



## **BIOCON AND PFIZER ENTER INTO GLOBAL COMMERCIALIZATION AGREEMENT**

***Creates global alliance well positioned to deliver essential Insulin treatments to Diabetes patients worldwide***

**Bangalore and New York, October 18, 2010** – Biocon, Asia’s premier biotechnology company, and Pfizer, the world’s leading biopharmaceutical company, today announced that they have entered into a strategic global agreement for the worldwide commercialization of Biocon’s biosimilar versions of Insulin and Insulin analog products: Recombinant Human Insulin, Glargine, Aspart and Lispro. Pfizer will have exclusive rights to commercialize these products globally, with certain exceptions, including co-exclusive rights for all of the products with Biocon in Germany, India and Malaysia. Pfizer will also have co-exclusive rights with existing Biocon licensees with respect to some of the products, primarily in a number of developing markets.

Biocon will remain responsible for the clinical development, manufacture and supply of these biosimilar Insulin products, as well as for regulatory activities to secure approval for these products in various geographies. Biocon’s Recombinant Human Insulin formulations are approved in 27 countries in developing markets, and commercialized in 23, while Glargine has been launched in its first market, India.

Under the terms of the agreement, Pfizer will make upfront payments totaling \$200 million. Biocon is also eligible to receive additional development and regulatory milestone payments of up to \$150 million and will receive additional payments linked to Pfizer’s sales of its four Insulin biosimilar products across global markets.

### **DIABETES: A GLOBAL PANDEMIC**

Diabetes is one of the fastest-growing and largest disease burdens globally, with nearly 230 million diabetic patients worldwide and 3 million deaths attributed to the disease



annually. Although Insulin is the primary response to address Diabetes and is included on The World Health Organization's (WHO) Essential Medicines List, it remains inaccessible on an uninterrupted basis in many parts of the developing world. The WHO estimates that 70% of people afflicted with Diabetes live in low and middle income countries, with India alone accounting for 40 million patients. It is estimated that Diabetes will affect 400 million people globally by 2030 <sup>(1)</sup>, with an expected 1 in 5 diabetics in India.<sup>(2)</sup>

The Diabetes pandemic is also alarming in developed countries, including the United States, which has 18 million diabetic patients and a healthcare cost burden of approximately \$200 billion per year associated with the disease. By 2030, the number of people living with Diabetes in the U.S. is expected to increase to 30 million.<sup>(3)</sup>

Commenting on this major alliance, Kiran Mazumdar-Shaw, Chairman and Managing Director of Biocon, said: "This is indeed a significant inflection point in our globalization path. Pfizer and Biocon bring together a winning combination of marketing, manufacturing and research excellence which can build a formidable global footprint in Diabetes care. Pfizer brings brand strength and a vast and unrivalled global marketing network that will enable Biocon to realize its objective of seeing its Insulin portfolio have a worldwide presence."

"We are excited to join forces with Biocon in the battle against the disease and economic burden that Diabetes poses to global health. Our alliance with Biocon will enable the delivery of biosimilar Insulin products, providing attractive, cost-effective treatment options to more Diabetes patients." said David Simmons, President and General Manager of Pfizer's Established Products Business Unit. "In addition, this collaboration supports our stated efforts to become a strong player in follow-on biologics as well as in the Diabetes disease area, by adding to Pfizer's broad biotherapeutics portfolio, ranging from biosuperiors to biosimilars, across multiple therapeutic areas, which we've said we will supplement with both our in-house development efforts and selective collaborations."

The 2010 market for Diabetes drugs and devices is estimated at \$40 billion with Insulins accounting for \$14 billion or 35% of the Diabetes segment.<sup>(1)</sup> By 2015, a number of Insulin analogs are expected to lose patent protection, resulting in a significant opportunity for the



biosimilars market. With this alliance, Pfizer and Biocon expect to be well positioned to be first movers in this potentially large market opportunity.

- (1) The World Health Organization
- (2) King, H. & Rewers, M. (1998) Global burden of diabetes; 1995-2025: prevalence, numerical estimates and projections. Diab. Care 21:1414-1431.[Abstract]  
(<http://jn.nutrition.org/cgi/content/full/134/1/205>)
- (3) Wild S, Roglic G, Green A, Sicree R, King H: Global prevalence of diabetes: estimates for the year 2000 and projections for 2030. Diabetes Care 27:1047-1053, 2004  
(<http://care.diabetesjournals.org/content/27/5/1047.full.pdf>)

### **About Biocon**

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. With successful initiatives in clinical development, bio-processing and global marketing, Biocon delivers products and solutions to partners and customers in approximately 75 countries across the globe. Many of these products have USFDA and EMEA acceptance. 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).

