February 1, 2016

Generic Gleevec Launched
Sun announced the launch of its AB-rated generic to Novartis’ Gleevec® (imatinib mesylate), a drug first approved in 2001 for treating Philadelphia chromosome positive (Ph+) chronic myeloid leukemia. It is also approved to treat certain patients with Ph+ acute lymphoblastic leukemia, myelodysplastic/myeloproliferative diseases, aggressive systemic mastocytosis, hypereosinophilic syndrome/chronic eosinophilic leukemia and dermatofibrosarcoma protuberans. Sun was granted 180 days of generic exclusivity, preventing FDA from approving additional generics until late-July 2016. Full prescribing information can be found on the company’s website at: www.imatinibrx.com

At a Glance
- **Brand (Generic) Name:** Gleevec® (imatinib mesylate - Novartis)
- **Generic Manufacturer:** Sun Pharma
- **Launch Date:** February 1, 2016
- **Indication:** Treating certain patients with Philadelphia chromosome positive (Ph+) chronic myeloid leukemia, Ph+ acute lymphoblastic leukemia, myelodysplastic/myeloproliferative diseases, aggressive systemic mastocytosis, hypereosinophilic syndrome/chronic eosinophilic leukemia and dermatofibrosarcoma protuberans.
- **Dosage Forms Available:** 100mg and 400mg tablets
- **Annual U.S. Sales:** 5 billion for the most recent twelve months ending in August 2015, according to IMS Health.
- Sun received final approval for its generic to Gleevec tablets in December 2015. However, following the terms within a settlement agreement, the company was allowed to launch its generic on Feb. 1, 2016.
- **Specialty Status:** The generic to Gleevec will be added to Express Scripts’ specialty drug list.