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NEWS RELEASE

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FDA APPROVES ADDITION OF SUSTAINED OVERALL SURVIVAL BENEFIT TO LABEL FOR VELCADE® (BORTEZOMIB) FOR INJECTION FOR PATIENTS WITH PREVIOUSLY UNTREATED MULTIPLE MYELOMA

--VELCADE is first front-line multiple myeloma therapy to include overall survival benefit after three-year follow-up in label--

CAMBRIDGE, Mass., January 4, 2010 – [Millennium: The Takeda Oncology Company](http://www.millennium.com)

today announced that the U.S. Food and Drug Administration (FDA) has approved a supplemental new drug application (sNDA) for VELCADE, which expands the label to include long-term (median follow-up 36.7 months) overall survival (OS) data from the landmark VISTA¹ trial and provides specific dosing recommendations for patients with hepatic impairment. The VISTA trial examined the use of VELCADE based therapy in patients with previously untreated multiple myeloma (MM).

The updated survival data, presented at the 51st Annual Meeting of the American Society of Hematology (ASH), confirmed the OS benefit observed at the original interim analysis that led to the front-line approval of VELCADE in MM in June 2008. This presentation of long-term follow-up data demonstrated that patients treated with VELCADE, melphalan and prednisone (VcMP) continued to have significantly longer OS than those treated with melphalan and prednisone (MP) alone, a commonly used standard of care (p=0.0008). These results translated into a 35 percent reduction in risk of death (hazard ratio 0.65). The OS benefit of VcMP was observed despite the use of subsequent therapies at relapse, including VELCADE based regimens.

“With multiple myeloma, there is a need for treatments that are clearly and unequivocally demonstrated to help patients live longer,” said Deborah Dunsire, M.D., President and CEO, Millennium. “VELCADE has been shown to provide a significant long-term survival benefit for patients, and we are thrilled to have this prolonged survival data added to the prescribing information.”

¹ VELCADE as Initial Standard Therapy in multiple myeloma: Assessment with melphalan and prednisone

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The VISTA trial is the largest Phase III registration study to report long-term overall survival in previously untreated multiple myeloma patients. This multicenter, international 682-patient clinical trial compared VcMP to MP in patients with previously untreated MM who were not eligible for stem cell transplantation. In the original interim analysis of the VISTA data, the VcMP arm demonstrated a statistically significant improvement above the MP arm in time-to-disease progression (24 months vs. 17 months), complete response (35% vs. 5%), response rate (69% vs. 34%), progression-free survival (18.3 months vs. 14 months), and OS (hazard ratio 0.61) compared to the MP arm. The updated results presented at ASH included the following facts:

- There was a 35 percent reduced risk of death in the VcMP arm, compared with the MP arm (hazard ratio =0.65, p=0.0008).
- The median survival was not reached in the VcMP arm, while the median OS in the MP arm was 43.1 months.
- The safety profile of VELCADE in combination with MP was consistent with the known safety profiles of both VELCADE and MP.

In VISTA, the most commonly reported adverse events for VELCADE in combination with MP vs MP, respectively, were thrombocytopenia (52% vs 47%), neutropenia (49% vs 46%), nausea (48% vs 28%), peripheral neuropathy (47% vs 5%), diarrhea (46% vs 17%), anemia (43% vs 55%), constipation (37% vs 16%), neuralgia (36% vs 1%), leukopenia (33% vs 30%), vomiting (33% vs 16%), pyrexia (29% vs 19%), fatigue (29% vs 26%), lymphopenia (24% vs 17%), anorexia (23% vs 10%), asthenia (21% vs 18%), cough (21% vs 13%), insomnia (20% vs 13%), edema peripheral (20% vs 10%), rash (19% vs 7%), back pain (17% vs 18%), pneumonia (16% vs 11%), dizziness (16% vs 11%), dyspnea (15% vs 13%), headache (14% vs 10%), pain in extremity (14% vs 9%), abdominal pain (14% vs 7%), paresthesia (13% vs 4%), herpes zoster (13% vs 4%), bronchitis (13% vs 8%), hypokalemia (13% vs 7%), hypertension (13% vs 7%), abdominal pain upper (12% vs 9%), hypotension (12% vs 3%), dyspepsia (11% vs 7%), nasopharyngitis (11% vs 8%), bone pain (11% vs 10%), arthralgia (11% vs 15%) and pruritus (10% vs 5%).

