You are invited!

VELCADE® (bortezomib) FOR INJECTION

Establishing a Plan for Length of Therapy in Multiple Myeloma

Presented by

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Thursday, November 13, 2014
6:30 PM

Stage Left
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Hosted by

Eleda Espinoza

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This program will discuss how clinical evidence supports the use of VELCADE (bortezomib) in patients with previously untreated and relapsed multiple myeloma, how to establish a plan for length of therapy with VELCADE, as well as patient management strategies, including subcutaneous administration.

RSVP via email to epic@theselvagroup.com
or fax to 800-660-8857 before 11/11/2014.

Full Name _____ Credentials _____ Title _____

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License Number (only if licensed in MA or MN) _____ Meeting Code E6959

Sponsored by Millennium Pharmaceuticals, Inc. Please note that this is not a Continuing Medical Education (CME) program.

VELCADE® (bortezomib) is indicated for the treatment of patients with multiple myeloma. VELCADE is indicated for the treatment of patients with mantle cell lymphoma who have received at least 1 prior therapy.

VELCADE is contraindicated in patients with hypersensitivity (not including local reactions) to bortezomib, boron, or mannitol, including anaphylactic reactions. VELCADE is contraindicated for intrathecal administration. Fatal events have occurred with intrathecal administration of VELCADE.

Please see Important Safety Information on page 2 and full Prescribing Information, available at VELCADEHCP.com.

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Indications and Important Safety Information for VELCADE® (bortezomib)

INDICATIONS: VELCADE (bortezomib) is indicated for the treatment of patients with multiple myeloma. VELCADE is indicated for the treatment of patients with mantle cell lymphoma who have received at least 1 prior therapy.

CONTRAINDICATIONS: VELCADE is contraindicated in patients with hypersensitivity (not including local reactions) to bortezomib, boron, or mannitol, including anaphylactic reactions. VELCADE is contraindicated for intrathecal administration. Fatal events have occurred with intrathecal administration of VELCADE.

WARNINGS AND PRECAUTIONS: VELCADE is for subcutaneous or IV administration only. Because each route of administration has a different reconstituted concentration, caution should be used when calculating the volume to be administered.

- **Peripheral neuropathy,** including severe cases, may occur. Patients should be monitored for symptoms and managed with dose modification or discontinuation. Patients with preexisting symptoms may experience worsening peripheral neuropathy (including ≥Grade 3). Starting with VELCADE subcutaneously may be considered for patients who either have preexisting or are at high risk for peripheral neuropathy.
- **Hypotension:** Caution should be used when treating patients receiving antihypertensives, those with a history of syncope, and those who are dehydrated.
- **Cardiac toxicity,** including acute development or exacerbation of congestive heart failure and new onset of decreased left ventricular ejection fraction, has occurred. Isolated cases of QT-interval prolongation have been reported. Patients with risk factors for, or existing, heart disease should be closely monitored.
- **Pulmonary toxicity:** Acute respiratory distress syndrome (ARDS) and acute diffuse infiltrative pulmonary disease of unknown etiology have occurred (sometimes fatal). Pulmonary hypertension, in the absence of left heart failure or significant pulmonary disease, has been reported. In the event of new or worsening cardiopulmonary symptoms, consider interrupting VELCADE until a prompt and comprehensive diagnostic evaluation is conducted.
- **Posterior reversible encephalopathy syndrome** has occurred. Consider MRI imaging for onset of visual or neurological symptoms; discontinue VELCADE if suspected.
- **Gastrointestinal toxicity,** including nausea, diarrhea, constipation, and vomiting, has occurred and may require use of antiemetic and antidiarrheal medications or fluid replacement. Interrupt VELCADE for severe symptoms.
- **Thrombocytopenia/Neutropenia:** Manage with dose and/or schedule modifications. Complete blood counts should be monitored frequently during treatment. There have been reports of gastrointestinal and intracerebral hemorrhage. Transfusions may be considered.
- **Tumor lysis syndrome:** Closely monitor patients with high tumor burden and take appropriate precautions.
- **Hepatic toxicity:** Monitor hepatic enzymes during treatment. Upon occurrence, interrupt therapy with VELCADE to assess reversibility.
- **Embryo-fetal risk:** Women should avoid breast-feeding or becoming pregnant while on VELCADE.
- **Patients with diabetes** may require close monitoring and adjustment of the antidiabetic medications.

DRUG INTERACTIONS: Closely monitor patients receiving VELCADE in combination with strong CYP3A4 inhibitors. Avoid concomitant use of strong CYP3A4 inducers.

ADVERSE REACTIONS

- **Previously untreated multiple myeloma (MM):** In the phase 3 study of VELCADE administered intravenously with melphalan and prednisone (MP) vs MP alone, the most commonly reported adverse reactions (ARs) were thrombocytopenia (48% vs 42%), neutropenia (47% vs 42%), peripheral neuropathy (46% vs 1%), nausea (39% vs 21%), diarrhea (35% vs 6%), neuralgia (34% vs <1%), anemia (32% vs 46%), and leukopenia (32% vs 28%).
- **Relapsed MM and mantle cell lymphoma:** In the integrated analysis of 1163 patients in phase 2 and 3 studies of VELCADE administered intravenously, the most commonly reported ARs were nausea (49%), diarrhea NOS (46%), fatigue (41%), peripheral neuropathy NEC (38%), and thrombocytopenia (32%). A total of 26% of patients experienced serious ARs. The most commonly reported serious ARs included diarrhea, vomiting, and pyrexia (each 3%); nausea, dehydration, and thrombocytopenia (each 2%); and pneumonia, dyspnea, peripheral neuropathies NEC, and herpes zoster (each 1%).
- **Relapsed MM subcutaneous vs IV:** In the phase 3 study of VELCADE administered subcutaneously vs intravenously in relapsed MM, safety data were similar between the two treatment groups. The most commonly reported ARs in the subcutaneous vs IV treatment groups were peripheral neuropathy (37% vs 50%) and thrombocytopenia (30% vs 34%). The incidence of serious ARs was similar in the subcutaneous treatment group (20%) and the IV treatment group (19%). The most commonly reported serious ARs were pneumonia and pyrexia (each 2%) in the subcutaneous treatment group and pneumonia, diarrhea, and peripheral sensory neuropathy (each 3%) in the IV treatment group.

Please see accompanying full Prescribing Information, also available at VELCADEHCP.com.

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Millennium Pharmaceuticals, Inc., Cambridge, MA 02139
 Printed in USA V-13-0368 11/13

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