

VELCADE* for multiple myeloma receives front-line approval in Canada

Research shows VELCADE combination treatment improves overall survival*

TORONTO, Ontario – September 8, 2008 – VELCADE* (bortezomib) for Injection has received Health Canada approval for front-line (first) treatment of multiple myeloma, a fatal blood cancer. As part of combination therapy, VELCADE is indicated for the treatment of patients with previously untreated multiple myeloma who are unsuitable for stem cell transplantation. With this new approval, patients with multiple myeloma can now receive VELCADE earlier following initial disease diagnosis, which may help to slow, reverse or halt disease progression.

“Living with this relentless type of cancer for the past year, I know firsthand how debilitating the rapid progression of the disease can be,” says Monique Racine, a Canadian patient diagnosed with multiple myeloma. “By receiving VELCADE earlier in this disease, other patients may have an even greater benefit from the treatment. This medication, which has done so much good for me, has empowered me and given me a stronger desire to fight my disease.”

“Having access to proven effective combination therapies upon disease diagnosis is very important in the fight against multiple myeloma because it gives patients of this fatal disease a chance to extend their life expectancy and their quality of life,” comments Dr. Andrew Belch, Hematologist, Department of Oncology, University of Alberta, Cross Cancer Institute, Edmonton, Alberta. “Multiple myeloma is an aggressive disease that advances rapidly, with the patient’s condition deteriorating exponentially. The front-line approval of VELCADE is a positive step forward and should bring renewed hope to multiple myeloma patients and their families.”

VELCADE’s front-line approval is based on the phase III VISTA (VELCADE as Initial Standard Therapy in Multiple Myeloma: Assessment with Melphalan and Prednisone) trial, recently published in the New England Journal of Medicine (NEJM)¹. VISTA is a randomized, international, open-label phase III trial that Canadian investigators participated in. The trial compared VELCADE in combination with the current standard of care versus the standard of care alone in 682 previously untreated patients who were unsuitable for stem cell transplantation. VISTA demonstrated that patients receiving the standard of care plus VELCADE achieved a greater overall survival rate at 24 months (83 per cent) compared to those who only received standard of care alone (70 per cent)². The complete response in the VELCADE combination arm was 30 per cent versus four per cent in the standard of care arm alone².

“The approval of VELCADE as a front-line therapy is a great step forward in the fight against this challenging disease,” says Dr. Donna Reece, Hematologist, Toronto, Ontario. “As a physician, it is outstanding that we now have an effective treatment to offer our patients immediately following diagnosis that can not only help to improve their quality of life, but can also extend their life – this is so meaningful for both the patients and their families.”

About Multiple Myeloma in Canada

As of 2003, an estimated 6,200 Canadians have multiple myeloma³. In 2008, new cases of multiple myeloma are estimated to reach 2,100⁴, an increase of 13.5 per cent since 2005⁵. Furthermore, the number of deaths from this disease in 2008 is estimated at 1,350⁴, which demonstrates an increase of eight per cent since 2005⁵.

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. 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 grows.

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 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 modification. 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 (decrease in blood clotting cells), neutropenia, leucopenia, lymphopenia, anemia, nausea, diarrhea, constipation, vomiting, peripheral neuropathy (numbness of the hands, arms, feet or legs), neuralgia, fever, fatigue and asthenia.

In Canada, VELCADE is marketed by Ortho Biotech, a division of Janssen-Ortho Inc.

Ortho Biotech - Division of Janssen-Ortho Inc.

Ortho Biotech (Canada) is a biopharmaceutical healthcare company and the leader in the treatment of anemia with a commitment to developing treatments for Canadians suffering from cancer.

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Dr. Donna Reece and Dr. Belch act as consultants for Ortho Biotech.

References:

¹ Jf San Miguel, R Schlag, NK Khuageva, MA Dimopoulos, O Shpilberg, M Kropff, I Spicka, MT Petrucci, A Palumbo, OS Samoilova, A Dmoszynska, KM Abdulkadyrov, R Schots, B Jiang, M-V Mateos, KC Anderson, DL Esseltine, K Liu, A Cakana, H van de Velde, PG Richardson; VISTA-MMY-3002 study investigators. Bortezomib plus melphalan and prednisone for initial treatment of multiple myeloma. *NEJM* 2008 [August 28, 2008].

² Product Monograph VELCADE*, updated as of August 29, 2008.

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 2008, available at: www.cancer.ca.

⁵ Canadian Cancer Society/National Cancer Institute of Canada: Canadian Cancer Statistics 2004, available at www.cancer.ca.