

Press Release

Biocon & Mylan Win Patent Litigation Asserted by Sanofi for Insulin Glargine Device Patent in U.S. Brings Biocon Closer to Commercializing Semglee in U.S. in 2020

Bengaluru, India – March 11, 2020

Biocon Ltd. (BSE code: 532523, NSE: BIOCON) announced today that it has won a U.S. court ruling that invalidated a Sanofi patent on the Insulin Glargine device, removing a key legal hurdle to commercializing Semglee® (Insulin Glargine) co-developed with Mylan, in the U.S.

The U.S. District Court of New Jersey found the device patent claims (U.S. Patent No. 9,526,844) asserted by Sanofi against Biocon and Mylan's Insulin Glargine product 'not infringed' and 'invalid' for lack of written description. Separately, as previously announced, Sanofi's formulation patents (U.S. Patent No. 7,476,652 and U.S. Patent No. 7,713,930) were previously affirmed to be invalid by the Federal Circuit.

The 505(b)(2) New Drug Application (NDA) for Semglee is under active review by the U.S. Food and Drug Administration (FDA). The FDA has set a Target Action Date for our Insulin Glargine application in June 2020. Biocon remains confident of being able to commercialize the product in calendar year 2020. The market opportunity for Insulin Glargine in the U.S. is estimated at US\$ 2.2 billion.

Dr Christiane Hamacher, CEO, Biocon Biologics said, *"We are extremely pleased with the U.S. court ruling in favour of our Insulin Glargine device as this takes us closer towards bringing a more affordable Insulin Glargine for patients with diabetes in the U.S. Today, patients in parts of Europe, Australia, India and key emerging markets are already benefiting from our Insulin Glargine. Once approved and commercialized our Semglee® will expand access to this therapy. This patent win endorses our commitment to innovation and value creation through incisive IP strategy. Biocon Biologics remains committed to use its science, scale and expertise to shift the access paradigm for patients in need of insulins across the globe."*

Insulin Glargine is a long-acting insulin used to treat adults with Type 2 diabetes and adults and paediatric patients with Type 1 diabetes for the control of high blood sugar.

Biocon's Insulin Glargine has received regulatory approval in ~70 countries around the world and has also been commercialized in many emerging markets such as Brazil, Mexico, Malaysia, South Korea, UAE, as well as, developed markets like Japan, Australia and parts of Europe.

Notes to the Editor:

In October 2017, Sanofi had initiated patent infringement litigation against our NDA in the U.S District Court for the District of New Jersey that included the formulation patents covering Insulin Glargine as well as patent covering the Insulin Glargine injection pen, triggering a 30-month stay on the product's approval.

About the Biocon and Mylan Partnership

Mylan and Biocon Biologics are exclusive partners on a broad portfolio of biosimilar and insulin products. Insulin Glargine is one of the 11 biologic products being co-developed by Mylan and Biocon for the global marketplace. Mylan has exclusive commercialization rights for Insulin Glargine in the U.S., Canada, Australia, New Zealand, the European Union and European Free Trade Association countries. Biocon has exclusive rights for Japan and a few emerging markets, and co-exclusive commercialization rights with Mylan in the rest of the world.

About Biocon Limited

Biocon Limited, publicly listed in 2004, (BSE code: 532523, NSE Id: BIOCON, ISIN Id: INE376G01013) is an innovation-led global biopharmaceuticals company committed to enhance affordable access to complex therapies for chronic conditions like diabetes, cancer and autoimmune. It has developed and commercialized novel biologics, biosimilars, and complex small molecule APIs in India and several key global markets as well as generic formulations in the US and Europe. It also has a pipeline of promising novel assets in immunotherapy under development. www.biocon.com
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Biocon Biologics is a subsidiary of Biocon Ltd. It is uniquely positioned as a fully integrated ‘pure play’ biosimilars organization in the world and aspires to transform patient lives through innovative and inclusive healthcare solutions. The Company’s portfolio of biosimilar molecules comprises a rich pipeline of approved and in-development biosimilars, which are an outcome of its high end R&D and global scale manufacturing expertise. The Company has commercialized three of its biosimilars in the developed markets like EU, U.S., Japan and Australia. It is a leading global insulins player with over 15 years of experience in addressing the needs of patients with diabetes, having provided over 2 billion doses of human insulin worldwide, thus far. Follow-us on Twitter: @BioconBiologics

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Forward-Looking Statements: Biocon

This press release may include statements of future expectations and other forward-looking statements based on management's current expectations and beliefs concerning future developments and their potential effects upon Biocon and its subsidiaries/ associates. These forward-looking statements involve known or unknown risks and uncertainties that could cause actual results, performance or events to differ materially from those expressed or implied in such statements. Important factors that could cause actual results to differ materially from our expectations include, amongst other: general economic and business conditions in India and overseas, our ability to successfully implement our strategy, our research and development efforts, our growth and expansion plans and technological changes, changes in the value of the Rupee and other currency changes, changes in the Indian and international interest rates, change in laws and regulations that apply to the Indian and global biotechnology and pharmaceuticals industries, increasing competition in and the conditions of the Indian and global biotechnology and pharmaceuticals industries, changes in political conditions in India and changes in the foreign exchange control regulations in India. Neither Biocon, nor our Directors, or any of our subsidiaries/associates assume any obligation to update any particular forward-looking statement contained in this release.