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Biocon's novel anti-psoriasis biotech drug Itolizumab released in India

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After geting the regulatory approval in early 2013, Biocon, India's number two biotech company by revenues, released the much awaited Itolizumab with the brand name Alzumab in India on August 9. The monocolonal anti-body, the second novel biological drug developed entirely in India, is an anti-CD6 antibody based product.

"Biocon's Alzumab is the first anti-CD6 monoclonal antibody to be commercialized, an outcome of path breaking research in India," said Biocon's CMD, Kiran Mazumdar-Shaw, while launching the product in Bangalore on August 10. "We are proud that this will be the first instance of a breakthrough innovation from India with a potential to treat multiple autoimmune diseases and making a difference to a much larger patient population across the world."

A vial of the injectible medicine (25 mg/5 ml) will cost $131 (INR 7,950) compared to four other multinational products currently available in the Indian market at more than double this price. A patient has to take 28 injections and 12 maintenance shots every alternate weeks over 24 weeks. The approximate cost of treatment will be $5,243 (INR 3.2 lakh).

More than the cost, Alzumab is believed to be better than the existing biological products such an Enbrel (Pfizer), Humira (Abbott), and Remicade, because studies indicate that there are no appreciable side-effects. On the other hand, other drugs are known to reduce immunity and increase the incidence of tuberculosis in many patients. These are a class of anti-immune drugs which treat all such diseases.

Biocon started work on this drug more than 10 years ago, said Mazumdar-Shaw, and the drug went through one of the largest clinical trials for a biological drug in the country. More than 400 patients in the age group of 18 to 65 were enrolled for the trials. She said patients with Alzumab showed remission only after 24 weeks compared to 5-20 weeks in the case of existing drugs. A woman patient enrolled in the trial showed 97 per cent improvement after eight weeks of treatment and no relapse occurred even after six months.

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There are about 100 autoimmune diseases like psoriasis that affect humans. Other prominent auto-immune diseases are multiple scelorsis, rheumatoid arthritis, lupus. Drugs have been developed only to treat about 10 diseases so far. Approximately one to two percent of population in USA and Europe suffers from psoriasis. In India also, it is estimated that about two percent or 12-24 million are affected by psoriasis.

Mazumdar-Shaw said Biocon started working on this drug 10 years ago on a Th1 pathway but serendipitously arrived at the Th17 pathway few years ago when the results were very encouraging.

Current treatments include a regiment of conventional immunosuppressants in most people and only a very minuscule section of patients in India and abroad are treated using biological drugs due to high costs.

Mazumdar-Shaw said Alzumab prices could come down if more patients start using it and efforts were on to make it widely available by educating doctors and the medical community about the effectiveness of Alzumab. Many patient access programmes will be developed in cooperation with patient advocacy groups.

Biocon officials are hopeful that the entry of an affordable version of the anti-psoriasis drug will lead to market creation and ensure more patients start using it. Currently, due to high prices most of the patients discontinue treatment of biological drugs mid-course. Biocon hopes that a few thousand patients will benefit from their affordable drug in a year.

Mazumdar-Shaw said the company will soon be filing an IND (investigational new drug) application with the US regulator FDA along with a partner company for making the drug available in the US. Talks were on to identify suitable partners. She was hopeful that due to the high quality of the clinical data generated in India, it may be possible to shorten the process in the US.

Alzumab is the second novel biological drug developed by Biocon. In 2006, Biocon released BIOMab EGFR, a monoclonal anti-body to treat head and neck cancers. More than 20,000 patients in 27 countries have benefited from the drug so far.