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US FDA okays Ranbaxy's generic drug

Rupali Mukherjee | TNN

Mumbai: There is finally some positive news for beleaguered Ranbaxy. The US Food and Drug Administration has approved the company's application, pending since September 2012, to launch Valsartan, the generic version of Novartis' blockbuster hypertension drug, Diovan, in the US. And the launch will happen immediately, sources said.

Investors and the company had been eyeing the launch of the Diovan generic by Ranbaxy for some time. This is because the management, despite the delay in seeking an approval from the regulator, had retained 180 days of exclusive marketing rights for the drug in the US market.

The total US market for Diovan, a patented product of Novartis AG, is estimated at around $1.5 billion annually. With the sole marketing rights for 180 days, it may capture around 50% market share, and earn a revenue of around $150 million, according to analyst estimates.

It is understood that the company had sought permission from the US FDA to shift manufacturing of the drug to its New Jersey-based Ohm Laboratories. This is because all its three domestic plants—at Poanta Sahib (Himachal Pradesh), Dewas (Madhya Pradesh) and Mohali (Punjab)—have been barred from supplying medicines to the US. In January this year, the company's main API manufacturing factory at Toansa, around 150 km from Mohali, was also banned.

Company