PRESS INFORMATION BUREAU
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भारत सरकार

Financial Chronicle, Delhi
Thursday 27th March 2014, Page: 8
Width: 4.11 cms, Height: 27.22 cms, a3, Ref: pmin.2014-03-27.48.73

Novartis heart drug not fit for sale: FDA

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NOVARTIS'S experimental heart failure medication shouldn't be approved for sale, US regulators said, potentially dealing a blow to the company's plan to build a portfolio of cardiac therapies around the drug.

"There is insufficient evidence to support" Novartis's claim the drug, serelaxin, helps prevent worsening of the disease that causes the heart to malfunction, food and drug administration (FDA) staff said on Wednesday in a document posted online. The FDA on March 27 will convene advisers to consider serelaxin.

Serelaxin, which is similar to the hormone relaxin that is elevated in pregnant women, is being developed along with another experimental compound for heart failure called LCZ696. Serelaxin could generate $523 million in sales in 2018, based on the average of eight analysts' estimates compiled by Bloomberg.

The Basel, Switzerland-based drugmaker needs to make up for anticipated revenue losses as the heart medicine Diovan and cancer treatment Gleevec, its biggest sellers, start to face generic competition.

Novartis relied on one clinical trial instead of two that the FDA prefers, and the benefit serelaxin showed may not be meaningful, according to the clinical review prepared by the FDA's Melanie Blank and Tzu-Yun McDowell. Novartis's main goal in the trial was to measure serelaxin's effect on laboured breathing even though the company is seeking approval to reduce worsening of heart failure, which the FDA staff called "an exploratory finding" in the study.

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