The FDA also reviewed other data derived from an ongoing National Cancer Institute (NCI) study. The analysis supported that patients with mild hepatic impairment did not require dose adjustments while patients with moderate or severe hepatic impairment should begin therapy with VELCADE at a reduced dose and be closely monitored for toxicities.

About Multiple Myeloma

Multiple myeloma is the second most common hematologic malignancy. In the U.S., more than 50,000 individuals have MM and 20,000 new cases are diagnosed each year. Worldwide there are approximately 74,000 new cases and over 45,000 deaths annually.

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About VISTA

The international Phase III VISTA trial was conducted by Millennium and its co-development partner Johnson & Johnson Pharmaceutical Research & Development (JJPRD). The trial randomized 682 patients with newly diagnosed multiple myeloma, ineligible for stem cell transplantation, to receive either VELCADE, melphalan and prednisone (VcMP) or melphalan and prednisone (MP) alone. The primary endpoint of the trial was time-to-disease progression, with secondary endpoints including overall survival, progression-free survival, response rates, and safety.

About VELCADE

VELCADE is co-developed by Millennium Pharmaceuticals, Inc. and Ortho Biotech Oncology Research & Development, a unit of Johnson & Johnson Pharmaceutical Research & Development, L.L.C., and approved worldwide. Millennium is responsible for commercialization of VELCADE in the U.S., Janssen-Cilag is responsible for commercialization in Europe and the rest of the world. Janssen Pharmaceutical K.K. is responsible for commercialization in Japan. VELCADE is currently approved in more than 87 countries worldwide.

Important Safety Information

In the U.S., VELCADE is indicated for the treatment of patients with multiple myeloma. VELCADE also is indicated for the treatment of patients with mantle cell lymphoma who have received at least one prior therapy. VELCADE is contraindicated in patients with hypersensitivity to bortezomib, boron or mannitol. VELCADE should be administered under the supervision of a physician experienced in the use of antineoplastic therapy.

Risks associated with VELCADE therapy include new or worsening peripheral neuropathy, hypotension throughout therapy, cardiac and pulmonary disorders, reversible posterior leukoencephalopathy syndrome, gastrointestinal adverse events, thrombocytopenia, neutropenia, tumor lysis syndrome and hepatic events. Women of childbearing potential should avoid becoming pregnant while being treated with VELCADE. Nursing mothers are advised not to breastfeed while receiving VELCADE. Cases of severe sensory and motor peripheral neuropathy have been reported. The long-term outcome of peripheral neuropathy has not been studied in mantle cell lymphoma. Acute development or exacerbation of congestive heart failure, and new onset of decreased left ventricular ejection fraction has been reported, including reports in patients with no risk factors for decreased left ventricular ejection fraction. There have been reports of acute diffuse infiltrative pulmonary disease of unknown etiology such as pneumonitis, interstitial pneumonia, lung infiltration and Acute Respiratory Distress Syndrome in patients receiving VELCADE. Some of these events have been fatal. There have been reports of Reversible Posterior Leukoencephalopathy Syndrome (RPLS) in patients receiving VELCADE. RPLS is a rare, reversible, neurological disorder which can present with seizure, hypertension, headache, lethargy, confusion, blindness, and other visual and neurological disturbances. VELCADE is associated with thrombocytopenia and neutropenia. There have been reports of gastrointestinal and intracerebral hemorrhage in association with VELCADE. Transfusions may be considered. Complete blood counts (CBC) should be frequently monitored during

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treatment with VELCADE. Cases of acute liver failure have been reported in patients receiving multiple concomitant medications and with serious underlying medical conditions. Patients who are concomitantly receiving VELCADE and drugs that are inhibitors or inducers of cytochrome P450 3A4 should be closely monitored for either toxicities or reduced efficacy. Patients on oral antidiabetic medication while receiving VELCADE should check blood sugar levels frequently.