Visit us at [www.Biocon.com](http://www.Biocon.com)

### **Pfizer Inc.: Working together for a healthier world™**

At Pfizer, we apply science and our global resources to improve health and well-being at every stage of life. We strive to set the standard for quality, safety and value in the discovery, development and manufacturing of medicines for people and animals. Our diversified global health care portfolio includes human and animal biologic and small molecule medicines and vaccines, as well as nutritional products and many of the world's best-known consumer products. Every day, Pfizer colleagues work across developed and emerging markets to advance wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company,



we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at [www.pfizer.com](http://www.pfizer.com).

#### *DISCLOSURE NOTICE*

*The information contained in this release is as of October 18, 2010, Biocon and Pfizer assume no obligation to update forward-looking statements contained in this release as the result of new information or future events or developments.*

*This release contains forward-looking information that involves substantial risks and uncertainties concerning an agreement between Biocon and Pfizer for the worldwide commercialization of Biocon's portfolio of biosimilar Insulin and Insulin analog products. Such risks and uncertainties include, among other things, the uncertainties inherent in clinical development; decisions by regulatory authorities regarding whether and when to approve drug applications that have been or may be filed in various markets for such products as well as their decisions regarding labeling and other matters that could affect the availability or commercial potential of such products; the speed with which regulatory approvals, pricing approvals and product launches may be achieved; the ability to successfully commercialize such products in markets worldwide; and competitive developments.*

*A further description of risks and uncertainties can be found in Pfizer's Annual Report on Form 10-K for the fiscal year ended December 31, 2009 and in its reports on Form 10-Q and Form 8-K.*



Press Release : 2

## **Biocon and CIM to Collaborate in Immunology Research Program**

**Bangalore, September 27, 2010:** Biocon Limited (NSE: BIOCON), Asia's premier biotechnology companies, and the Center of Molecular Immunology (CIM), based in Havana, Cuba, have strengthened their existing research partnership by joining forces for an integrated antibody program in immunology. Both entities have successfully collaborated for almost a decade on an integrated program to manufacture and clinically evaluate recombinant proteins with the aim of building a portfolio based on therapeutic biotechnology products for chronic diseases. Two drugs have already been approved for medical use in India and other territories. A novel monoclonal antibody targeting the Epidermal Growth Factor Receptor for the treatment of cancer, and the human recombinant Erythropoietin – for the control of anemia in chronic kidney diseases – were developed under stringent medical regulatory standards.

Looking to build on this successful partnership, Biocon and CIM are moving to create an innovative product pipeline focused on autoimmune diseases and cancer. Fundamental research performed at CIM and Biocon has defined the anti-inflammatory capacity of a novel monoclonal antibody, an Anti-CD6 Monoclonal Antibody. This molecule targets lymphocytes, the key players in the immuno-pathology of autoimmune diseases. Experimental data supports its effect in controlling inflammation that can cause damage of tissues. Research results have been endorsed by scientific journals and discussed in international congresses.

“This Anti-CD6 targeting antibody is a First in Class molecule which has recently transited to advanced clinical trials for the treatment of Psoriasis and Rheumatoid Arthritis patients,” says Kiran Mazumdar-Shaw, Chairman and Managing Director of Biocon Limited. Consequently, a bi-national translational research workshop on this pioneering targeted therapy was organised in Bangalore on September 26 and 27, 2010. Scientists and clinicians from various institutions from both countries gathered to discuss this novel molecule.

This meeting played an important role in dissecting the intellectual challenges that lie ahead at the interplay of laboratory science and the clinical setting, a critical step linked to drug discovery. The deliberations also explored whether the current experience could be extended to other potential medical indications.

“In the long run, it would contribute to the joint development of a scientific program based on Biocon’s and CIM’s complementary capacities. Consequently, this South-South scientific and commercial partnership will continuously provide accessibility to a high standard of therapeutics to a growing population of patients who would otherwise be precluded because of the high cost factor,” says Dr. Enrique Montero, a leading scientist at CIM.

