

## Biocon and Bentley Announce Approval and Expansion of Bentley's Nasulin®; Phase II Studies in India

*Biocon's Clinigene International Private Limited to conduct clinical trials*

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India's largest Insulin producer, Biocon Limited has announced today that its licensing partner, Bentley Pharmaceuticals, Inc. (NYSE: BNT), a specialty pharmaceutical company, has received approval from the Drug Controller General of India (DCGI) to proceed with a Phase II clinical evaluation of Nasulin®; in Type II diabetic patients. Nasulin®; is Bentley's intranasal insulin product utilizing its proprietary delivery technology CPE-215. As per the licensing agreement, Biocon is responsible for developing and marketing Nasulin®; in India and select territories. Biocon provides a source of insulin powder and Cardinal Health has manufactured the clinical supplies for this Phase II study under contract with Bentley.

This approval follows the completion of Bentley's pharmacokinetic clinical studies of Nasulin®; studies in India. The Phase II study will be initiated in March 2007 and is expected to be completed before the end of the year.

Mr. John Sedor, President of Bentley commented, **'This expansion marks an incremental milestone in the clinical development of Nasulin®;. We are encouraged by the progression of data we've accumulated in the insulin program which further validates our intranasal delivery technology platform and its potential to deliver other therapeutic peptides in similar formulations to insulin.'**

Mr. Rakesh Bamzai, President Marketing, Biocon said **'We are very excited about the progress made in the nasal insulin program with Bentley. Biocon truly believes that non injectable insulins will drive the future of diabetes therapy the world over.'**

Clinigene, a CAP accredited CRO and wholly-owned subsidiary of Biocon, Ltd., will administer the complex program. Dr. A. S. Arvind, Chief Operating Officer, Clinigene International Private Limited said, **'Phase II clinical studies for this product will consist of 80 patients and will be conducted in six centers in India under the direction of top clinical investigators. The patients will self-administer Nasulin®; spray three times per day for twelve weeks. They will be monitored for control of their post-prandial blood sugar and HbA1c (a subtype of hemoglobin, used to measure effectiveness of the therapy).'**

Chairman and CEO of Bentley, James Murphy, remarked, **'Biocon has been a reliable partner for several years and has significant experience in developing insulin products. The Bentley researchers together with the clinicians and regulatory staff of Biocon and its subsidiaries are fully committed to the clinical advancement of Nasulin®;.'**

Data received from the Nasulin®; Phase II program in India will supplement Bentley's Phase II studies already underway in the U.S. under the direction of Dr. Sherwyn Schwartz at the Diabetes & Glandular Disease Clinic (DGD) in Texas. Bentley also expects to complete a significant portion of the U.S. Phase II studies before the end of 2007.

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### **About Bentley**

Bentley Pharmaceuticals, Inc. is a specialty pharmaceutical company focused on advanced drug delivery technologies and generic pharmaceutical products. Bentley's proprietary drug delivery technologies enhance the absorption of pharmaceutical compounds across various membranes. Bentley manufactures and markets a growing portfolio of generic and branded generic pharmaceuticals in Europe for the treatment of cardiovascular, gastrointestinal, infectious and central nervous system diseases through its subsidiaries -- Laboratorios Belmac, Laboratorios Davur, Laboratorios Rimafar and Bentley Pharmaceuticals Ireland. Bentley also manufactures and markets active pharmaceutical ingredients through its subsidiary, Bentley API.

Additional information regarding Bentley Pharmaceuticals may be obtained through Bentley's web site at <http://www.bentleypharm.com/>.

### **About Biocon**

Established in 1978, Biocon Limited is one of India's premier biotechnology companies. Biocon and its two subsidiary companies, Syngene International Pvt Ltd and Clinigene International Pvt Ltd form a fully integrated biotechnology enterprise, specializing in biopharmaceuticals, custom research, clinical research and enzymes. With successful initiatives in clinical development, bio-processing and global marketing, Biocon delivers products and solutions to partners and customers across the globe. Many of these products have USFDA and EMEA acceptance. Biocon launched the world's first recombinant human insulin, INSUGEN<sup>®</sup>; using Pichia expression and India's first indigenously produced monoclonal antibody BIOMAb-EGFR<sup>®</sup>. Visit us at [www.biocon.com](http://www.biocon.com)

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