



## **Biocon Announces Positive Efficacy Data with its Novel Monoclonal Antibody Itolizumab in a Pivotal Psoriasis Study**

**Bengaluru, India /San Francisco, USA:** January 9, 2012:

Biocon, Asia's premier biotechnology Company today, announced positive results from its Double Blind, Placebo Controlled, Phase 3, TREAT-PLAQ Study with **Itolizumab** in chronic plaque psoriasis. Itolizumab, the first humanized anti CD-6 monoclonal antibody, successfully met the pre-specified primary endpoint of significant improvement in PASI-75 (*Psoriasis Area and Severity Index*) score after 12 weeks of treatment in patients with moderate to severe psoriasis compared to placebo. It also met multiple secondary endpoints after 12 and 28 weeks of treatment.

This **52 week study conducted in India**, had a 12 week placebo controlled phase, 16 week consolidation and 24 week randomized withdrawal phase. It enrolled over 200 patients across placebo and two active treatment regimens. In this **28 week interim analysis, both treatment regimens were statistically significantly better than placebo with the fixed dose regimen** of 1.6 mg/kg every two weeks for 12 weeks followed by 1.6 mg/kg every 4 weeks for 16 weeks demonstrating response rate of 36% ( $p < 0.0043$ ) at Week 12 and 46% at Week 28. The response rates for patients with PASI > 20 at baseline was 43% and 54% at Week 12 and 28 respectively. **The molecule also exhibited an excellent safety and tolerability profile** with very low rates of infection (~10%) in active treatment arms suggesting a **favorable risk benefit profile compared to currently available biologic treatments**. Biocon plans on presenting the safety and efficacy data from the entire 52 week study at an upcoming scientific meeting.

**Expressing her excitement at the outcome of the study Ms. Kiran Mazumdar-Shaw, Chairman & Managing Director, Biocon said, "Itolizumab represents a significant advancement in the treatment of psoriasis and potentially other autoimmune diseases with an excellent risk-benefit profile. This could possibly become the first novel biologic developed and approved from India and is an important milestone for Biocon in its pursuit of affordable innovation. We look forward to taking this molecule to the market across multiple indications with a global partner to ensure that affordable innovation reaches patients worldwide in a timely manner."**

*“We strongly believe in this molecule and are pleased with the results from the TREAT-PLAQ study. The low opportunistic infection rate despite the study being conducted in India validates the preclinical findings and along with **novel mechanism of action opens new treatment paradigms** for treatment of psoriasis and other autoimmune diseases. We are looking forward to accelerating clinical development in other autoimmune conditions like MS (Multiple Sclerosis) and RA (Rheumatoid Arthritis)”* said **Abhijit Barve, M.D., Ph.D., President R&D, Biocon**. *“We would like to sincerely thank all the patients and their families, investigators and colleagues at Biocon, Clinigene and other partners for their participation in this complex study”*

### **About Itolizumab**

Itolizumab is a ‘first-in-class’ investigational 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. A total of about 300 patients have been treated with Itolizumab, of these, about 100 patients have received the drug for 52 weeks with encouraging safety and tolerability profile.

### **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)

**Clinigene International Enters into Collaborative Clinical Research Services  
Agreement with Pacific Biomarkers**

**Press Release: 2**

**Bangalore, India – December 21, 2011:** Clinigene International Limited, a subsidiary of Biocon, India's largest Biotech Company, and Pacific Biomarkers Inc. (PBI), a Seattle, WA-based limited liability company announce a collaborative agreement to address the specialty biomarker and high-end clinical trial laboratory needs of the global pharmaceutical and biotechnology industry.

Clinigene, is an India-based Clinical Research Organization (CRO) that offers end-to-end clinical and laboratory services for accelerating clinical research, and Pacific Biomarkers Inc. (PBI), is a Seattle, WA-based company that provides premier biomarker and specialty efficacy testing services to the drug development industry.

*"PBI is a recognized global leader in providing specialty biomarkers and clinical diagnostic assay services to discovery- and development-based life science enterprises. We are delighted that PBI has selected Clinigene as its partner in India and we look forward to supporting PBI in extending and expanding its specialist service offerings,"* said Peter Bains, Director of Research Services business.

*"This partnership with Clinigene provides us access to India, an emerging hub for drug development and contract research. Further, Clinigene's state-of-the-art facilities and highly qualified staff help us offer to all of our clients an economic option to conduct their biomarker and specialty clinical lab tests. We are also excited about Clinigene's unique capabilities in cell-based assays and immunoanalytical testing services, which are of great interest to the global pharmaceutical and biotechnology community,"* said Ronald Helm, CEO of Pacific Biomarkers.

