Press Release

BSE: 500257	NSE: LUPIN	REUTERS: LUPIN.BO	BLOOMBERG: LPC IN

Lupin in alliance with Natco receives FDA approval for Imatinib Mesylate Tablets

Mumbai, Baltimore, March 05, 2019: Pharma major Lupin Limited (Lupin) and Natco Pharma Limited (Natco) announced the final ANDA approval for Imatinib Mesylate Tablets, 100 mg (base) and 400 mg (base) from the United States Food and Drug Administration (FDA) to market a generic version of Novartis Pharmaceuticals Corporation's (Novartis) Gleevec® Tablets, 100mg and 400mg.

Lupin and Natco's Imatinib Mesylate Tablets, 100 mg (base) and 400 mg (base) is the generic version of Novartis' Gleevec® Tablets, 100 mg and 400 mg. It is indicated for the treatment of :

- Newly diagnosed adult and pediatric patients with Philadelphia chromosome positive chronic myeloid leukemia (Ph+ CML) in chronic phase.
- 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.
- 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 as determined with an FDA-approved test.
- 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.
- 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).

Imatinib Mesylate Tablets, 100 mg (base) and 400 mg (base) had annual sales of approximately USD 655 mn in the US (IQVIA MAT December 2018).

About Lupin Limited

Lupin is an innovation led transnational pharmaceutical company developing and delivering a wide range of branded & generic formulations, biotechnology products and APIs globally. The Company is a significant player in the Cardiovascular, Diabetology, Asthma, Pediatric, CNS, GI, Anti-Infective and NSAID space and holds global leadership position in the Anti-TB segment.

Lupin is the 8th largest generics pharmaceutical company in terms of market capitalization (28th December 2018, Bloomberg) and the 8th largest generics pharmaceutical company in terms of revenues (30th September 2018, Bloomberg LTM) globally. The Company is the 3rd largest pharmaceutical player in the US by prescriptions for the Total Market (IQVIA MAT December 2018); 3rd largest Indian pharmaceutical company by global revenues (30th September 2018, Bloomberg LTM); 6th largest generic pharmaceutical player in Japan (IQVIA MAT December 2018) and 5th largest company in the Indian Pharmaceutical Market (IQVIA MAT December 2018).

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For the financial year ended 31st March, 2018, Lupin's Consolidated sales and Net profits before exceptional items were at Rs. 155,598 million (USD 2.41 billion) and Rs. 13,934 million (USD 216 million) respectively. Please visit http://www.lupin.com for more information. You could also follow us on Twitter – www.twitter.com/lupinglobal

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**Safe Harbor Statement*

Gleevec® is a registered trademark of Novartis AG Corporation Switzerland.