Adverse Reaction Data

Safety data from Phase II and III studies of single-agent VELCADE 1.3 mg/m²/dose twice weekly for 2 weeks followed by a 10-day rest period in 1163 patients with previously treated multiple myeloma (N=1008, not including the Phase III, VELCADE plus DOXIL® [doxorubicin HCl liposome injection] study) and previously treated mantle cell lymphoma (N=155) were integrated and tabulated. In these studies, the safety profile of VELCADE was similar in patients with multiple myeloma and mantle cell lymphoma.

In the integrated analysis, the most commonly reported adverse events were asthenic conditions (including fatigue, malaise and weakness) (64%), nausea (55%), diarrhea (52%), constipation (41%), peripheral neuropathy NEC (including peripheral sensory neuropathy and peripheral neuropathy aggravated) (39%), thrombocytopenia and appetite decreased (including anorexia) (each 36%), pyrexia (34%), vomiting (33%), anemia (29%), edema (23%), headache, paresthesia and dysesthesia and headache (each 22%), dyspnea (21%), cough and insomnia (each 20%), rash (18%), arthralgia (17%), neutropenia and dizziness (excluding vertigo) (each 17%), pain in limb and abdominal pain (each 15%), bone pain (14%), back pain and hypotension (each 13%), herpes zoster, nasopharyngitis, upper respiratory tract infection, myalgia and pneumonia (each 12%), muscle cramps (11%), and dehydration and anxiety (each 10%). Twenty percent (20%) of patients experienced at least 1 episode of ≥Grade 4 toxicity, most commonly thrombocytopenia (5%) and neutropenia (3%). A total of 50% of patients experienced serious adverse events (SAEs) during the studies. The most commonly reported SAEs included pneumonia (7%), pyrexia (6%), diarrhea (5%), vomiting (4%), and nausea, dehydration, dyspnea and thrombocytopenia (each 3%).

In the Phase 3 VELCADE + melphalan and prednisone study, the safety profile of VELCADE in combination with melphalan/prednisone is consistent with the known safety profiles of both VELCADE and melphalan/prednisone. The most commonly reported adverse events for VELCADE in combination with MP vs MP, respectively, were thrombocytopenia (52% vs 47%), neutropenia (49% vs 46%), nausea (48% vs 28%), peripheral neuropathy (47% vs 5%), diarrhea (46% vs 17%), anemia (43% vs 55%), constipation (37% vs 16%), neuralgia (36% vs 1%), leukopenia (33% vs 30%), vomiting (33% vs 16%), pyrexia (29% vs 19%), fatigue (29% vs 26%), lymphopenia (24% vs 17%), anorexia (23% vs 10%), asthenia (21% vs 18%), cough (21% vs 13%), insomnia (20% vs 13%), edema peripheral (20% vs 10%), rash (19% vs 7%), back pain (17% vs 18%), pneumonia (16% vs 11%), dizziness (16% vs 11%), dyspnea (15% vs 13%), headache (14% vs 10%), pain in extremity (14% vs 9%), abdominal pain (14% vs 7%), paresthesia (13% vs 4%), herpes zoster (13% vs 4%), bronchitis (13% vs 8%), hypokalemia (13% vs 7%), hypertension (13% vs 7%), abdominal pain upper (12% vs

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For more information about VELCADE clinical trials, patients and physicians can contact the Millennium Medical Product Information Department at 1-866-VELCADE (1-866-835-2233).

About Millennium

Millennium: The Takeda Oncology Company, a leading biopharmaceutical company based in Cambridge, Mass., markets VELCADE® (bortezomib) for Injection, a first-in-class proteasome inhibitor, and has a robust clinical development pipeline of product candidates. Millennium Pharmaceuticals, Inc. was acquired by Takeda Pharmaceutical Company Ltd. in May, 2008. The Company's research, development and commercialization activities are focused in oncology. Additional information about Millennium is available through its website, www.millennium.com.

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Editors' Note: This press release is also available under the Media section of the Company's website at: www.millennium.com.