Wockhardt receives US FDA approval for generic version of Parkinson’s drug Comtan

To launch with 180-days exclusivity

Parsippany, New Jersey, Aug 20, 2012

Mumbai, Aug 20, 2012

Pharmaceutical and biotechnology major Wockhardt has received US FDA approval for marketing a generic version of 200mg tablets containing Entacapone, which is used in the treatment of Parkinson’s disease. Entacapone tablet is the generic name for the brand Comtan®, owned by Orion Corporation and marketed in the US by Novartis. Wockhardt will launch the product on Sept 30, 2012.

Incidence of Parkinson’s disease is increasing worldwide. According to IMS Health, the total market for this product in the US is about $98 million.

“Wockhardt was the first-to-file with paragraph-IV certification on this product,” said Dr. Habil Khorakiwala, Wockhardt Founder Chairman & Group CEO. “Pursuant to a settlement of the litigation between Wockhardt and Orion Corporation, Finland, the holder of the NDA, Wockhardt will launch an authorized generic version from Sept 30, 2012, with 180-days of exclusivity. The product involved development of a complex API as well as a challenging formulation. Generic Entacapone is the second authorized generic with 180-days exclusivity for Wockhardt, which will further accelerate growth of our US business,” he further added.

In the US generic pharmaceutical market, Wockhardt has been consistently growing market shares for all its products. In many instances, Wockhardt, by virtue of being amongst the few players to market technically challenging products has reaped the advantage of being an early entrant.

About Wockhardt:

Wockhardt is a high-technology intensive global pharmaceutical and biotechnology company with multidisciplinary and innovative R&D programmes. It has 3 research centres globally and manufacturing facilities across India, USA, UK and Ireland. Wockhardt has a significant presence in USA, Europe and India, with 75% of its global revenues coming from international businesses. With a large pool of Patents and Intellectual Property knowhow, Wockhardt is home to 578 scientists, of whom 80 are doctorates. In all, Wockhardt has 164 Patents granted worldwide. In biotechnology research, it has built a competent ‘Concept to Market’ capabilities in all facets of development and manufacture of recombinant biopharmaceuticals. Wockhardt boasts of a multi-ethnic workforce of more than 7,900 people from 21 different nationalities.

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