

KIRAN MAZUMDAR-SHAW/BIOCON

# PiSA deal will bolster Biocon's presence in global insulin market

HEMANT MISHRA/MINT

BY LATHA VENKATESH & REEMA TENDULKAR  
CNBC-TV18

**B**iocon Ltd's agreement with Mexican drug maker Laboratorios PiSA S.A. de C.V (PiSA) to develop insulin for the US market is important, as US commands 40% of global insulin market, said company chairman and managing director Kiran Mazumdar-Shaw.

According to the agreement, PiSA will manufacture the drug while Biocon will provide the drug substance or active ingredient. Mazumdar-Shaw said the insulin market currently has only a few players and provides huge scope for growth. The company will file its first insulin analogue dossier in FY17, she added. Edited excerpts:



Growth scope: Kiran Mazumdar-Shaw.

### What this agreement with PiSA of Mexico is going to mean for you in terms of profit and loss?

This is an important opportunity for Biocon because the US market commands 40% of the global insulin's market which is right now around \$5 billion in size and, therefore, the \$2 billion opportunity which is in the US is a large opportunity for us. It is at an attractive price point and we believe that it is important for us to develop this asset for the US market.

We have a long-standing relationship with PiSA. We have a very dominant share of the insulin market in Mexico which PiSA is partnering us in and PiSA has a partnership with Biocon where Biocon provides the insulin drug substance and they manufacture the drug product in Mexico. We will be using the same model for US co-development partnership that we have entered into because we believe that this partnership will give us very optimal supply chain efficiency because of its proximity to the US market and its North American Free Trade Agreement (NAFTA) membership.

Could you tell us what will be the

## INTERVIEW

### revenue share between you and PiSA?

I am not able to disclose that but suffice to say that Biocon has a very attractive commercial interest in this partnership

### By when will the product be ready and when will the commercial sales begin? What percentage of the market opportunity, which you said is \$2 billion, do you hope to garner?

It is very early days to forecast the market share that we expect to attain but at this point in time I can say that Biocon has a strong focus on the insulin market share globally and we will try and garner as much market share as we possibly can in the US.

### Is this a start of more such a partnership, will you deepen the partnership with this company itself?

We have already partnered in insulin analog with Mylan NV and as you also have heard before from me that we are in the process of filing our first insulin analog Glargine dossier coming fiscal. So I think we are in good shape. I think this is an important space for Biocon. There are very few players in the insulin market and Biocon is in that select group of companies which includes a handful like Novo, Lilly and Sanofi. So we are in very good company, we have a good presence in the insulin market globally and we want to strengthen this position.

### What's your take on the government banning the fixed-dose combinations?

My view is that there can be a rational in terms of why they are banning these fixed-dose combinations but having said there needs to be a proper process followed because taking sudden

decisions on approved products is what I think the industry is concerned about and there needs to be a greater dwell into how we go about banning any product in the future because you cannot do an instantaneous recall of everything on one particular day.

### Is this a limited competition drug and also tell us what the status of the drug is. Has it completed, what trial stage is it, when can we expect the commercial sales of it?

Biocon's bio-similar insulin is marketed in over 40 countries right now. So as a product it has been developed but we have to follow certain bio-similar guidelines as prescribed by the USFDA and European Medicines Evaluation Agency (EMA). So in the USFDA guideline, we will have to go through the entire process and we expect that it will take us at least two years to complete the process.

# Biocon ties up with Mexican co for sale of generic insulin in US

## Expects To Launch In US Before 2020

TIMES NEWS NETWORK



**Biocon CMD Kiran Mazumdar-Shaw said the US market is significant for the company and they will adopt a judicious discounting strategy when they hit market**

US, the Bengaluru-based company said on Thursday. The drug substance (active ingredients) will be made by Biocon, while the drug product will be made by PiSA at its Mexico facility. Rh-insulin is the most widely used form of insulin globally.

Biocon, which had Rs 3,143 crore in revenue last fiscal, said it will take between 12 and 18 months for PiSA's Mexico plant to get the US Food & Drug Administration (FDA) approval, post which it

will file the drug application with the FDA. It will then have to conduct clinical trials in the US. It expects to launch in the US market before 2020.

"Our objective is to provide access to affordable insulins to patients in the US. This collaboration will enable us to manufacture the rh-insulin drug product at PiSA's facilities in Mexico and commercialize it under Brand Biocon in US market," Biocon chairperson & MD Kiran Mazumdar-Shaw said.

The size of the generic insulin business is about \$2 billion in the US, which has a huge diabetes burden with over 1.4 million people diagnosed with the disease every year. Shaw did not specify the market share that Biocon would be targeting but said it will be "significant." "US is the best market for us due to pricing and we will adopt a judicious discounting mechanism when we hit the market."

The move will help Biocon take advantage of PiSA's proximity to the US market and Mexico's NAFTA (North American Free Trade Agreement) membership, which will ensure an efficient and optimal supply chain.

Biocon has marketing approvals for its rh-insulin in over 60 countries.

**Bengaluru:** Biopharmaceutical company Biocon has entered into an agreement with Mexico's Laboratorios PiSA (PiSA) for the co-development and commercialization of generic recombinant human insulin (rh-insulin) for the US market.

This is a cost and profit-sharing agreement, with Biocon responsible for clinical development, regulatory approvals, and commercialization of the product in the