

Wockhardt Receives US FDA Approval for cancer drug

Mumbai, April 10, 2019

Pharmaceutical and biotechnology major Wockhardt has received approval from the United States Food & Drug Administration (US FDA) for an ANDA for 50mg injection of Decitabine, which is used to treat certain forms of cancer. Wockhardt's Decitabine Injection is a generic version of Dacogen[®], marketed in USA and other countries by Otsuka.

Decitabine is used to treat Myelodysplastic syndromes (MDS), a group of cancers in which immature blood cells in the bone marrow do not mature and therefore do not become healthy blood cells. According to IQVIA February 2019 data, the product has sales of \$120 million in the US.

"This is the third US FDA approval for an oncology product for Wockhardt during the past three months, and has added to our growing portfolio of cancer drugs" said Dr. Habil Khorakiwala, Founder Chairman, Wockhardt Group. "Wockhardt has been sustaining growth in the US and worldwide through an increasing portfolio of specialty products including oncology drugs" 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.

Dacogen[®] is a registered trademark of Astex Pharmaceuticals, Inc., a member of Otsuka group