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Biocon set to seek US FDA approval for biosimilars

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INDIA'S largest biopharma company, Biocon, is gearing up to enter the regulated markets of the US and the UK with a portfolio of biosimilars. The company is in advanced stages of completing global phase-III trials for four out of nine biosimilar programmes in partnership with Mylan, a US-based drug maker.

"Based on the clinical advancement thus far, the Biocon-Mylan biosimilars partnership is progressing well towards four regulatory filings in the US and EU in this calendar year," Kiran Mazumdar-Shaw, chairperson and managing director of Biocon, told *FE*.

Biosimilars are copies of biological drugs with same safety and efficacy as original products. The addressable market for Biocon in these countries is more than $30 billion. "These filings should provide us with an early mover advantage for these products in these key developed markets," Mazumdar-Shaw said.

She said Biocon will be filing for regulatory approvals in these markets in a phased manner during 2016 for four biosimilars — Trastuzumab (to treat breast cancer), Pegfilgrastim (for chemo-induced Neutropenia), Adalimumab (for chronic plaque psoriasis) and Insulin Glargine.

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> **KIRAN MAZUMDAR-SHAW,** CMD, Biocon

The company has made huge investments on research and development to develop biosimilars along with Mylan. It entered into a partnership with Mylan in 2009 for joint research and development of a variety of biosimilar molecules for global markets.

"As an innovation-led company, high R&D spends are inherent to our business. We have said our biosimilars programs for Trastuzumab, Pegfilgrastim, Adalimumab and Insulin Glargine continue to cross critical milestones in global phase-III clinical trials," Mazumdar-Shaw said.

Biocon invested ₹169 crore in FY14 and ₹329 crore in FY15 in R&D. In the first nine months of FY16, gross R&D expenses stood at ₹275 crore. However, she refused to comment on the exact timeline for securing approvals in the US and the EU. "It's extremely difficult for us to predict regulatory timelines, but we are confident of being among the first wave of biosimilars players to enter global markets," she said.

"We are planning to have four filings in this year. As far as the approval timelines are concerned, we do not wish to comment on that at this stage, but safe to say it would take probably a year or longer," Arun Chandavarkar, CEO & joint MD of Biocon, recently said during an analyst call.

Biocon has made significant amount of investment on setting up new factories to manufacture new biosimilar products as and when it gets approval in the regulated markets.

"We are fully geared to address this unfolding biosimilars opportunity. We have global scale manufacturing facilities in Bengaluru for insulins and biosimilar monoclonal antibodies and further expansion of insulins facility is underway. Our Malaysia facility also has undergone process qualification and is on track to file for approvals in FY17," Mazumdar-Shaw said.

For insulins, Biocon will be catering to these markets largely out of Malaysia and has adequate capex plans to expand capacities as it increases market share. The company has invested around $200 million to set up an integrated insulin manufacturing facility in Malaysia.