Sun Pharmaceutical Industries Ltd Sun House, Plot No 201, B/1 Western Express Highway, Goregaon East Mumbai – 400 063, Maharastra, India Board: +91 22 4324 4324

Fax: +91 22 4324 4343 www.sunpharma.com

CIN: L24230GJ1993PLC019050



# FOR IMMEDIATE RELEASE

# Sun Pharma extends Imatinib Mesylate Savings Card program benefits for patients in USA

MUMBAI / NEW JERSEY – AUGUST 8, 2016: As part of the company's philosophy of putting patients interests first, Sun Pharma (Reuters: SUN.BO, Bloomberg: SUNP IN, NSE: SUNPHARMA, BSE: 524715, Sun Pharmaceutical Industries Ltd and includes its subsidiaries or associate companies) announced the extension of its Imatinib Mesylate Savings Card Program beyond July 31, 2016. Sun Pharma launched this program as part of the Imatinib Mesylate launch in February 2016. The program is aimed at delivering greater access to the drug by patients who have commercial insurance, but whose out-of-pocket cost may exceed an affordable amount.

As part of the Imatinib Mesylate savings card program extension, Sun Pharma will continue to offer up to US\$ 700 reduction on each eligible patient's initial out-of-pocket cost from their commercial insurer thereby reducing the patient's out-of-pocket co-payment to as low as \$10. This benefit will cover a patient's monthly fills for a 30-day supply of Sun Pharma's Imatinib Mesylate prescribed for Ph+CML, a form of chronic myeloid leukemia through the extension period.

During the first six months following its launch on February 1st, more than 5,000 prescriptions for Sun Pharma's Imatinib Mesylate have been filled by patients utilizing this savings card program. The benefit to patients was in the range of a 50% to 60% reduction in out-of-pocket costs. Patients in USA who wish to utilize this program can download the savings card by visiting Sun Pharma's Imatinib Mesylate website at www.imatinibrx.com. The company will also continue its Hub service wherein patients can call and speak with a trained healthcare professional and discuss FDA approved uses for Imatinib Mesylate (under Sun Pharma's ANDA.) Patients in USA can access Sun Pharma's Hub service through the toll-free helpline number +1 844-502-5950. Since the launch of Imatinib Mesylate in February 2016, www.imatinibrx.com received over 560,000 hits.

#### **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

Sun Pharmaceutical Industries Ltd Sun House, Plot No 201, B/1 Western Express Highway, Goregaon East Mumbai – 400 063, Maharastra, India

Board: +91 22 4324 4324 Fax: +91 22 4324 4343 www.sunpharma.com

CIN: L24230GJ1993PLC019050



(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-PDGFRα fusion kinase (mutational analysis or FISH demonstration of CHIC2 allele deletion) and for patients with HES and/or CEL who are FIP1L1- PDGFRα 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 unrespectable and/or metastatic malignant gastrointestinal stromal tumors (GIST)." As a result, the FDA has not approved Sun Pharma's Imatinib Mesylate Tablet products for this indication.

#### **IMATINIB MESYLATE - WARNINGS AND PRECAUTIONS:**

- Edema and severe fluid retention have occurred. Weigh patients regularly and manage unexpected rapid weight gain by drug interruption and diuretics.
- Cytopenias, particularly anemia, neutropenia, and thrombocytopenia, have occurred. Manage with dose reduction or dose interruption and in rare cases discontinuation of treatment. Perform complete blood counts weekly for the first month, biweekly for the second month, and periodically thereafter.
- Severe congestive heart failure and left ventricular dysfunction have been reported, particularly in patients with comorbidities and risk factors. Patients with cardiac disease or risk factors for cardiac failure should be monitored and treated.
- Severe hepatotoxicity including fatalities may occur. Assess liver function before initiation of treatment and monthly thereafter or as clinically indicated. Monitor liver function when combined with chemotherapy known to be associated with liver dysfunction.
- Grade 3/4 hemorrhage has been reported in clinical studies in patients with newly diagnosed CML.
- Gastrointestinal perforations, some fatal, have been reported.
- Cardiogenic shock/left ventricular dysfunction has been associated with the initiation of Imatinib Mesylate in patients with conditions associated with high eosinophil levels (e.g., HES, MDS/MPD and ASM).
- Bullous dermatologic reactions (e.g., erythema multiforme and Stevens- Johnson syndrome) have been reported with the use of Imatinib Mesylate.
- Hypothyroidism has been reported in thyroidectomy patients undergoing levothyroxine replacement. Closely monitor TSH levels in such patients.
- Fetal harm can occur when administered to a pregnant woman. Women should be apprised of the potential harm to the fetus.
- Growth retardation occurring in children and pre-adolescents receiving Imatinib Mesylate has been reported. Close monitoring of growth in children under Imatinib Mesylate treatment is recommended.
- Tumor lysis syndrome. Close monitoring is recommended.
- Reports of motor vehicle accidents have been received in patients receiving Imatinib Mesylate. Caution patients about driving a car or operating machinery.

