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KIRAN MAZUMDAR-SHAW/BIOCON

Launch of Glargine trial presents a very large global opportunity

BY EKTA BATRA
CNBC-TV18

Drug maker **Biocon** has announced phase-3 global trials of Glargine, a slow-release insulin, in partnership with **Mylan Inc.**, the US-based drug maker. Kiran Mazumdar-Shaw, chairperson and managing director of Biocon, said the launch of the trial presents "a very large global opportunity" for the two partners. Edited excerpts from an interview:

ABHIJEET CHOUGHULE/MINT

Marketing plan: *Mazumdar-Shaw says though the Glargine trial is primarily focused on the EU and US markets, the firm hopes to market the product in developing and emerging economies, too, in the interim.*

The news that Biocon is reacting to is that Mylan has announced the initiation of two phase three trials for glargine which is Lantus or Sanofi's Lantus. Can you take us through the details of this?

This is an important milestone for the two partners because Glargine, or Insulin Glargine, which is an important basal insulin analog, is a very large global opportunity for the two partners. This is a big announcement for Mylan and Biocon because the phase three clinical trials on both type 1 and type 2 diabetics are extremely important, because it is now a signal that this product is going to closely follow (US drug manufacturer) Eli Lilly's very successful approval that they have got for their Insulin Glargine. Therefore, we as partners now are very confident that we will make it to the market before too long.

Can you give us a sense in terms of the details of this, for example the phase three trials will be for the European as well as for the American markets and what would be the time-line in terms of completion of the phase three trials? When could Biocon see some amount of financial accretion to the profit and loss on account of this?

The phase three trial for these two types of diabetics —type 1 and type 2—is a harmonised approach that we have taken which will allow us to pursue a global clinical strategy that we expect to be completed by the end of 2016. If you then look at the review process then we should be able to commercialise this opportunity by 2018.

What is the competitive launch space by then, because Eli Lilly already has an approval for a similar product?

Eli Lilly is an innovator. Their approach in terms of commercialising a biosimilar Glargine will have a very different positioning compared with what Mylan will be doing in terms of its commercial opportunity for the same product. The space is not at all crowded. Diabetes is a growing pandemic. Diabetics need both basal and other forms of insulin in a very incremental way and Biocon and Mylan will be able to expand the diabetes (medicines) market in a significant way in terms of insulin analogs that we are jointly developing between us. Therefore, this is a huge opportunity, it is underserved at the present time and we will be able to make a huge global opportunity of this particular product.

Could you also quantify—because you said 2017-18—in terms of the kind of money that you expect by FY17-18?

I will not be able to comment specifically on this particular question but the insulin analog opportunity is now approaching $20 billion and this is growing in double digits, so by the time we get to the market, the opportunity is going to be sizeable and both partners are very focused on maximising this opportunity between us.

When you say clinical trials on global basis and you say possibly commercialisation by 2018, would that include developed markets such as the US as well as the European Union (EU)?

This whole trial is focused on the EU and US as the primary target markets. But in the interim we also hope to market these products in the developing economies and in the emerging economies. We already have Glargine registered in nearly 10 countries globally, which itself is a huge opportunity but the real big opportunity where the optics is focused is on US and Europe and what we have done, is to conduct one trial which will allow us to enter both EU and US. In the past we have segregated these two markets, but this is a new approach where we will get approvals both in the US and in Europe by doing this kind of harmonised trials.

While you cannot comment on the financials of this particular deal, can you tell us would it entail Biocon receiving royalties post commercialisation, or would it also be some amount of milestone payments during the trial phase as well?

We have disclosed the fact that this is a profit share arrangement with Mylan. Therefore, it's a very important deal for us.

A word on Syngene (a Biocon subsidiary). What is happening on that because you re-acquired some stake and could that mean that you have a potential timeline in mind for Syngene's listing?

We are very focused on very well-worked-out strategic plan for Syngene which will lead to an initial public offering and listing in the market. So, all this is as a part of that strategic plan, so you will see what is happening along the way as we eventually prepare for listing.

Any specific timeline in terms of possible listing? When could you file a Draft Red Herring Prospectus or anything of that sort that you could share?

I do not think I will be able to give you much more than I have just said, but in due course I will be happy to shed more light on this topic.

New drug