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Wockhardt Receives US FDA Approval for Leukemia drug

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PRESS RELEASE

Pharmaceutical and biotechnology major Wockhardt has received approval from the United States Food & Drug Administration (US FDA) for an ANDA for 100mg and 400mg tablets of Imatinib Mesylate, which is used to treat many kinds of cancers and tumors. Wockhardt's Imatinib Mesylate tablets are a generic version of Gleevec[®], marketed in USA and other countries by Novartis.

Imatinib stops the cancer cells from growing and is indicated for treating cancers like Leukemia and some Gastro-Intestinal tumors. According to IMS MAT1118, the product has sales of \$707 million in the US.

"Wockhardt is building a portfolio of oncology products in the US and has several pending ANDA's for oncology products" said Dr. Habil Khorakiwala, Wockhardt Founder Chairman and Group CEO. "Further, oncology and other specialty products have always been a priority area for our US business and this product will further boost this focus" he said.

Wockhardt will be launching this product in the United States, in a short period of time. With its nationwide distribution network and its excellent relationship with all major trade, retail and institutional customers, Wockhardt is already a significant player in the US pharmaceutical market.

The product is being manufactured at a contract manufacturing facility, based near Hyderabad, India.

About Wockhardt:

Wockhardt is a Global Pharmaceutical and Biotech company employing over 9,000 people and 27 nationalities with presence in USA, UK, Ireland, Switzerland, France, Mexico, Russia and many other countries. It has manufacturing and research facilities in India, USA & UK and a manufacturing facility in Ireland. Wockhardt has a significant presence in USA, Europe and India, with 60% of its global revenues coming from international businesses. Wockhardt is home to 600 plus scientists, of whom, 70 plus are doctorates. Wockhardt is the only company in the world where USFDA has given QIDP Status (Qualified Infectious Diseases Programme) for 5 of our Anti-bacterial discovery programmes – 2 of them are Gram Negative and 3 Gram Positive effective against untreatable "Superbugs". Wockhardt's entire Anti-infective portfolio particularly addresses the specific bacterial organism where resistances are high and breakthrough antibiotics are needed.

Gleevec[®] is a registered trademark of Novartis Pharmaceuticals Corporation.