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We're expanding biosimilar pipeline: Mazumdar-Shaw

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

The submission of the biosimilar breast cancer drug Trastuzumab for approval to the US Food and Drug Administration is an important milestone for Biocon, said chairperson and managing director Kiran Mazumdar-Shaw, adding that the review process is expected to take 18-24 months. Huge opportunities exist for Biocon in the US biosimilars market, she said in an interview. She said the company has also filed for three biosimilars with the European Union regulator and is likely to file those with the US FDA as well. She said while exports have not been hurt by demonetization, Biocon's Indian business has seen lower sales over the last month. However, she said, the company's dependence on domestic business is quite small. The management is expecting to sustain revenue and margins at second quarter levels, Shaw said. Edited excerpts:

This is our first conversation since the company filed for Trastuzumab, the biosimilar for breast cancer with the US FDA. When do you expect the approval and what is the already approved biosimilars, there is a huge uptake of biosimilars and a few organizations have already adopted almost 90% of approved biosimilars.

Therefore, it's an exciting opportunity for Biocon and Mylan to take a large part of this market and given the fact that there are a few others who will also be joining us in this particular market for biosimilar Trastuzumab, we do expect there to be competition. But I also believe that there is a large

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with the US FDA very soon. We have also filed insulin glargine with EMA and we will be hopefully submitting that with the US FDA before too long.

We have other products in the pipeline which are also under development like other insulin analogs and other antibodies. So all going well, we expect to file all of these within the next fiscal or two—that's the plan and when it comes to these products and their approvals in emerging markets.

markets. Trastuzumab is a product where we are already in the Algerian market but there are other opportunities in other emerging markets and we expect that to happen sooner than later. A very large opportunity for these products in the emerging markets because these are billion dollar opportunities for sure even in the emerging markets collectively. So it's an important opportunity for Biocon's business in terms of focusing on these biosimilars and of course we are expanding the biosimilar pipeline as we speak, so that

usage has been impacted but since our dependence on this business is not huge, it doesn't impact the overall business. In fact we have benefited from a weaker rupee in terms of our export realisations.

Any guidance on the domestic business and how it will fare in Q3 with the impact of demonetization and also halting of sales of cancer drug Abraxane in the second quarter?

Abraxane has had a huge impact on our India business because it was a large component of our Oncotherapeutics portfolio. So that definitely has a big impact for the rest of the year and therefore we are going to see a decline in growth in terms of our branded formulations business because of this one impact.

But having said that, we are now basically focusing on building our insulin and our onco drugs, especially CANMAb which is our biosimilar Trastuzumab and we expect to see pretty good growth going forward. We have been rationalising our business, we have had certain leadership challenges in the branded formulations business but all of that is getting addressed and hopefully you will see a strong growth next fiscal.

Will margins be maintained at above 20% lev-