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STOCKS SURGE TO RECORD HIGH Approval takes Biocon closer to getting FDA's marketing approval for trastuzumab, which has a multi-billion-dollar market globally

US FDA Panel Nod for Biocon Breast Cancer Drug Biosimilar

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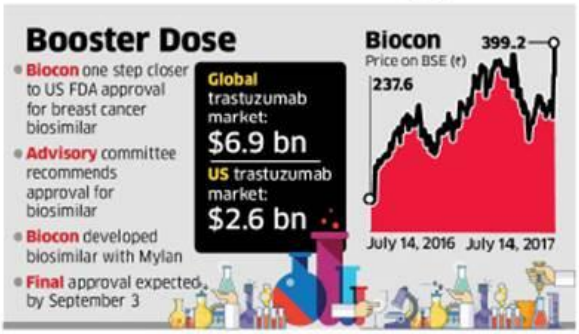
Mumbai | New Delhi: A US Food and Drug Administration panel unanimously recommended approval for Biocon's biosimilar breast-cancer drug, sending the Indian biopharmaceutical company's shares to a record high on Friday.

The recommendation takes Biocon closer to getting the FDA's marketing approval for trastuzumab, which has a multibillion dollar market globally. Trastuzumab, developed originally by Roche, is one of the most commonly used drugs to treat HER2-positive breast cancer. The Swiss company's drug is sold under the brand Herceptin worldwide and Herclon in India. A biosimilar is a copy of a biologic drug.

Biocon's shares rose as much as 10.19% to an all-time high of ₹404 on the Bombay Stock Exchange, before paring the gain and closing Friday's trading at ₹399.20, still up 8.88% in a market that remained little changed. The stock has gained 19% this week.

Biocon has developed the biosimilar in collaboration with US drug maker Mylan. The US FDA's Oncology Drugs Advisory Committee voted 16-0 in favour of the eligible indications of the original product, the panel tweeted early Friday India time.



The next step for the two companies is to get a final approval from the US FDA to commercially launch the product. Biocon hopes for this approval by September 3, chairperson Kiran Mazumdar-Shaw said.

The product will be manufactured by Biocon for all markets globally and it also has a profit-sharing arrangement with Mylan for its markets. Globally, the trastuzumab market opportunity is close to $6.9 billion and in the US alone it is around $2.6 billion at the originator product price, she said.

While the development is positive for the company, some experts said it also signals the need for Biocon to strengthen its technical capabilities, especially since the French regulator had recently found quality-related lapses during a pre-approval inspection at its Bomassandra plant for three of its products.

"This is only the start of the process. There is no reason to be positive or negative at the moment," said Surajit Pal of Prabhudas Lilladher. "This process is also expected to take care of the GMP (Good Manufacturing Practice) activities currently under question," he added.

Biocon aims to address all concerns about its drug product facility over the next one quarter in an "expeditious manner" in order to seek an early re-inspection, Mazumdar-Shaw said. She added that Biocon was awarded a GMP certification for its drug substance facility for trastuzumab and pegfilgrastim, another biologic drug used in the treatment of cancer.

Meanwhile, analysts said the 19% gain in the stock this week has been excessive, given the risks related to production of this medicine.

"The current price fully captures the upsides in this stock," said Vishal Manchanda, analyst at Nirmal Bang. "There are multiple risks that investors must account for before the drug goes into production. The main one being a delay in approval due to eight observations given by the USFDA and 11 serious observations by the European regulator recently. If the drug's production is delayed by more than a year, the first mover advantage for the company could be gone."

Analysts said there were also other players also that are looking to capture market share in this drug and that they will be filing for approvals in the coming months for the drug, reducing the market opportunity for Biocon.

Some analysts prefer Aurobindo Pharma over Biocon because that stock could see a faster re-rating while its valuations continue to be cheap.