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High BP pill brings revenue-sharing anxiety for Ranbaxy

■ Income may get hit if Toansa unit comes under USFDA alert

Jayati Ghose

New Delhi, Jan 16: Ranbaxy Laboratories may have to share 30% of the revenues from sale of the generic version of Novartis' blockbuster anti-hypertensive 'Diovan' with the multinational firm it has tied up with for the raw material used to make the drug.

Revenue opportunities from other big first-to-files in the US, including anti-viral Valcyte and antacid Nexium, could also be affected if Ranbaxy's Toansa plant comes under import alert from the US Food and Drug Administration (USFDA), said analysts. Such a situation would force Ranbaxy to seek partnerships with foreign players to procure raw material or active pharmaceutical ingredients (APIs), which, at present, are supplied from Toansa.

Analysts said the total estimated revenue from the launch of Diovan, Nexium and Valcute is around $800 million for the six-month exclusivity period.

Earlier, Ranbaxy had tied up with an MNC firm to source API for Lipitor. The company had to share 45% of its profits from the sale of the generic version of Pfizer's blockbuster Lipitor with its API partner.

Last week, the FDA rapped Ranbaxy for not maintaining its Toansa plant in line with the required manufacturing standards.

Girish Bakhru, analyst at HSBC Securities, said: "While it is possible that the FDA may approve a partnership for Ranbaxy to source API, it would trim the potential opportunity as the company would have to share part of its profits with the partner".

Diovan (generic name valsartan) is a first-to-file opportunity for Ranbaxy in the US and the company could make $200 million from sales during the six-month exclusivity period. The drug is used to treat high blood pressure and congestive heart failure. It went off-patent in September 2012 and enjoys sales of over $2 billion in the US market.

Bakhru added that the share of potential profits would be around 30% as "API

sourcing for valsartan should be easier given multiple players awaiting approval post Ranbaxy".

On September 21, 2012, soon after Diovan went off patent, Mylan started selling generic Diovan HCT, its low-cost version of a combination of valsartan and hydrochlorothiazide. Sandoz, the generic arm of Novartis, also launched the same low-cost combination drug with licence from Novartis.

The USFDA had given Aurobindo Pharma a tentative approval for Diovan on April 1, 2013. However, the agency has not granted a final approval for the drug to any other firm.

Sources said that Ranbaxy has also moved its application for the Diovan generic to Ohm Laboratories after USFDA issued an import alert to the company's manufacturing facility at Mohali (from where the original application was submitted) last year.