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ANALYST CORNER

FDA concerns a worry; neutral on Ranbaxy

HSBC

A RECENT report indicated that Ranbaxy may have inked a deal with an MNC for API (bulk ingredient) for generic Diovan in the US. Diovan is a first-to-file opportunity for Ranbaxy in the US; however, it has seen delays due to FDA inspection concerns at the company's facilities. A recent inspection at an API facility at Toansa for Diovan produced several Form 483-related observations (deviations from cGMP), which we believe explains why Ranbaxy might look for a partner to commercialise this long-awaited opportunity.

While it is possible that the FDA may approve a partnership for Ranbaxy to source API (given it was a similar case in the approval of gLipitor), this would trim the potential opportunity as the company would have to share part of its profits with the partner.

Diovan is a c$2-billion sales opportunity, unlike Lipitor, which was nearly 3x its size. However with a strong 50% market share at c40-50% price discount, the company could make c$ 200 million sales (c10% of CY14e total sales) in the six-month exclusivity period. Key risk is if the Taonsa plant goes into warning or import alert, affecting API requirements for existing and other big FTFs planned in the US (Valcyte and Nexium).

We revert to earlier assigned PE of 18x from 16x to factor in improved visibility in US business on the back of big FTF dpportunities. Key risk is import alert on Taonsa, non-approval of API deal by FDA. Upgrade to neutral.

Regulatory -