

Wockhardt receives US FDA approval for generic version of Aricept® tablets

Mumbai, April 25, 2011

Pharmaceutical and biotechnology major Wockhardt has received tentative approval from the United States Food & Drug Administration (US FDA) for marketing 5mg and 10mg tablets of Donepezil HCl, which is used for treatment of Alzheimer's disease and dementia. Donepezil is the generic name for the brand Aricept®, marketed in the United States by Eisai in partnership with Pfizer. Wockhardt will be launching the product in the US market on May 28, 2011. According to IMS Health, the total market for this product in the US is about \$2.5 billion.

"This is our second ANDA approval in less than a week and marks a good beginning to our fiscal year 2012", said Wockhardt Chairman Habil Khorakiwala. "We are continuing to get a steady stream of FDA approval and are able to launch them on the date the generic market opportunity opens. While business on the existing products have been growing, we have been augmenting our growth through a steady infusion of new products."

Donepezil is amongst the most widely used drugs in treating Alzheimer's disease, incidences of which are rapidly increasing the world over due to a steady increase in aging population.

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 first to market, has reaped the advantage of being an early entrant.

Wockhardt manufactures both the tablets as well as the API used in the formulation. The tablets will be manufactured at the US FDA certified formulation plant at Waluj, Aurangabad and the API will be manufactured at the FDA approved API plant in Ankleshwar, Gujarat. Both, the API and the tablets were developed in-house.

Wockhardt is one of the few 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 high technology global pharmaceuticals and biotechnology major with innovative multi-disciplinary research and development programmes. It has 5 research centres and 21 world-class manufacturing plants in India, USA, UK, France and Ireland. Wockhardt has a multi-ethnic workforce of over 6500 people from 14 different nationalities.