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Biocon eyes global markets to supply drug

SAMREEN AHMAD
Bengaluru, 13 July

While Biocon has received the Drug Controller General of India's (DCGI's) nod to market its novel biologic drug itolizumab in India for treating patients with moderate-to-severe Covid-19 complications, its partner Equillium is planning to carry out a clinical trial in the US, which could lead to a huge spike in demand for the product. The US has over 3 million cases and has reported more than 132,000 deaths to date in the country. Currently, there are more than 280,000 active cases in India.

The drug has been priced at ₹8,000 per vial

According to the WHO, 80 per cent cases are mild, 15 per cent are severe that require oxygen support, and 5 per cent are critical that require ventilation.

"By that estimate, the patient pool would range between 42,000 and 56,000 for itolizumab, which would translate into an addressable market of ₹39 crore (not incorporating the international market)," said ICICI Securities. In India, itolizuman, known by the brand name ALZUMAb, has been priced at ₹8,000 per vial, with most patients requiring four vials, taking the total cost of the therapy to ₹32,000. The drug will be manufactured as an intravenous injection at Biocon's facility in Bengaluru.

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THE COMPASS

Covid drug nod a shot in the arm for Biocon

Progress in biologics, projects in the pipeline driving prospects

UJJVAL JAUHARI

Rising almost 10 per cent in intra-day trade, shares of Biocon scaled an all-time high of ₹455 apiece on Monday, before closing the day with minor gains. The Drug Controller General of India's (DCGI's) nod for the launch of Covid-19 treatment biologic Itolizumab (ALZUMAb) in an injectable form for emergency use, coupled with the company's claim of its efficacy, constituted major triggers.

Analysts say Biocon's product has an advantage and is to be used for patients suffering from moderate- to severe-respiratory distress. While many players have launched drugs for emergency use in Covid cases, actual sales will depend on a successful response to the drugs. Further, while these products may give some immediate revenue mileage, given that their use is limited to hospital emergencies for now, major sustainable benefits can only be seen once companies can establish their efficacy after extensive trials.

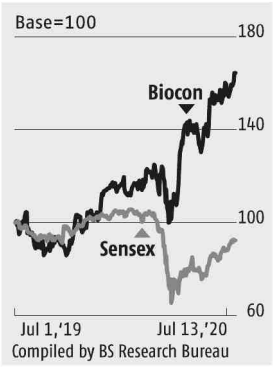
For now, the outlook for Biocon hinges on its biologics pipeline for developed markets such as the US and Europe, and that remains healthy.

Though the March quarter (Q4) performance remained soft due to supplies being impacted by the lockdown, Biocon has remained confident of achieving its target of $1 billion in sales from biologics by financial year (FY) 2022. The stock, too, has seen strong gains of 26 per cent since Q4 results, with additional triggers coming from its partner, Mylan, which recently received approval for the launch of insulin glargine in the US, which validates steady progress in biosimilars.

The insulin glargine's market in the US is significant, with sales of $1.3 billion reported by Lantus (Sanofi's product) in calendar year (CY) 2019, point out analysts. Opportunities are abundant for Biocon-Mylan amid increasing demand for cheaper insulin products in the US. There is also ample capacity at Biocon's Malaysia insulin plant, which has already received an EIR (establishment inspection report) in April, easing concerns over US FDA inspections.

While the launch of insulin glargine is expected shortly, there are other triggers too. As sales of already-launched oncology biologics in the US (Ogivri and Fulphila) could drive growth, Mylan is expected to launch the biosimilar etanercept in the European Union during the second half of CY 2020. Etanercept is used to treat autoimmune diseases. The approval of biosimilar bevacizumab (oncology), aspart (rapid-action insulin) and recombinant human insulin (rh-insulin), which are other products in the pipeline for developed markets are also awaited.

On the whole, there are multiple catalysts for Biocon over the next few months, say analysts at HSBC, who have increased their FY21-23 earnings estimates by 1.8-7.7 per cent in view of a visible improvement in execution of biosimilars. They expect FY21 and FY22 earnings growth of 50.6 to 57.5 per cent, respectively.



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