

In collaboration with the Food and Drug Administration (FDA), and as a service to our members, the Oncology Nursing Society will provide information about newly approved therapies for cancer patients. This will allow the FDA to inform ONS members of recent approvals in a timely manner. Included in the information from the FDA will be a link to the product label, which will provide the relevant clinical information on the indication, contraindications, dosing, and safety. In sending this information, ONS does not endorse any product or therapy and does not take any position on the safety or efficacy of the product or therapy described. The following is a message from the FDA's Office of Oncology Drug Products Director, Dr. Richard Pazdur:

On June 20, 2008, the U.S. Food and Drug Administration approved bortezomib for injection (Velcade®, Millennium Pharmaceuticals, Inc., The Takeda Oncology Company, and Johnson and Johnson Pharmaceutical Research and Development) for the treatment of patients with multiple myeloma. This approval results from a clinical trial using Velcade® as an initial treatment for patients with multiple myeloma. Velcade® was previously approved in 2005 for the treatment of patients with multiple myeloma who had received at least one prior therapy and in 2003 for the treatment of more refractory multiple myeloma.

The current approval was based on an international, multicenter, open label, active-control trial in previously untreated patients with symptomatic multiple myeloma. Patients were randomized to receive either nine 6 week cycles of oral melphalan (M) plus prednisone (P), or MP plus bortezomib. Patients received M (9 mg/m²) plus prednisone (60 mg/m²) daily for four days every 6 weeks or the same MP schedule with bortezomib, 1.3 mg/m² iv on days 1, 4, 8, 11, 22, 25, 29, and 32 of every 6 week cycle for 4 cycles then once weekly for 4 weeks on days 1, 8, 22 and 29 of every 6 week cycle for 5 additional cycles. Time-to-progression (TTP) was the primary efficacy endpoint. Overall survival (OS), progression-free survival (PFS), and response rate (RR) were secondary endpoints. The majority of the patients enrolled were ≥ 65 years of age. A total of 682 patients were randomized: 338 to receive MP and 344 to receive the combination of bortezomib plus MP. Demographics and baseline disease characteristics were similar between the two groups.

The trial was stopped following a pre-specified interim analysis showing a statistically significant improvement in TTP with the addition of bortezomib to MP (median 20.7 months) compared with MP (median 15 months) [HR: 0.54 (95% CI: 0.42, 0.70), p= 0.000002]. OS, PFS, and RR also were significantly superior for the bortezomib-MP combination.

The most common adverse reactions (incidence ≥30%) in clinical studies of bortezomib include asthenic conditions, diarrhea, nausea, constipation, peripheral neuropathy, vomiting, pyrexia, thrombocytopenia, psychiatric disorders, anorexia and decreased appetite, neutropenia, neuralgia, leukopenia and anemia. Dose adjustment guidelines for hematologic and neurologic toxicity are detailed in the label (package insert).

Full prescribing information, including clinical trial information, safety, dosing, drug-drug interactions and contraindications is available at www.fda.gov/cder/foi/label/2008/021602s0151bl.pdf.

If you would like to subscribe/unsubscribe to this particular ONS communication, please e-mail ONSlist@ons.org

Don't worry about being overloaded with e-mails. ONS knows that your time is valuable and has a strict policy of not selling or sharing your e-mail address. Read our privacy statement at: <http://www.ons.org/privacy.shtml>