dying each year from the disease .