Interview: Kiran Mazumdar-Shaw â?? Chairwoman and Managing Director, Biocon, India

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A pioneer of the biotechnology industry in India and the head of the countryâ??s leading biotechnology enterprise, Kiran Mazumdar-Shaw, discusses

the recent US FDA approval of Ogivriâ?¢, the first biosimilar for trastuzumab and the sixth approved biosimilar in the US overall, and how Biocon is implementing a low-value high-volume model in its strategy.

Ms. Mazumdar-Shaw, you are a first-generation entrepreneur as well as a pioneer of the biotechnology industry in India. How has your approach to business evolved over the years to make Biocon Asiaâ??s leading bio-pharmaceutical enterprise?

It has been a very long four-decade journey and over time we have evolved from being an enzyme-focused biotech company to a biopharmaceutical-focused biotech company. Biopharmaceuticals is a very important sector for India and for the world and I think what we have focused on as a company is looking at biopharmaceuticals as a class of medicines which are beyond the reach of most patients in the developing world. It is this very focus of providing affordable access that gave us the strategic intent to build a global biopharmaceutical company that had global scale both in terms of manufacturing and providing affordable access.

We realized that biopharmaceuticals required huge investments both in terms of R&D and creating manufacturing facilities â?? and this is what I decided to do as an entrepreneur as I felt there was a big need as well as an opportunity to differentiate ourselves from the rest of the biopharmaceutical companies in India. Today, Biocon stands apart as a very different kind of biopharmaceutical company in India as we have strong leadership due to our strong global perspective of what we do. The fact that our biosimilar trastuzumab is the first biosimilar to trastuzumab approved by the US FDA is a testimony to that focus.

Indeed, FDAâ??s approval of Ogivri™, the first biosimilar to trastuzumab, demonstrates Bioconâ??s robust scientific capabilities in developing complex products. What does this mean for Biocon?

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This was a drug that was approved in India in 2014 and I am very pleased that our strategic intent, which was to provide affordable access to patients in the developing world, was met through this approval. In India we made a big difference because we expanded the market in terms of volume as we brought down the prices significantly â?? we forced down the prices I would say â?? and if you look at the discounted prices these products are sold in India it is a tenth of what it used to be elsewhere. Getting the approval of Ogivri*TM* is a great endorsement of the quality of this product and to our capabilities to develop these complex drugs for global markets. As a company, we have focused very much on taking a path of differentiation which is doubtlessly a path full of challenges and risks because biosimilars require deep pockets and taking regulatory risks that are unknown â?? but we decided to go for it. This approval is, once again, a great validation of our strategy.

Bioconâ??s first novel biologic product was Nimotuzumab, an antibody drug for head and neck cancer. Since then, you launched several products, like human insulin and monoclonal antibodies for cancer and autoimmune diseases. What is your scope of activities and your product portfolio today?

Biocon has a good balance between novel and biosimilar drugs, but we also have a strong focus on APIs and generic finished formulations. We have a leading role in immunosuppressants in the field of APIs and that has kept us in a good position. We then moved up the value chain and decided to integrate our business into ANDAs and we have just entered this field. Biopharmaceuticals, however, are our main focus and as a company we are quite unique because we have already two antibodies in the Indian market and both molecules are very differentiated molecules. We are doing very well with BIOMAb EGFRÂ® (Nimotuzumab) for head and neck cancer and ALZUMAbâ?¢ (Itolizumab) for psoriasis.

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India is very new to biologic treatments and we want to change the paradigm of treatment for diseases like cancer and autoimmune diseases. Itolizumab, specifically, is a very unique molecule as it is a â??first in classâ?? biologic, a humanized recombinant anti-CD6 monoclonal antibody for the treatment of patients with active moderate to severe chronic plaque psoriasis. It plays in a very exclusive pathway and has a novel mechanism of action, different from that of TNFÎ± or IL inhibitors. While India is not well known for novel drugs, we are trying to change that. And I think we will because we have a very exciting pipeline of novel drugs.

