

Wockhardt Receives US FDA Approval for Prostate cancer drug

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Pharmaceutical and biotechnology major Wockhardt has received approval from the United States Food & Drug Administration (US FDA) for an ANDA for 250mg tablet of Abiraterone acetate, which is used to treat Prostate Cancer. Wockhardt's Abiraterone acetate tablet is a generic version of Zytiga®, marketed in USA and other countries by Johnson & Johnson.

Abiraterone is used to treat men with prostate cancer that has spread to other parts of the body. According to IQVIA December 2018 data, the product has sales of \$1.26 billion in the US.

“This is one more product in Wockhardt’s growing 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. “Along with oncology products, specialty products remain a focus area for our US business and for creating a sustainable growth worldwide” 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.

Zytiga® is a registered trademark of Johnson & Johnson