

Press Release

**Biocon's* Partner Mylan Receives Favourable Ruling from
U.S. PTAB on Sanofi's Four Device Patents for Lantus® SoloSTAR®
An Important Milestone towards Enabling Patient Access
to Semglee® after U.S. FDA Approval**

Bengaluru, India – June 1, 2020

Biocon Ltd. (BSE code: 532523, NSE: BIOCON) today announced that the U.S. Patent and Trademark Appeal Board (PTAB) has ruled in favour of Mylan, Biocon's* partner in inter partes review (IPR) proceedings finding all challenged claims of Sanofi's Lantus® SoloSTAR® device patents, U.S. Patent Nos. 8,603,044, 8,992,486, and 9,526,844 unpatentable. The PTAB found three claims of the 9,604,008 patent unpatentable, and two claims to be patentable. However, Mylan and Biocon have previously obtained a covenant not to sue from Sanofi on the '008 patent and therefore this ruling does not impact Biocon and Mylan's ability to commercialize Semglee® (Insulin Glargine) upon final approval from the U.S. Food and Drug Administration. The PTAB also found Sanofi's proposed amended claims for the '486 and '844 patents unpatentable.

Dr Christiane Hamacher, CEO & Managing Director, Biocon Biologics said, "We are extremely pleased with the U.S. PTAB's ruling in favour of our partner Mylan for four device patents of Sanofi's Lantus SoloSTAR. This strengthens our resolve to provide a high quality affordable Insulin Glargine to diabetic patients in the U.S. and generate savings for their healthcare system. Our partner's New Drug Application (NDA) for Semglee is under active review by the U.S. FDA and this favourable ruling further clears the path for the anticipated launch of our Glargine in the U.S. in mid-CY20.. *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.*"

Last month, the PTAB held the sole challenged claim of another Lantus SoloSTAR device patent as unpatentable for U.S. Patent No. 8,679,069, and in March, Mylan and Biocon announced that the U.S. District Court of New Jersey found the asserted claims of the '844 patent not infringed by Mylan's Insulin Glargine product and invalid for lack of written description. Sanofi's formulation patents (U.S. Patent Nos. 7,476,652 and

7,713,930) were previously affirmed to be invalid by the Federal Circuit by a non-appealable decision.

The positive IPR developments are greatly encouraging as we believe greater competition in the U.S. insulins market will help rationalize the cost of therapy and generate savings for the healthcare system. Once approved and commercialized our co-developed Semglee will expand access to insulin therapy.

Lantus is a long-acting insulin used to treat adults with type 2 diabetes and adults and pediatric patients with type 1 diabetes for the control of high blood sugar. Our partner, Mylan's 505(b)(2) New Drug Application (NDA) is under active review by the U.S. Food and Drug Administration.

Sanofi sells the product in vials (Lantus) and as a disposable injection pen (Lantus SoloSTAR®).

Sanofi's total IQVIA sales for the 12 months ending March 31, 2020, were approximately USD 1.71 billion for Lantus 100 Units/mL and about USD 4.32 billion for Lantus SoloSTAR.

Notes: *Biocon is a real party in interest pursuant to 37 C.F.R. §42.8 (b)(1) in these IPRs

About the Biocon Biologics 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 Biologics for the global marketplace. Mylan has exclusive commercialization rights for the product in the U.S., Canada, Australia, New Zealand and in the European Union and European Free Trade Association countries. Biocon Biologics 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 Follow-us on Twitter: @bioconlimited

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 developed markets like EU, U.S., Japan, Canada 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

FOR MORE INFORMATION	
MEDIA RELATIONS Seema Ahuja Sr. VP & Global Head, Corporate Communications ☎ +91 80 2808 2222 📠 +91 99723 17792 ✉ seema.ahuja@biocon.com	INVESTOR RELATIONS Saurabh Paliwal Head, Investor Relations ☎ +91 80 6775 2040 ✉ investor.relations@biocon.com

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.