Shilpa Medicare Limited



Manufacturers and Exporters of Bulk Drugs

12-6-214/A1, Hyderabad Road, RAICHUR - 584 135. Karnataka, India.

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E-mail: info@vbshilpa.com Website: www.vbshilpa.com

CIN No. L85110KA1987PLC008739

Dated: 06.04.2020

Corporate Relationship Department, BSE Limited Phiroze Jeejeebhoy Towers, Dalal Street, Fort, **Mumbai-400 001** National Stock Exchange of India Limited Exchange Plaza, 5th Floor, Plot No. C/1, G Block Bandra Kurla Complex, Bandra (E) MUMBAI-400 051

Dear Sir/Madam,

Shilpa Medicare Limited, through its UK subsidiary Koanaa Healthcare Limited, received UK MHRA approval for Imatinib oral solution.

The approval of Imatinib Oral Solution represents a major step forward in treatment options for cancers in pediatric and geriatric patients, patients with swallowing difficulties and also offers dose titration across the patient population.

Imatinib Oral Solution, a first of its kind in the world, is the only approved product which facilitates accurate dose titrations and avoids unnecessary overdosing due to fixed doses, 100 mg and 400 mg, in the presently available marketed tablets.

Imatinib Oral Solution will allow health care providers, oncologists and patients to jointly take control of their condition using a product with the same proven and safe mechanism of action as seen with currently available tablets.

Unlike current prescription treatments which are solid oral doses, Imatinib Oral Solution is ready solution, taken once a day or as prescribe, allows patients to adjust the dose according to patient requirements.

Imatinib Oral Solution is available as 80mg/mL.

Imatinib Oral Solution is expected to be available in the UK in the second quarter of 2020 will be supplied from a UK based state of the art manufacturing facility LM pharmaceuticals.

Imatinib Oral Solution is an innovative product and is expected to have patent protection until 2038.

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About Imatinib Mesylate: Imatinib is an anti-cancer drug for the treatment of certain kinds of cancers including CML, Ph+ CML, Ph+ ALL, myelodysplastic/myeloproliferative diseases (MDS/MPD), advanced hyper eosinophilic syndrome (HES) and/or chronic eosinophilic leukemia (CEL), unresectable dermatofibrosarcoma protuberans (DFSP). Imatinib, a 2-phenyl amino pyrimidine derivative, is an oral protein-kinase inhibitor that inhibits the bcr-abl tyrosine kinase, the constitutive abnormal tyrosine kinase created by the Philadelphia chromosome abnormality in CML. Imatinib inhibits proliferation and induces apoptosis in bcr-abl positive cell lines as well as fresh leukemic cells from Philadelphia chromosome positive chronic myeloid leukemia. Imatinib inhibits colony formation in assays using ex vivo peripheral blood and bone marrow samples from CML patients. In vivo, Imatinib inhibits tumor growth of bcr-abl transfected murine myeloid cells as well as bcr-abl positive leukemia lines derived from CML patients in blast crisis. Imatinib is also an inhibitor of the receptor tyrosine kinases for platelet-derived growth factor (PDGF) and stem cell factor (SCF), c-kit, and inhibits PDGF- and SCF-mediated cellular events.

First approved in 2001 by US FDA, the current market size according to IQVIA MAT Q4 2019 data, the World Wide market is approximately \$1.6 billion and in UK is approximately \$104.4 million

About Shilpa Medicare Limited, Shilpa Medicare Ltd. is a research-driven, global, integrated pharmaceutical organization. It is ranked among the top 100 Pharma & Biotech companies in India. Shilpa is a pioneering player in the manufacture of oncological APIs and formulations.

Shilpa has several molecules in various stages of development in the oncology segment and is planning to bring a few oncology drugs as cheaper versions for first-time in India.

Shilpa has manufacturing facilities for APIs and formulations and have four R&D centers. The Generics business of Shilpa caters to the requirements of the US, Europe and other emerging markets apart from India. Shilpa supplies its APIs to over 20 countries, including the US, various countries in the EU, South America and India.

With Regards,

For SHEPA MEDICARE LIMITED

Sushil Bajaj

Chief Financial Officer (CFO)