

Biocon gets marketing authorization for Psoriasis drug

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Biocon recently announced that it has received marketing authorization from the DCGI (Drugs Controller General of India) for its novel biologic Itolizumab, an anti CD6 molecule, for the treatment of chronic plaque Psoriasis. Itolizumab, is a first in class therapy with a unique mechanism of action and a promising safety profile as indicated during the 52 week Phase III multi-centric clinical study conducted in India. It is the second novel biologic developed by Biocon at Asia's largest biotech hub in Bangalore, BioMab EGFR, an anti-cancer monoclonal antibody, being the first.

This approval paves the way for the launch of Biocon's Alzumab in India, later during 2013. Alzumab is a differentiated biologic drug with a superior safety profile compared to other approved biologic therapies given its very low opportunistic infection rates. A novel biologic indicated for the treatment of moderate-to-severe Psoriasis, Alzumab will be marketed by Biocon's Immunotherapy Division. Alzumab, will be manufactured and formulated as an infusion drug at Biocon's biopharma manufacturing facility at Biocon Park, Bangalore.

Ms. Kiran Mazumdar-Shaw, Chairman & Managing Director, Biocon said, that they were very excited with this development. She added that, "This approval paves the way for us to extend clinical development for other indications like Rheumatoid Arthritis (RA), Multiple Sclerosis (MS) and Vitiligo. We also intend to file a US IND shortly to enable us to embark on a global clinical development plan. This is a defining moment for Biocon as it reaches a significant milestone in its mission of delivering affordable innovation to patients worldwide."

Alzumab is expected to provide a safe & effective treatment option for Psoriasis, a socially debilitating disease affecting 2-3 % of Indian population. The global Psoriasis market size is estimated to cross \$8 bn by 2016.

Itolizumab has shown promising preclinical and clinical efficacy in other auto immune diseases like RA, MS. The company aims to file a US IND in 2013 to facilitate global clinical trials in Psoriasis, RA and other indications as a subcutaneous formulation. Biocon plans to develop this molecule with a global partner for various markets across the world. Itolizumab is a 'first in class' humanized IgG1 monoclonal antibody that selectively targets CD6 cells.