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Ontario Government Announces Reimbursement of Velcade (*) as First-Line Treatment for Newly-diagnosed Blood Cancer Patients

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Myeloma Canada, Patients and Professionals Applaud Ontario for its Leadership in Providing Patients with Treatment Access

Today, Ontarians diagnosed with multiple myeloma, a severely painful and fatal form of blood cancer, will have access to funding for VELCADE (*) (bortezomib), the first novel agent used as a first-line treatment for the disease. VELCADE is now listed on Cancer Care Ontario's New Drug Funding Program (NDFP) Formulary after a positive recommendation from the Committee to Evaluate Drugs (CED) in Ontario. The CED also acts as an interim review body on behalf of the Joint Oncology Drug Review, a cross-jurisdictional review process for oncology drugs in all provinces except Quebec.

As a first-line therapy for patients who are not candidates for stem cell transplants, VELCADE is combined with the current standard of treatment - melphalan and prednisone (MP)¹. The combination of VELCADE and MP has demonstrated improved efficacy compared to current standard of treatment alone². VELCADE received a Notice of Compliance from Health Canada in 2008 for first-line treatment of multiple myeloma¹ and is marketed by Ortho Biotech, a division of Janssen-Ortho Inc.

"Multiple myeloma continues to increase in prevalence in Canada. It is essential that patients have access to the most effective and safest combination treatment that provides them with the best opportunity for survival," said John Lemieux, President, Myeloma Canada.

Carolyn Henry, a multiple myeloma patient and leader of the London and District Myeloma Support Group knows firsthand the challenges of the disease. "Living with this cancer, I understand how important new treatment combinations are to maintaining my health and quality of life. Ontarians are fortunate to have access to VELCADE as a first-line treatment that will offer newly-diagnosed patients a new approach and renewed hope in fighting this tenacious disease."

Addition of VELCADE Improves Overall Survival

The recommendation for funding was based on the findings of the "VELCADE as Initial Standard Therapy in Multiple Myeloma: Assessment with Melphalan and Prednisone" (VISTA) trial, which demonstrated that the addition of VELCADE to the current standard treatment significantly improved the time to progression of the disease, complete response to treatment and the treatment-free interval time². The VISTA study results showed that the overall survival rate, at 24 months, for myeloma patients was 82.6 per cent for patients who received VELCADE along with MP combination treatment compared to only 69.5 per cent for those who received MP combination alone¹.

¹ VELCADE Product Monograph, August 29, 2008.

² San Miguel, Jesus F., "Bortezomib plus Melphalan and Prednisone for Initial Treatment of Multiple Myeloma," New England Journal of Medicine, vol. 359, August 28, 2008, pp 906-917.

"As an oncologist, until now, I have diagnosed all too many patients with advanced stage myeloma who could have benefited from VELCADE as a first-line treatment," said Dr. Donna Reece, Haematologist, Toronto. "Today's news will allow me to provide a highly effective, fast-acting treatment that will improve the life expectancy of my patients. As the new standard of first-line care, VELCADE and MP allows patients to experience longer treatment-free intervals so they can live fuller, more productive lives."

About Multiple Myeloma in Canada

As of 2003, an estimated 6,200 Canadians were living with multiple myeloma³. In 2009, new cases of multiple myeloma are estimated to reach 2,200 and the number of deaths from this disease is estimated to reach 1,400⁴.

About VELCADE (bortezomib) for Injection

VELCADE offers a completely novel approach to treating multiple myeloma by acting on a unique target in cells called the proteasome. By blocking the proteasome, VELCADE disrupts processes related to the growth and survival of cancer cells. The proteasome is a structure that exists in all cells and plays an important role in breaking down proteins that control how the cell lives and grows⁵.

VELCADE was first approved in Canada under a Notice of Compliance with Conditions in January 2005 for the treatment of patients with multiple myeloma who have relapsed following front-line therapy and are refractory to their most recent therapy.

VELCADE was also recently approved for the treatment of patients with mantle cell lymphoma (MCL), who have relapsed or are refractory to at least one prior therapy. MCL is a type of non-Hodgkin's lymphoma, which is a cancer of the blood that affects the white blood cells.

VELCADE is currently funded across Canada for the treatment of relapsed or refractory multiple myeloma. Ortho Biotech will continue to seek funding across Canada for this new indication of front-line treatment of newly diagnosed, previously untreated multiple myeloma patients.

The safety profile of VELCADE in combination with melphalan/prednisone is consistent with the known safety profiles of both VELCADE and melphalan/prednisone. In most cases side effects are manageable with appropriate monitoring and, if necessary, dose reduction. VELCADE is contraindicated in patients with hypersensitivity to bortezomib, boron, or any of the excipients. In the VISTA clinical trial, the most commonly reported adverse events included thrombocytopenia, neutropenia, leucopenia, lymphopenia, anemia, nausea, diarrhoea, constipation, vomiting, peripheral neuropathy, neuralgia, fever, fatigue and asthenia.

³ Calculated Canadian estimate based on US prevalence (according to "Orphan Products: Hope for People With Rare Diseases" By Carol Rados, FDA Consumer magazine, November-December 2003 Issue, about 63,000 people in the United States are affected by multiple myeloma).

⁴ Canadian Cancer Society/National Cancer Institute of Canada: Canadian Cancer Statistics

⁵ Health Canada. Condition Approval of VELCADE Fact Sheet. January 27, 2005.

Ortho Biotech - Division of Janssen-Ortho Inc.

Ortho Biotech is a leading Canadian biopharmaceutical healthcare company committed to bringing innovative treatments to Canadians in the areas of anemia, oncology, and nephrology.

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