Sun Pharmaceutical Industries Ltd Sun House, Plot No 201, B/1 Western Express Highway, Goregaon East Mumbai – 400 063, Maharastra, India

Board: +91 22 4324 4324 Fax: +91 22 4324 4343 www.sunpharma.com

CIN: L24230GJ1993PLC019050



#### **IMATINIB MESYLATE - PREGNANCY AND BREASTFEEDING:**

Imatinib Mesylate can cause harm to the fetus when administered to a pregnant woman. Women should be advised not to become pregnant when taking Imatinib Mesylate. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be made aware of the potential hazard to the fetus. Imatinib Mesylate and its active metabolite are excreted into human milk. Because of the potential for serious adverse reactions in nursing infants from Imatinib Mesylate, a decision should be made whether to discontinue nursing or to discontinue the drug, taking into account the importance of the drug to the mother.

#### **IMATINIB MESYLATE - ADVERSE REACTIONS:**

Patients are advised to tell their doctor if they experience side effects during Imatinib Mesylate Tablets therapy including fever, shortness of breath, blood in their stools, jaundice, sudden weight gain, symptoms of cardiac failure, or if they have a history of cardiac disease or risk factors for cardiac failure.

The most frequently reported drug-related side effects have been edema, nausea and vomiting, muscle cramps, musculoskeletal pain, diarrhea, rash, fatigue, and abdominal pain.

To report SUSPECTED ADVERSE REACTIONS, contact Ranbaxy Pharmaceuticals Inc. at 1-800-406-7984 or FDA at 1-800-FDA-1088 or <a href="https://www.fda.gov/medwatch">www.fda.gov/medwatch</a>.

## Please see Full Prescribing Information at:

http://www.imatinibrx.com/wp-content/uploads/2016/01/Imatinib Mesylate Tablets PI.pdf

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

Sun Pharma is the world's fifth largest specialty generic pharmaceutical company and India's top pharmaceutical company. A vertically integrated business, economies of scale and an extremely skilled team enable us to deliver quality products in a timely manner at affordable prices. It provides high-quality, affordable medicines trusted by customers and patients in over 150 countries across the world. Sun Pharma's global presence is supported by 47 manufacturing facilities spread across 6 continents, R&D centres across the globe and a multi-cultural workforce comprising over 50 nationalities. The consolidated revenues for 12 months ending March 2016 are approximately US\$ 4.3 billion, of which US contributes US\$ 2.1 billion. In India, the company enjoys leadership across 13 different classes of doctors with 30 brands featuring amongst top 300 pharmaceutical brands in India. Its footprint across emerging markets covers over 100 markets and 6 markets in Western Europe. Its Global Consumer Healthcare business is ranked amongst Top 10 across 4 global markets. Its API business footprint is strengthened through 14 world class API manufacturing facilities across the globe. Sun Pharma fosters excellence through innovation supported by strong R&D capabilities comprising about 2,000 scientists and R&D investments of over 8% of annual revenues.

For further information please visit www.sunpharma.com & www.imatinibrx.com Follow us on Twitter @SunPharma Live

### **FOR FURTHER DETAILS CONTACT:**

**Sun Pharma Corporate Communications** 

Frederick Castro | +91 9920665176 | frederick.castro@sunpharma.com

**Sun Pharma Investor Relations** 

Nimish Desai | +91 9820330182 | nimish.desai@sunpharma.com

Registered Office: SPARC, Tandalja, Vadodara - 390 020. India