**VELCADE® (bortezomib) Now Approved to Treat Newly-Diagnosed Mantle Cell Lymphoma Patients in Canada**

*Patients with this aggressive form of blood cancer have a new treatment option that's been shown to significantly delay disease progression*

**Toronto, ON – April 15, 2015** – Janssen Inc. announced today that Health Canada has approved VELCADE® (bortezomib) as part of combination therapy for the treatment of patients with previously untreated mantle cell lymphoma (MCL) who are unsuitable for stem cell transplantation. Mantle cell lymphoma is a type of non-Hodgkin's lymphoma, which is a cancer of the blood that affects B-cells. This aggressive blood cancer is typically associated with a poor prognosis, with a median survival rate of three to four years.[1]

To gain this approval of VELCADE® for newly-diagnosed MCL patients in Canada, the medicine was studied in combination with rituximab, cyclophosphamide, doxorubicin and prednisone (known as VcR-CAP). The study results showed significant benefits when treating patients with MCL using the VELCADE®-based combination VcR-CAP, compared to a widely-used, current standard of care, R-CHOP (rituximab, cyclophosphamide, doxorubicin, vincristine, and prednisone), which does not include VELCADE®.[2]

Specifically, the VcR-CAP regimen significantly improved progression-free survival (PFS), the primary endpoint of the trial. An independent review committee reported the increase in PFS to be 59 per cent (median 24.7 vs. 14.4 months; HR 0.63; p<0.001), whereas the study investigators reported the increase in PFS to be 96 per cent (median 30.7 vs. 16.1 months; HR 0.51; p<0.001).[3] Secondary endpoints, including time taken for the disease to progress and time until the need to start another treatment, were almost doubled with the VcR-CAP regimen compared with R-CHOP.[4]

This VELCADE® phase 3 clinical trial, named LYM-3002, was a randomized, open-label, active-controlled, multicentre, international, prospective study. LYM-3002 included 487 patients with newly diagnosed MCL who were ineligible, or not considered, for bone marrow transplantation. The objective was to compare the efficacy and safety of VcR-CAP with R-CHOP.[5]

The use of VcR-CAP in the study was associated with additional, but manageable, toxicity when compared to R-CHOP.[6] Overall, among patients receiving VcR-CAP compared to R-CHOP, serious adverse events (AE) were reported in 38 per cent vs. 30 per cent of patients and grade ≥3 AEs were reported in 93 per cent vs. 85 per cent. Discontinuations of treatment due to AEs were eight per cent (VcR-CAP) vs. six per cent (R-CHOP) and on-treatment drug-related deaths were two per cent vs. three per cent.[7]

The approval of VELCADE® for front-line treatment of MCL is an important milestone, underscoring Janssen's commitment to patients with B-cell malignancies like MCL and chronic lymphocytic leukemia. In 2008, VELCADE® received its first indication in MCL for patients who relapsed or are unresponsive to at least one prior therapy.

**About VELCADE®**

VELCADE® contains an active substance called bortezomib and is the first in a class of medicines known as proteasome inhibitors. Proteasomes are present in all cells and play an important role in controlling cell function, growth and how cells interact with other cells around them. Bortezomib reversibly interrupts the normal activity of cell proteasomes, including cancerous cells, causing them to stop growing and die.[8]

VELCADE® has a predictable safety profile and a favourable benefit–risk ratio, and can be used in elderly patients.[9] The most common side effects reported with VELCADE® include fatigue, gastrointestinal adverse events, transient thrombocytopenia and neuropathy.[10]

VELCADE® was first approved in Canada under a Notice of Compliance with Conditions in January 2005 for the treatment of patients with multiple myeloma (MM) who have relapsed following front-line therapy and are unresponsive to their most recent therapy. In June 2008, VELCADE® was also approved for the treatment of patients with MCL who have relapsed or are unresponsive to at least one prior therapy. Further to this, in September 2008, VELCADE® was approved for the treatment of patients with previously untreated MM who are unsuitable for stem cell transplantation.

In March 2012, an additional route of administration, subcutaneous injection, was approved for VELCADE® for the treatment of patients with MCL who have relapsed or are unresponsive to at least one prior therapy. VELCADE® then received Health Canada approval in June of 2013, as part of a medically recognized combination therapy for induction treatment of patients with previously untreated MM who are suitable for stem cell transplantation (studies were conducted with intravenous administration of VELCADE®).[11]

VELCADE® is co-developed by Millennium, the Takeda Oncology Company, a wholly owned subsidiary of Takeda Pharmaceutical Company Limited, and Janssen Pharmaceutical Companies. In Canada, Janssen Inc. commercializes VELCADE®. Approved in more than 90 countries, VELCADE® has been used to treat more than 550,000 patients worldwide. Janssen is committed to continuously developing therapeutic solutions to treat hematologic cancers and diseases.

**About MCL**
Mantle cell lymphoma is a rare and aggressive type of blood cancer that affects a specific group of white blood cells (lymphocytes) called b-cells.[12,13] It accounts for six per cent of all non-Hodgkin lymphomas and typically occurs more often in men than in women, usually over the age of 50.[14] In Canada, it is estimated that about 480 adults were diagnosed with MCL in 2014.[15] Patients often have advanced stages of MCL at diagnosis and face a median survival rate of three to four years.[16] Those who undergo chemotherapy normally relapse within 12-18 months.[17]

**About Janssen Inc.**
Janssen Inc. is one of the Janssen Pharmaceutical Companies, which are dedicated to addressing and solving some of the most important unmet medical needs in oncology, immunology, neuroscience, infectious diseases and vaccines, and cardiovascular and metabolic diseases. Driven by our commitment to patients, we bring innovative products, services and solutions to people throughout the world. Please visit www.janssen.ca for more information.

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