Teva Pharmaceuticals Confirms the BD PhaSeal[™] System is Compatible with Chemotherapy Drug Treanda® Injection

FDA Updates March 2015 Safety Alert on CSTD Compatibility for Treanda® Injection

September 29, 2015 - Today BD (Becton, Dickinson and Company), notified customers that the U.S. Food and Drug Administration (FDA) has updated its March 2015 Safety Alert based on Teva Pharmaceuticals' (Teva) findings which include that the BD PhaSeal[™] System is the only closed system drug transfer device (CSTD) compatible with the chemotherapy drug, Treanda[®] Injection (bendamustine HCI) based on the testing performed by Teva from February through June 2015.

Consistent with all previous BD PhaSeal System testing, Teva's independent studies confirmed the compatibility of the BD PhaSeal CSTD consisting of: BD PhaSeal Protector (P14), BD PhaSeal Injector (N35), and BD PhaSeal Infusion Adapter (C100). The raw materials used in the system are chosen for their chemical resistance and these products do not contain polycarbonate or ABS in the fluid path – material shown to interact with hazardous drugs that contain the solvent N,N-Dimethylacetamide. In addition, Teva also identified the BD PhaSeal Secondary Set (C60) is compatible for IV administration of Treanda Injection.

Treanda is indicated for the treatment of patients with chronic lymphocytic leukemia (CLL) and bendamustine is recognized by the National Comprehensive Cancer Network (NCCN) as a first line therapy for CLL. The BD PhaSeal System is not contraindicated for any known hazardous drugs, including those that contain N, N-dimethylacetamide as a solvent.

"BD is committed to providing health care workers with the proper protection required to handle hazardous drugs that can help save the lives of patients in need," said Lynne Kelley, MD, FACS, Vice President, Worldwide Medical Affairs, BD Medication & Procedural Solutions, BD Medical. "We are proud to offer one of the most comprehensive portfolios to empower protection of healthcare workers from hazardous drug exposure. Our goal is to help ensure that every patient around the world receives the necessary medication required for their specific treatment plan, without jeopardizing the health of the hospital workers who handle these hazardous drugs."

BD shares the FDA's focus on educating health care providers about the proper use of its products to ensure safe medication practices and the safe handling of hazardous drugs. Earlier this month, Teva Pharmaceuticals issued a letter to health care providers summarizing the compatibility results from their internal testing, which was immediately followed by an updated Safety Alert from the FDA confirming the compatibility between Treanda Injection and the BD PhaSeal System – the only CSTD verified by Teva to be compatible with its chemotherapy drug.

For more information on the BD PhaSeal System please visit: <u>http://www.bd.com/pharmacy/phaseal/</u>.

About BD

BD is one of the largest global medical technology companies in the world and is advancing the world of health by improving medical discovery, diagnostics and the delivery of care. The company supports the heroes on the frontlines of health care by developing innovative technology, services and solutions that help advance both clinical therapy for patients and clinical process for health care providers. BD and its 65,000 employees have a passion and commitment to help enhance the safety and efficiency of clinicians' care delivery process, enable laboratory scientists to accurately detect disease and advance researchers' capabilities to develop the next generation of diagnostics and therapeutics. BD has a presence in virtually every country and partners with organizations around the world to address some of the most challenging global health issues. By working in close collaboration with customers, BD can help enhance outcomes, lower costs, increase efficiencies, improve safety and expand access to health care. For more information on BD, please visit <u>bd.com</u>

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