Date	:	February 01, 2017
Publication	:	Mint

We expect Malaysia unit to break even next year: Mazumdar-Shaw

BY ISHA TRIVEDI
isha.t@livemint.com

BENGALURU

mint INTERVIEW

Biocon Ltd, India's leading biopharmaceutical firm will likely see its biosimilars business take off in the US and the European Union in the next three years, enabling it to reach the guided $1-billion revenue mark by 2018-19. Its application for breast cancer biosimilar trastuzumab was recently accepted by the US Food and Drug Administration (FDA) for review and applications for three biosimilars have been accepted by the European Medicines Agency. In an interview, Biocon's chairperson and managing director Kiran Mazumdar-Shaw says that launch of trastuzumab in the US, once approved, will not be immediate and its Rs460-crore insulin supply pact with the Malaysian government will de-risk Biocon's investment in setting up the plant there. Edited excerpts:

Biocon has filed applications for three biosimilars in the EU and one in the US. By when do you expect these products to be approved and launched?

The US FDA has given the target action date for trastuzumab as 3 September, 2017, which is very soon. It is a very good date to get as it means that our dossier is worthy of review. Even if they give us approval around that time, we still have patent issues to circumvent. So, it is not as if once you get approval, you can launch the product tomorrow. We will have to overcome certain patent disputes that the innovator is going to raise. Once we get over that we will get clarity on the launch date, so as of now, I am unable to give you any optics on that. EU is less of a hassle because patents are not there and that might give us an earlier entry point into the EU. I think we have done the best we can and we are very confident and optimistic about getting a favourable response from the regulators.

Trastuzumab is filed both in the US and EU, while pegfilgrastim and insulin glargine are filed only in the EU so far. When does the company plan to file these two products in the US?

We will file the other products too. Pegfilgrastim is the next one in the US, which we will do soon. Glargine will also follow it. The requirements of the US and the EU are slightly different, so even though we have filed glargine in the EU, it will take a little longer to file in the US. Both the filings are likely to be made this year. Apart from these, we are on track to submit the filing of another biosimilar adalimumab in FY18.

Biocon's chairperson and managing director Kiran Mazumdar-Shaw.
HEMANT MISHRA/MINT

The company launched insulin glargine in Japan a few months back. What has been the response to the drug and are you gaining market share?

It is doing pretty well. Japan is not such a big market for us. It is an about $140-million market and both Eli Lilly and Biocon are there in the biosimilar insulin glargine space. Biocon is marketing the product through Fujifilm Pharma. Sanofi's share has been eroded. Fujifilm is far more optimistic about market share now than they were in the initial stages. Patients and doctors are very happy with our product and our device. Therefore we have an opportunity to garner good market share.

Now that the Malaysian insulin facility has been commercialized, can you tell us which markets will be catered to by that plant and will the investments made for setting up the plant put some stress on the company's balance sheet?

The biggest news for us was our offtake agreement with Malaysia's health ministry. It is a very important event for us because it defrays a lot of our capital investment in Malaysia, which otherwise we would have had to keep idle till we got product approvals in regulated markets. Our investment in the Malaysian facility is $250 million. We are confident that a large part of our fixed costs, depreciation and interest costs for the Malaysian plant will be catered to by the Malaysian government's offtake agreement and our emerging market supplies.

So next year we expect either a break-even or a marginal loss for the Malaysia facility and in the scheme of things, at the consolidated level, the impact will be negligible. Meanwhile, we are getting inspected by some of the emerging markets, so once they sign off we will start supplying to them from Malaysia. The European application for glargine is filed from Malaysia, so once the approval comes, we will be able to supply to Europe. We do not want to starve any market. Right now we are starving markets because our India capacity is completely sold out. Going forward, we want to make our supply capabilities so flexible that at any point of time any market need can be catered to by either of the two facilities.