Date	:	October 24, 2016
Publication	:	Mint

Biocon is betting big on biosimilars: Mazumdar-Shaw

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CNBC-TV18

Biocon chairman and managing director Kiran Mazumdar-Shaw. HEMANT MISHRA/MINT

Biocon will soon file for a biosimilar version of trastuzumab, used for the treatment of breast cancer, in the US, said Kiran Mazumdar-Shaw, chairman and managing director of Biocon. Currently, the company is filed marketing rights for the drug in Europe and expects the regulators to clear it within the next 12-18 months, she said, adding that the launch of insulin glargine in Japan, too, has been positive. Approval in Japan has opened up other markets for glargine, Shaw said in an interview. Edited excerpts:

Revenue growth of around 20% on the whole, that is a fairly good set of numbers. Syngene's growth at around 14-15%, we have seen even 18%. What is the outlook? Also, a quick word on the margins of around 25%. I was looking at your research and development (R&D) cost in terms of percentage on sales. It is at around 8-9%. You said that it is going to go even above 10%, so are you confident of holding on to these margins of around 24-25%?

The business is well-positioned. You have seen all our businesses deliver very strongly this quarter and we are confident that many of the events that we have announced this quarter, such as the tentative nod that we have received for Rosuvastatin calcium tablets which will herald a foray into the US generics market.

The launch of our biosimilar insulin glargine in Japan through our partners, Fujifilm Pharma has been well accepted and received by both patients and doctors augurs well for growth in that market. Our Malaysia facility has been approved.

We expect commercial sales to start from that plant in H2 (second half). We have seen two dossiers now being accepted for review by European Medicines Agency (EMA), which means that we will be entering the European market for our biosimilars within the next 12-18 months. So, everything is well positioned now for us to start seeing good traction.

Our small molecules vertical has also delivered very robustly for this quarter and we expect to see that perform similarly for the rest of the year.

I wanted to concentrate a little bit on the triggers such as your entry into the US generics market. For Crestor generic, when do you expect final approval from the US Food and Drug Administration (FDA) as well as where exactly would those two approvals stand?

We have got a tentative nod, so the final approval should come very soon and we expect definitely to be in the US market during this fiscal.

So, that is the expectation and thereafter, of course, we will have hopefully other generic approvals next fiscal.

So, what would your filing or your Abbreviated New Drug Application (ANDA) pipeline look like for the US generics market and maybe a year or two years down the line, how much would be the US generics market as a percentage of sales, considering that we are seeing pricing pressure and other competitive intensities increasing.

INTERVIEW

Generics is going to be a very small part of our overall business. It is a sub-segment of our small molecules business because we want to basically vertically integrate our business and move up the value chain.

So, we do not expect it to be a significant part of our overall business. However, what we are betting on big is our biosimilars business and that is something where we are seeing a lot of good uptake in emerging markets in the near-term.

And obviously, when it gets approved in the US and Europe, these are going to be big growth drivers for us in the future. So, that is where the growth is going to come from. So, generics per se is not something that we are betting big on.

Generics is going to be a very small part of our overall business

Biocon is focusing on a very small niche portfolio of generics for the US market and it is a strategy of adding value to our active pharmaceutical ingredient (API) business.

Let me just take ask you about the biosimilars business, because everybody is waiting by to see what happens with Trastuzumab in the European markets. When can we hear something from the European Union (EU) regulators and when can we expect a US filing?

The earliest you can expect approval from the European agency could be within 12 months.

But it is generally a 12-18 month time frame. The data is very good. We believe our dossiers is very robust and high quality dossiers. So, we should be able to get approval hopefully in the next fiscal, hopefully, in calendar year 2017. That is the expectation, but we need to see how the regulators look at our dossiers and give us that final approval, the marketing authorisation, so to speak. We expect to also be filing in the US very shortly. We already indicated that we are on track for filings this fiscal and we remain committed to that filing.

The one reason why the stock is seeing a re-rating in 2016 is because of your insulin glargine launch in Japan. Can you tell us how exactly the insulin glargine launch has done in Japan? If you could share some financials on that and what is the plan to scale it up into other markets as well?

I cannot give you too much optics on that because it has just entered the Japanese markets. The Japanese glargine market is about $140 million in size and Fujifilm Pharma has just informed us that our product has been very well accepted by patients and doctors and they are hopeful of garnering a good market share in the Japanese markets. But more importantly, that was a trigger to indicate the quality of our product, the quality of our dossier and the higher attributable, approvability of our glargine dossier, both in the EU and in the US. That was the main trigger because the Japanese market and the Japanese regulatory system is very stringent and therefore, getting approval in Japan was a very big event for this particular molecule.

Having said that, the Japanese approval has certainly opened up many more emerging markets and we have entered into many more licensing deals for glargine in many emerging markets. Therefore, we believe that the insulins portfolio per se is going to be a very important segment for us going forward.