

## Press Release

# Biocon Receives Marketing Authorization for its Novel Biologic Itolizumab for Psoriasis

**Bangalore, India:** January 08, 2013

Biocon, Asia's premier biotechnology company today announced that it has received **Marketing Authorization** from the Drugs Controller General of India (DCGI) for its **Novel Biologic Itolizumab**, anti CD6 molecule, 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. It is the **second Novel Biologic** developed by **Biocon** at Asia's largest Biotech hub in Bangalore.

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.

Commenting on this development **Ms. Kiran Mazumdar-Shaw, Chairman & Managing Director, Biocon** said, *"We are very excited to receive this marketing authorization for Itolizumab from DCGI which 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, 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**. 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.

### ***About Itolizumab***

Itolizumab is a 'first in class' humanized IgG1 monoclonal antibody that selectively targets CD6 cells. CD 6 is a pan T cell marker involved in co-stimulation, adhesion and maturation of T cells. Itolizumab, by binding to CD6, down regulates T cell activation, causes reduction in synthesis of pro-inflammatory cytokines and possibly plays an important role by reducing T cell infiltration at sites of inflammation. In addition to TREAT-PLAQ study, two positive Phase 2a dose finding studies have been conducted one each in RA and psoriasis.

### ***About Biocon Limited***

Established in 1978, Biocon Limited (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is India's largest biotechnology company by revenue. The Group, promoted by Ms. Kiran Mazumdar-Shaw, is a fully-integrated, innovation-driven healthcare enterprise with strategic focus on biopharmaceuticals and research services. Biocon's value chain traverses the entire length of discovery, development and commercialization of novel therapeutics. Biocon's robust product offering includes the world's first Pichia-based recombinant human Insulin, INSUGEN(R) and India's first indigenously produced monoclonal antibody BIOMAb-EGFR(TM) [www.biocon.com](http://www.biocon.com)

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