India has huge capabilities â?? take for instance the clinical trials space. We have the best centers, the best clinicians, the best CROs but our environment has not been very conducive when it comes to developing new drugs. There are some challenges that the government has been facing in terms of novel drugs development â?? but now a lot of Indian companies want to innovate, be it in

biopharmaceuticals or pharmaceuticals. Sun Pharma, for instance, is investing a lot, Piramal, Lupin, Glenmark have also a great interest in innovating.

While private companies are heavily increasing their R&D spending, India as a country spends less than USD 1 per capita on healthcare research. Does India have the technological capabilities or the infrastructure to emerge as a biotech hub?

I think biopharmaceuticals have great and advanced infrastructure in India. If you look at Bangalore itself you have the Indian Institute of Science, the National Center for Biological Sciences, the Institute for Stem Cell Biology and Regenerative Medicine, the National Institute of Mental Health and Neurosciences and of course the whole genomic effort through various centers. There are very advanced centers and some of them collaborate with Trinity College and the University of Cambridge in the United Kingdom. We are 1,200 start ups in life sciences in India and 50 percent of them are in Bangalore. We have various incubators that foster these start-ups.

Research spending should not be looked in the broad sense, USD 1 spend per capita on healthcare research does not represent the current biopharma scene. When you deal with a population of 1.3 billion everything looks tiny. I would rather look at what is happening in biotech. If you look at the research spend on an academic level and the research spend at the industry level, you will notice that it is quite high. For instance, there is a company right now called Bugworks which is developing the next generation of antibiotics, because it realized that super bugs play a crucial role right now and because Bangalore has a huge capability in software and computational science, you find this kind of companies located in the city.

Quite recently, you launched BASALOGÂ®, your Insulin Glargine injection, in the Japanese market through your partner FFP. Can you talk us through the market access journey of the product in one of the worldâ??s most stringently regulated markets?

Our mantra is â??highest quality at lowest costâ?? and in order to prove that you have to have accreditation from top-notch regulatory agencies. For us, the US FDA is the crowning glory for any company aspiring to play in this business. Japan is also a very stringent market and we got our insulin glargine approved by the PMDA. It was a big milestone for us. Once again, this demonstrates our robust expertise and the fact that we are capable of having a product approved even in highly regulated markets like Japan. That gave us the confidence that we could start creating the label of â??high qualityâ?? for all our products. Every product we develop will get marketed in these countries whose regulators are synonymous with high quality. The WHO recently included trastuzumab and human insulin in their essential medicine list and we will contribute to their endeavour of making the treatment of cancer and diabetes affordable.

Shares of Biocon added two percent intraday earlier in a month as your partner Mylan resubmitted marketing authorization applications (MAAs) for the two biosimilars: Trastuzumab (Rocheâ??s Herceptin) and Pegfilgrastim (Amgenâ??s Neulasta) to the EMA. How is this long-standing partnership helping Biocon position itself as a world leader in biosimilars worldwide whilst being different from other global biotech companies?

Biocon and Mylan have always had a strategic partnership in the space of biosimilars and we recognized this opportunity in 2009. Even at that time, I think both companies recognized that this was going to be a huge need and a huge opportunity. Mylan recognized that biosimilars was going to drive growth for them and for us it was certainly a very important business strategy with which we could grow. We entered this partnership to develop a diverse portfolio of products, where Mylan, because of its stronger commercial profile, would actually lead the commercial side of the partnership in the US and the EU. So far, it has worked out very well for both partners and I do

believe that this a partnership that will deliver good returns for both parties.

What is the role that you would like Biocon to play locally and internationally in the future?

We see ourselves as a company that has great capabilities and is investing big time in not just expanding these capabilities but also expanding our focus on innovation and on building global scale in our operations. The Western model has been about low volume â?? high value, we believe in the opposite. This makes a difference to patients.

My legacy is about making a difference in human health and I would like India to be able to provide good quality basic healthcare. To the young aspiring entrepreneurs, I would like to say that there are endless possibilities to solve problems for countries like India and the world. If you have a deep-routed sense of purpose to make a difference, you can.

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