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November 30, 2011

Dear Health Care Provider:

Re: VELCADE®* (bortezomib) 3.5mg powder for solution for injection manufactured at Ben Venue Laboratories

We wanted to advise you about some important new developments regarding VELCADE® produced at one of our specialty contract drug manufacturing sites, Ben Venue Laboratories (BVL), Ohio, US. Issues were identified during a recent inspection, in November 2011, at this site.

All VELCADE® batches released to the market comply with release specifications and procedures. However, an inspection of the manufacturing facilities in November 2011 identified several problems in quality assurance of the sterilization process at BVL.
As a result, we are initiating a precautionary and voluntary Type II recall (pharmacy/hospital) of VELCADE® produced at BVL.

This precautionary and voluntary recall of **only** VELCADE® manufactured at BVL is being initiated based on the following considerations:

- VELCADE® 3.5 mg powder for solution for injection is also supplied in Canada by another manufacturing site, Pierre Fabre Medicament Production (PFMP).

- Importantly, in Canada there is sufficient VELCADE® 3.5 mg from our other qualified manufacturer, PFMP, to ensure patients can continue to receive VELCADE®. We do not expect this situation to impact treatment for existing VELCADE® patients or those starting treatment for the first time.

Details regarding the recall procedures will be provided to the hospital pharmacy directly and will not impact your current standard of care.

If you have further questions, please do not hesitate to contact your Janssen VELCADE® Territory Manager or the Janssen Medical Information department at 1-800-567-3331 or 1-800-387-8781 (option 4).

We apologize for any inconvenience caused,

Dr. Catherine Lau, Ph.D.
Vice-President, Regulatory Affairs & Quality Management