**About Clinigene International Limited**

Established in 2000, Clinigene ([www.clinigeneintl.com](http://www.clinigeneintl.com)) a fully owned subsidiary of Biocon Limited, is a full-service Contract Research Organization (CRO) providing early-stage as well as late-phase clinical solutions, and central laboratory, immunoanalytical and data management services. Clinigene operates a CAP-accredited Central Lab and GLP-compliant Bioanalytical Laboratory for small and large molecules, and a 104-bed clinical pharmaceutical unit in Bangalore, India. Clinigene's early-phase clinic and laboratories have been inspected by EMEA and the US FDA.

**About Biocon Limited**

Biocon is Asia's premier Biotechnology Company and India's largest 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. ([www.biocon.com](http://www.biocon.com))

**About Pacific Biomarkers (PBI)**

Established in 1989, PBI ([www.pacbio.com](http://www.pacbio.com)) provides biomarker laboratory services and contract research services to support pharmaceutical and diagnostic manufacturers conducting human clinical trial research. The Company provides expert services in the areas of cardiovascular and musculoskeletal diseases, diabetes, obesity, and nutrition. The PBI laboratory is accredited by the College of American Pathologists, New York State, and the Lipid Standardization Program. PBI's clients include many of the world's largest pharmaceutical, biotechnology, and diagnostic companies. PBI also provides clinical biomarker services focusing on the emerging field of biomarker assay development and testing. Services include validating and performing custom assays for novel clinical biomarkers, immunogenicity testing, mass spectrometry, and multiplex testing.

**Press Release: 3**

## **Biocon launches INSUPen<sup>®</sup>, a convenient and affordable reusable insulin delivery device**

**Bangalore, October 20, 2011:** Biocon, Asia's premier biotechnology company, launched in India its reusable insulin delivery device INSUPen<sup>®</sup> on October 17, 2011. A world-class, differentiated device based on proprietary German technology, INSUPen<sup>®</sup> is a first-in-class reusable delivery device - INSUPen *is insulin with ease*. It is designed for efficiency, accuracy and safety and can deliver both Basalog<sup>™</sup> and Insugen<sup>™</sup>, thus maximizing patient convenience.

INSUPen<sup>®</sup> was launched by Biocon Chairman and MD Kiran Mazumdar-Shaw at a gala event. INSUPen<sup>®</sup> is a breakthrough in Diabetes delivery devices because of three unique firsts:

- First German technology pen offering the best user-friendly features
- First to offer needles complimentary with every refill
- First to offer a choice of 3 colors for clear insulin differentiation.

To take INSUPen<sup>®</sup> ease to a totally new level for users, Biocon has created a support system that takes care of every possible need. Biocon has recruited a team of 125 Diabetic Care Advisors across India to support Biocon's existing helpline for Diabetics. Biocon's 'One call does all' offers complementary wide-ranging support for this device including at-home product demos, counseling on lifestyle changes, and answers to product-related queries.

One of the recurring costs that Diabetes patients must bear is the cost of needles. For the first time, Biocon offers two complimentary needles with every refill either of Basalog<sup>™</sup> Refil or Insugen<sup>™</sup> Refil. All variants of refill for both Basalog<sup>™</sup> and Insugen<sup>™</sup> work with INSUPen<sup>®</sup> and come in an innovative packaging. All that the patient needs to do is decide which colour INSUPen<sup>®</sup> they want to use for the Basalog insulin refill and which one for the Insugen refill.

"Designed keeping in mind the ease and convenience of Diabetic patients, INSUPen<sup>®</sup> will help transform their lives. Manufactured with high precision German technology, and offered with Biocon's Insugen<sup>™</sup> & Basalog<sup>™</sup> refills accompanied by complimentary needles, INSUPen<sup>®</sup> is a true value proposition. Biocon has also ensured that INSUPen<sup>®</sup> is affordable. Relative to top competitors, Biocon's Insugen<sup>™</sup> & Basalog<sup>™</sup> refills will have annual benefit of Rs 1200-Rs 1500 to the Diabetes patients (average usage). I am confident that INSUPen<sup>®</sup> will be a delight for patients and a value enhancer for all stakeholders," said *Rakesh Bamzai*, President, Marketing *Biocon*.

The reusable INSUPen<sup>®</sup> is available at an MRP of Rs 675. The Basalog Refil (3x3ml pack), is priced at Rs 1305 and the Insugen Refil (5x3ml pack) at Rs 779.50

Biocon is driven by the need to make a difference in the lives of the large number of people across the globe who are afflicted by Diabetes. India is the Diabetes capital of the world with over 40 million of the world's Diabetics being in India. Chances are, by 2025, 1 in 5 Diabetics worldwide is likely to be an Indian. Biocon hopes to make a difference to the lives of these Diabetics with INSUPen<sup>®</sup>.

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