

Wockhardt launches authorized generic of Parkinson's drug Stalevo® with 180-days exclusivity

Mumbai, April 24, 2012

Pharmaceutical and biotechnology major Wockhardt has launched an authorized generic version of four strengths (50mg, 75mg, 125mg and 200mg) of the triple-drug combination product containing Levodopa, Carbidopa and Entacapone, which are used in treatment of Parkinson's disease. The Levodopa + Carbidopa + Entacapone tablet is the generic name for the brand Stalevo®, owned by Orion Corporation and marketed in the United States by Novartis. Wockhardt launched the product on 23rd April 2012 and is entitled to 180-days of exclusivity.

"Wockhardt was the first-to-file with paragraph-IV certification on four out of six strengths of this product", said Wockhardt Chairman Dr. Habil Khorakiwala. "Pursuant to a settlement of the litigation between Wockhardt and Orion Corporation, Finland, the holder of the NDA, Wockhardt came to an arrangement to launch an authorized generic version with 180-days of exclusivity. The product involved development of a complex API as well as a triple-drug combination formulation", he added.

Incidence of Parkinson's disease is increasing worldwide. According to IMS Health, the total market for this product in the US is about \$55 million for the above four strengths and even after the 180-days exclusivity the number of competitors to enter the market is expected to be very limited.

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.

Wockhardt is one of the select companies with end-to-end integrated capabilities for its products, starting with manufacture of the oral and sterile API's, the dose forms and marketing through the wholly owned subsidiary in the US, enabling the company to capture maximum value.

About Wockhardt

Wockhardt is a technologically intensive global pharmaceuticals and biotechnology major with innovative research and development programmes. Globally, it has 3 research centres and manufacturing facilities in India, USA, UK and Ireland with a large pool of patents. Wockhardt has a multi-ethnic workforce of 6500 people from 14 different nationalities.

Stalevo® is a registered trademark of Orion Corporation.