

**FOR IMMEDIATE RELEASE**

## **Sun Pharma launches Imatinib Mesylate in USA**

***Imatinib Mesylate is the therapeutic equivalent to Gleevec<sup>®</sup> for indications approved by FDA***

*Announces Imatinib Mesylate Savings Card Program to deliver greater access of the medication to patients in USA*

*Unique Helpline service enables patients to discuss Imatinib Mesylate with trained healthcare professionals*

**MUMBAI & NEW JERSEY – FEBRUARY 1, 2016:** Sun Pharma (Sun Pharmaceutical Industries Ltd and its subsidiaries, Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715), today, announced the launch of Imatinib Mesylate Tablets (therapeutic equivalent to Gleevec<sup>®</sup> for indications approved by the FDA) in US market. Sun Pharma's subsidiary received final approval for Imatinib Mesylate from FDA in December 2015. Being a First-to-File product, it was granted 180 days of marketing exclusivity by FDA from the time of its launch.

As part of this launch, in addition to strengthening distribution in USA, the company has rolled-out unique Sun Pharma Imatinib Mesylate Savings Card program. This program aims to deliver greater access to the drug for patients who have a commercial insurance but their out-of-pocket may exceed an affordable amount. The savings card will reduce patient's co-payment (out-of-pocket) to \$10. In line with its philosophy of putting patients first, Sun Pharma's Imatinib Mesylate Savings Card will also offer patients additional savings benefit of up to US\$700 for a 30-day fill to offset any additional out-of-pocket cost should they be required to meet their deductible or co-insurance. Participating pharmacies across USA can use the patient's Sun Pharma's Imatinib Mesylate Savings Card as part of this program.

Sun Pharma has also launched an exclusive patient website [www.imatinibrx.com](http://www.imatinibrx.com) providing detailed information about its Imatinib Mesylate, approved indications, side effects etc. Additionally, the website features detailed FAQs on the product. Eligible patients can participate in Sun Pharma's Imatinib Mesylate Savings Card program by registering online at [www.imatinibrx.com](http://www.imatinibrx.com) or by requesting a savings card from their Oncologist. Sun Pharma will be supplying its Imatinib Mesylate Savings Cards to over 4,500 Oncologists.

Sun Pharma has established a Hub service where patients can dial-in to speak with a trained healthcare professional and discuss Imatinib Mesylate when used for indications approved by FDA under Sun Pharma's ANDA. Patients can access Sun Pharma's Hub service through toll-free helpline number +1 844-502-5950.

As part of its Patient Assistance Program (PAP), qualifying patients can receive Sun Pharma's Imatinib Mesylate at no cost. Based on qualifications for applying and including doctor's prescription, the Hub service will determine if a patient is qualified to receive Sun Pharma's Imatinib Mesylate for free. Upon acceptance, the prescription will be processed and delivered to the qualifying patient at no cost.

### **IMATINIB MESYLATE - INDICATIONS AND USAGE**

Imatinib Mesylate is a kinase inhibitor indicated for the treatment of:

- Newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukaemia (Ph+ CML) in chronic phase
- Patients with Philadelphia chromosome positive chronic myeloid leukaemia (Ph+ CML) in blast crisis (BC), accelerated phase (AP), or in chronic phase (CP) after failure of interferon-alpha therapy
- Adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
- Adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements
- Adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation or with c-Kit mutational status unknown
- Adult patients with hypereosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL) who have the FIP1L1-PDGFR $\alpha$  fusion kinase (mutational analysis or FISH demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1- PDGFR $\alpha$  fusion kinase negative or unknown
- Adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP)

***As stated in the FDA approval letter, Sun Pharma's Imatinib Mesylate ANDA contains a statement under section 505(j)(2)(A)(viii) of the FD&C Act representing that its application did not seek approval for the method of treatment covered under U.S. Patent No. 6958335 ('335 patent). According to the FDA's Orange Book, the '335 patent covers the "indication for the treatment of patients with KIT (CD117) positive unresectable and/or metastatic malignant gastrointestinal stromal tumors (GIST)." As a result, FDA has not approved Sun Pharma's Imatinib Mesylate Tablet products for this indication.***

**For safety information please refer to U.S. Full Prescribing Information  
at [www.imatinibrx.com](http://www.imatinibrx.com)**

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### **ABOUT SUN PHARMA (CIN - L24230GJ1993PLC019050)**

*Sun Pharma is world's fifth largest specialty generic and India's top pharmaceutical company. With a vertically integrated business, economies of scale, an extremely skilled team enabling delivery of quality products at affordable prices and trusted by customers and patients in over 150 countries globally. Sun Pharma's global presence is supported by 49 manufacturing facilities spread across 6 continents, R&D centres worldwide and a multi-cultural workforce representing more than 50 nationalities. The consolidated revenues for 12 months ending March 31, 2015 was approximately US\$ 4.5 billion, of which US contributed US\$ 2.2 billion. In India, Sun Pharma enjoys leadership across 12 different classes of doctors with 30 brands featuring amongst top 300 pharmaceutical brands. Its footprint across emerging markets covers more than 100 markets and six markets in Western Europe. The Global Consumer Healthcare business is ranked amongst Top 10 across 4 global markets and the API business footprint is strengthened through 14 world class API manufacturing facilities worldwide. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities comprising about 2,000 scientists and investments of over 7% of annual revenues.*

*For further information please visit [www.sunpharma.com](http://www.sunpharma.com)*

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