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## Mylan Launches Generic Gleevec® Tablets

HERTFORDSHIRE, England and PITTSBURGH, Sept. 29, 2017 /PRNewswire/ -- Mylan N.V. (NASDAQ, TASE: MYL) today announced the U.S. launch of Imatinib Mesylate Tablets, 100 mg and 400 mg, a generic version of Novartis's Gleevec® Tablets. Mylan received final approval from the U.S. Food and Drug Administration (FDA) for its Abbreviated New Drug Application (ANDA) for this product, which has multiple indications, including for several blood cancers.



Imatinib Mesylate Tablets, 100 mg and 400 mg, had U.S. sales of approximately \$1.7 billion for the 12 months ending July 31, 2017, according to QuintilesIMS.

Mylan is one of the largest suppliers of cancer medicines by volume in the U.S., with a robust oncology portfolio of more than 40 products.

To enhance access for eligible commercially insured patients, Mylan will offer a Savings Card for Imatinib Mesylate Tablets,\* which will help reduce a patient's out-of-pocket costs. The card provides up to \$700 off the monthly out-of-pocket costs for the product and is reusable up to 12 times per calendar year. Eligible patients can participate in Mylan's Savings Card for Imatinib Mesylate Tablets program by registering online at [activatethecard.com/imatinib](http://activatethecard.com/imatinib).

Currently, Mylan has 227 ANDAs pending FDA approval, representing approximately \$96.2 billion in annual brand sales, according to QuintilesIMS. Forty-five of these pending ANDAs are potential first-to-file opportunities, representing \$45.5 billion in annual brand sales, for the 12 months ending July 31, 2017, according to QuintilesIMS. Currently, one out of every 13 prescriptions filled in the U.S. - brand-name or generic - is a Mylan product.

Imatinib Mesylate Tablets are a kinase inhibitor indicated for the treatment of:

- 1 Newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase
- 1 Patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in blast crisis (BC), accelerated phase (AP) or in chronic phase (CP) after failure of interferon-alpha therapy
- 1 Adult patients with relapsed or refractory Philadelphia chromosome positive acute lymphoblastic leukemia (Ph+ ALL)
- 1 Adult patients with myelodysplastic/myeloproliferative diseases (MDS/MPD) associated with PDGFR (platelet-derived growth factor receptor) gene re-arrangements as determined with an FDA-approved test
- 1 Adult patients with aggressive systemic mastocytosis (ASM) without the D816V c-Kit mutation as determined with an FDA-approved test or with c-Kit mutational status unknown
- 1 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
- 1 Adult patients with unresectable, recurrent and/or metastatic dermatofibrosarcoma protuberans (DFSP)

*\*Eligibility restrictions apply. See [Terms and Conditions](#). This offer is not valid for patients covered by Medicare, Medicaid or any other federal or state funded healthcare program or where prohibited by law. Mylan Pharmaceuticals reserves the right to amend or end this program at any time without notice.*

Mylan is a global pharmaceutical company committed to setting new standards in healthcare. Working together around the world to provide 7 billion people access to high quality medicine, we innovate to satisfy unmet needs; make reliability and service excellence a habit; do what's right, not what's easy; and impact the future through passionate global leadership. We offer a growing portfolio of more than 7,500 marketed products around the world, including antiretroviral therapies on which approximately 50% of people being treated for HIV/AIDS in the developing world depend. We market our products in more than 165 countries and territories. We are one of the world's largest producers of active pharmaceutical ingredients. Every member of our more than 35,000-strong workforce is dedicated to creating better health for a better world, one person at a time. Learn more at [Mylan.com](http://Mylan.com).

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