Pfizer Logo

Biocon and Pfizer Enter Into Global Commercialization Agreement

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Creates Global Alliance Well Positioned to Deliver Essential Insulin Treatments to Diabetes Patients Worldwide

"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,"

(BUSINESS WIRE)--Biocon, Asia's premier biotechnology company, and Pfizer Inc. (NYSE: PFE), 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 (1), with an expected 1 in 5 diabetics in India.(2)

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.(3)

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.(1) 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.

The World Health Organization

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)

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://files\pressrelease_assets\pdf\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® and India's first indigenously produced monoclonal antibody, BIOMAb-EGFR™.

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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.

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.

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