

Press Release

Biocon Launches ALZUMAb™ - a 'First in Class' Novel Biologic Treatment for Psoriasis Patients in India

- **ALZUMAb™**-World's first novel anti-CD6 antibody developed by Biocon to address a large unmet need for the treatment of Psoriasis in India
- Excellent safety and efficacy profile with very low opportunistic infection rates and longer remission period
- Offers a new treatment option for Psoriasis with a less aggressive dosing regimen and a longer treatment free period, ensuring better patient compliance and convenience
- Is an innovative affordable treatment option with a promise to offer a better quality of life for the patient
- Will provide an effective biologic treatment solution to 1-2% of Indian population suffering from Psoriasis

- **ALZUMAb™**- (Itolizumab) has demonstrated preclinical and/clinical evidence in treating other autoimmune diseases like rheumatoid arthritis, psoriatic arthritis and multiple sclerosis.
- Biocon is committed to offering this novel anti -CD6 biologic from India to patients across the globe

Bangalore, (India): August 10, 2013

Biocon, Asia's premier biotechnology company, today announced the launch of its 'first in class' novel biologic ALZUMAb™ (Itolizumab), the world's first anti-CD6 monoclonal antibody to be introduced for treating patients with chronic plaque psoriasis, in India.

ALZUMAb™ with a unique Mechanism of Action (MOA) offers superior safety and similar efficacy profile compared to other existing therapies, and has a long remission period with very low opportunistic infection rate. Psoriasis is a socially debilitating disease affecting 2-3 % of world population. The global Psoriasis market size is estimated to cross \$8 bn by 2016.

Commenting on this development **Ms. Kiran Mazumdar-Shaw, Chairperson and Managing Director**, Biocon said, *“Biocon’s ALZUMAb™ (Itolizumab) is the first anti-CD6 monoclonal antibody to be commercialized, an outcome of path breaking research in India. This new line of treatment will usher in a paradigm shift in the management of psoriasis. 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.”*

Mr. Rakesh Bamzai President-Marketing, Biocon said: *“Biocon is committed to address the huge unmet need of patients suffering from Psoriasis through its ‘first in class’ biologic ALZUMAb™. Compared to existing therapies, ALZUMAb™ offers a better safety and efficacy profile to the patients with longer remission periods and lower infection rates that will lead to better patient compliance and overall reduction in the cost burden to the patient.”*

Indicated for the treatment of Moderate-to-Severe Psoriasis, **ALZUMAb™** is being introduced in India by Biocon's Immunotherapy Division. Formulated as an infusion drug it is manufactured at Biocon's Biopharma manufacturing facility at Biocon Park, Asia's largest biotech hub in Bangalore.

Biocon: Front runner in introducing a biologic based on TH 17 pathway

ALZUMAb™ is the world's first anti -CD6 biologic addressing the Th 17 pathway that has completed its 'Lab to Market' journey. Emerging data shows that in addition to Th 1, Th17 cells, play a critical role in autoimmune diseases, and Biocon is a front-runner in the race to develop biologics targeting the Th17 pathway with **ALZUMAb™** (Itolizumab).

This differentiated MOA positions Itolizumab as a potentially 'best-in-class' treatment for psoriasis, and other autoimmune diseases.

Itolizumab: A high potential biologic for a range of autoimmune diseases

ALZUMAb™ is an outcome of breakthrough innovation at Biocon which has the potential to transform the treatment options for several autoimmune diseases besides psoriasis like rheumatoid arthritis, multiple sclerosis and others. It is potentially a pipeline within a product.

Its launch in India for psoriasis is the first milestone on a promising and exciting journey towards new treatment options for life-changing autoimmune diseases. Biocon is committed to taking **ALZUMAb™** (Itolizumab) from India to patients worldwide with a global partner.

Notes to the Editor:

ALZUMAb™ (Itolizumab) Unique MOA

ALZUMAb™ (Itolizumab) is the world's 'first-in-class' humanized anti-CD6 MAb that has a unique mechanism of action (MOA) targeting the CD6 pathway. CD6 is a pan T-Cell marker involved in co-stimulation, adhesion and maturation of T-Cells, which have been found to play a leading role in autoimmune diseases.

ALZUMAb™ (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.



Unlike other biologics like cytokine inhibitors which act downstream in the pro-inflammatory cascade, Itolizumab acts upstream inhibiting the formation of cytokines, resulting in lower infection rates and longer remission periods.

Clinical Development

In addition to the Phase 3 TREAT-PLAQ study, two positive Phase 2a dose finding studies have been conducted one each in rheumatoid arthritis and psoriasis. A total of over 300 patients have been treated with ALZUMAb™ (Itolizumab), of these, about 100 patients have received the drug for 52 weeks with encouraging safety and tolerability profile. Itolizumab was approved by Drugs Controller General of India for treatment of Psoriasis in India in 2013

About Biocon Limited

Established in 1978, Biocon Limited, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is India's largest and Asia's leading biotechnology company with a strategic focus on biopharmaceuticals and research services. It is a fully integrated, innovation-driven biopharma enterprise offering affordable solutions for chronic diseases to patient's worldwide. Biocon's robust product portfolio includes the world's first Pichia-based recombinant human Insulin, INSUGEN®, Glargine, BASALOG® and India's first biologic BioMab-EGFR™ for head & neck cancer. It has now successfully developed its second novel biologic Itolizumab, a 'first in class' anti-CD6 monoclonal antibody, introduced as ALZUMAb™ for psoriasis in India, in 2013. www.biocon.com

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