

Biocon gets nod to sell insulin in Japan

Glargine would be a biosimilar insulin

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Biocon on Monday said it had approval from Japanese regulators to sell its biosimilar insulin, Glargine, in disposable pens in what is the largest market for insulin outside of the US and Europe.

The Japanese Glargine market is estimated to be \$144 million, Biocon said. It will make the ready-to-use prefilled disposable pen with Glargine at its unit here. This would be sold by its partner, Fujifilm Pharma, in Japan by June.

The Japanese entity had conducted local Phase-III clinical trials on over 250 Type-1 diabetes patients. Japanese regulators had visited the facility here, which produces Basalog One, the branded product sold in India, prior to the approval. The pen assembly facility was inaugurated in September 2015.

"The approval in Japan gives us huge credibility to take these products in other developed markets," said Arun Chandavarkar, chief executive, in a conference call. Biocon plans to now seek

A SUGARY TREAT FOR INDIAN PHARMA

- Japan is the first developed market to give approval to biosimilar Glargine
- Insulin Glargine to be sold in prefilled disposable pens
- Product manufactured in Bengaluru, also sold in India as Basalog One
- Japan market for Glargine is \$144 million
- Biocon has tied up with Mylan for Europe and US markets
- Expects to get approvals in these markets in 2017

approval for the Glargine insulin to sell in the US and Europe, for which it has tied up with Mylan. The latter is conducting clinical trials for the biosimilar product in these regions. "This approval in the highly regulated market of Japan marks a huge credibility milestone...we hope to enable the Japanese

government to bring down its health care expenditure on diabetes with the use of this biosimilar," chairperson and managing director Kiran Mazumdar-Shaw said.

Biocon's product is the generic version of Lantus, the insulin produced by Sanofi, which owns 90 per cent of the market in Japan.