### **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. With successful initiatives in clinical development, bio-processing and global marketing, Biocon delivers products and solutions to partners and customers in approximately 75 countries across the globe. Many of these products have USFDA and EMEA acceptance. Biocon’s robust product offering includes the world’s first recombinant human insulin, INSUGEN® and India’s first indigenously produced monoclonal antibody BIOMAb-EGFR(TM). For more information, visit [www.biocon.com](http://www.biocon.com)

### **About CIMAB**

CIMAB S.A. is the commercial branch of the Center of Molecular Immunology (CIM). CIM is one of the centres of the Scientific Pole in Cuba devoted to research, development and manufacturing human biotech products, while CIMAB is the marketing company. CIM research programs are focused in the areas of cancer therapeutics, autoimmune diseases and renal transplant. CIM utilizes its platform technology and development capabilities to facilitate the rapid and cost-effective discovery and development of novel anti-cancer drugs. Web page: [www.cim.sld.cu](http://www.cim.sld.cu)

### **Media contact:**

Paula Sengupta  
Biocon Limited  
Tel: +91 80 2808 2222  
Fax: +91 80 2852 3423  
Email: [paula.sengupta@biocon.com](mailto:paula.sengupta@biocon.com)

Varija Belliappa  
Biocon Limited  
Tel: +91 80 2808 2223  
Fax: +91 80 2852 3423  
Email: [varija.belliappa@biocon.com](mailto:varija.belliappa@biocon.com)

Press Release: 3

**Biocon partners with Teleradiology Solutions for Clinical Trials Radiology**  
*To help accelerate the drug discovery process*

**Bangalore 16<sup>th</sup> September 2010:** Biocon, India's largest biotechnology company, entered into an agreement with Teleradiology Solutions, a pioneer of the domain in India, to provide teleradiology reporting services to Clinigene, Biocon's Clinical Research Organization. Teleradiology Solution's quality-driven reporting process and cutting-edge technology platform have the potential to greatly benefit biotech and pharma companies, obviating delays in the completion of clinical trials by optimizing the radiology reporting process.

Clinical trials radiology is a unique class by itself. In clinical trials, the objective is to demonstrate formally the efficacy, safety and cost utility of a new therapy for regulatory approval, with the fewest patients and in the shortest time possible. Teleradiology Solutions offers pharmaceutical vendors, clinical research organizations, and biotechnology organizations the opportunity to shorten their development cycles by using TRS Clinical Trials Radiology Reporting service. The organisation offers quality reporting by radiologists experienced in RECIST (Response Evaluation Criteria In Solid Tumors) and WHO (World Health Organisation) measurement criteria.

According to **Kiran Mazumdar-Shaw, Chairman & Managing Director of Biocon Ltd**, "To achieve our main objective, *Accelerating Clinical Research*, we leverage on an adept mix of technology, experience and personal traits. Keeping in line with our mission, Teleradiology Solutions, given their impressive track record, was the partner of choice to meet our complex image analysis requirements. The signing of this agreement further endorses Bangalore as the hub of excellence, both in Biotechnology as well as in high end healthcare delivery to the world."

According to **Dr Arjun Kalyanpur, MD and Chief Radiologists, Teleradiology Solutions**, "For pharmaceutical and Biotechnology companies involved in drug development R&D, delays in the drug development cycle can be an issue of concern. These are in part related to delays in reporting of radiologic scans that are performed to confirm that the patient under treatment has responded positively to the drug being evaluated in the clinical trial. The delays are in turn related to the worldwide shortage of radiologists, estimated to be as high as 20% in some studies. We are happy to partner with Biocon and offer our services to ensure timely execution and quality evaluation for clinical trials in radiology."

## About Biocon

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. With successful initiatives in clinical development, bio-processing and global marketing, Biocon delivers products and solutions to partners and customers in approximately 75 countries across the globe. Many of these products have USFDA and EMEA acceptance. 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).

## About Teleradiology Solutions

**Teleradiology Solutions (TRS)** was founded in 2002 by **Dr. Arjun Kalyanpur** and **Dr. Sunita Maheshwari**. It was initially set up to provide hospitals in the United States with night shift radiology solutions and now provides teleradiology to hospitals in Singapore and India with other countries on the anvil. Teleradiology Solutions (US) is accredited by the **US Joint Commission of Accreditation of Healthcare Organizations (JCAHO)**. It is also the first organization outside Singapore to be accredited by the Ministry of Health, Singapore. The company provides teleradiology services to hospitals around the globe, which includes interpretation of all non-invasive imaging studies, namely CT, MRI, ultrasound, nuclear medicine studies and digitized Xrays. The company provides subspecialty consultations in cardiovascular and oncologic imaging to hospitals in India as well, and has joint research partnerships with major technology vendors such as GE, to explore new techniques in 3D imaging analysis.

## Media Contacts

Paula Sengupta  
Biocon Limited  
Tel: +91 80 2808 2222  
Fax: +91 80 2852 3423  
[paula.sengupta@biocon.com](mailto:paula.sengupta@biocon.com)

Varija Belliappa  
Biocon Limited  
Tel: +91 80 2808 2223  
Fax: +91 80 2852 3423  
[varija.belliappa@biocon.com](mailto:varija.belliappa@biocon.com)