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ASIA EDITION

Biocon gets DCGI nod for psoriasis drug itolizumab

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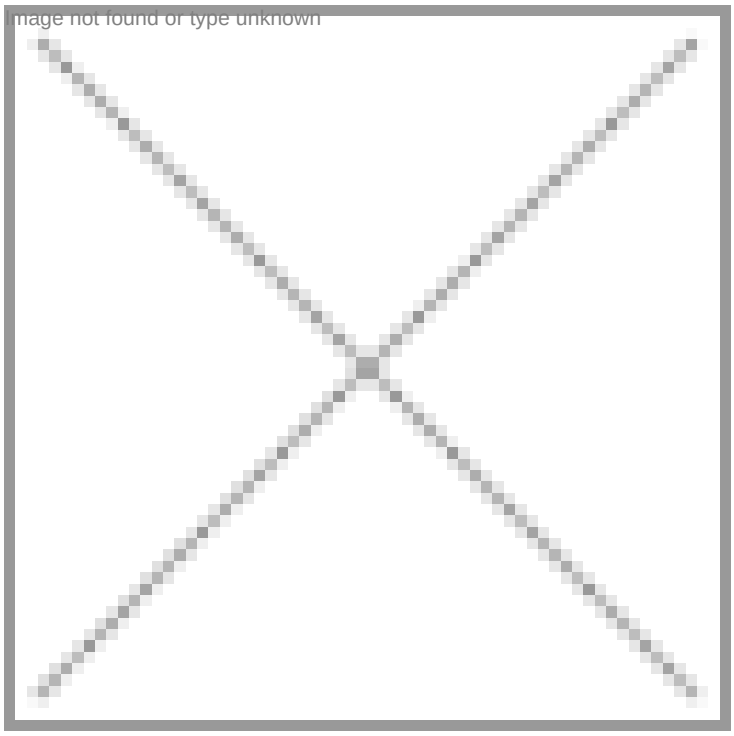

Bangalore: Biocon received marketing authorization from the Drugs Controller General of India (DCGI) for its novel biologic itolizumab, which is an anti-CD6 molecule used for the treatment of chronic plaque psoriasis.

Itolizumab is a first in class therapy with a unique mechanism of action (MoA) and an excellent safety profile as indicated during the 52 week phase III multi-centric clinical study conducted in India. Psoriasis is a socially debilitating disease affecting two-three percent of the Indian population. The global psoriasis market size is estimated to cross $8 billion by 2016. Biocon plans to develop this molecule with a global partner for various markets across the world.

This approval paves the way for the launch of Biocon's Alzumab in India during the later part of 2013. Alzumab, which is a differentiated biologic drug with a very low opportunistic infection rates, 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.

Dr Kiran Mazumdar-Shaw, chairman and managing director, Biocon, while commenting on this development, said that, "This marketing authorization for itolizumab from the DCGI will enable Biocon to introduce this novel, first-in-class biologic for the treatment of psoriasis patients in India. This is our second novel biologic that we have developed in India, with BioMab EGFR (an anti-cancer monoclonal antibody) being the first."

"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," she added.