



PRESS RELEASE

Biocon Biologics* Partner Viatris Wins U.S. Court Decisions on Sanofi Appeals for Lantus[®] Device Patents

Decisions reaffirm the ability of Biocon Biologics and Viatris to provide patient access to interchangeable Semglee[®]

Bengaluru, India, December 30, 2021 -

Biocon Biologics Ltd., a subsidiary of Biocon Ltd. (BSE code: 532523, NSE: BIOCON), today announced that the U.S. Court of Appeals for the Federal Circuit (USCAFC) has upheld the U.S. Patent and Trademark Appeal Board's decisions for unpatentability of five device patents for Sanofi's Lantus[®] SoloSTAR[®], as well as a district court decision on one of these patents. The Patent Trial and Appellate Board (PTAB) at the U.S. Patent and Trademark Office (USPTO) had in April and May 2020 found the challenged claims of U.S. Patent Nos. 8,679,069; 8,603,044; 8,992,486; 9,526,844; 9,604,008 unpatentable. Sanofi had appealed against all these PTAB decisions to USCAFC.

Of these five patents, the 9,526,844 ("the '844 Patent") was also held invalid and "not infringed" by the U.S. District Court for the District of New Jersey. The district court found non-infringement of the asserted claims for the '844 patent and held it invalid for lack of written description. Sanofi had appealed the district court decision for the '844 patent. Since the USCAFC affirmed PTAB's decision for the '844 patent, Sanofi's appeal against the district court's decision is held as moot and thus dismissed.

The Federal Circuit judgments reinforce the continuing efforts of Biocon Biologics and Viatris to break down barriers to patient access for important medicines such as Semglee[®]. Viatris and Biocon Biologics Ltd. launched their interchangeable Semglee[®] products (insulin glargine-yfgn) last month, which are the first, and currently the only, interchangeable biosimilars to Lantus[®], providing more affordable options for the millions of Americans living with diabetes.

The Semglee[®] products are available in vial and prefilled pen presentations and are interchangeable for the reference brand, Lantus[®], allowing for substitution at the pharmacy counter. Semglee[®] is indicated to help control high blood sugar in adult and pediatric patients with type 1 diabetes and adults with type 2 diabetes.

Shreehas Tambe, dCEO, Biocon Biologics, said: *"The decision of the U.S. federal court in favour of our partner Viatris, on all the five Sanofi Lantus® SoloSTAR® device patents is a vindication of our long-held position on intellectual property. These developments are very encouraging and will greatly help in breaking down barriers to patient access. With Semglee®, we will be able to offer people living with diabetes in the U.S. more*





treatment options, rationalize cost of therapy and generate savings for the overall healthcare system."

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

Sanofi's total sales in the U.S. as per IQVIA for the 12 months ending September 30, 2021, were ~USD 1.4 billion for Lantus[®] 100 Units/mL vial and ~USD 5.1 billion for Lantus[®] SoloSTAR[®] 100 Units/mL.

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

About the Viatris and Biocon Biologics Collaboration

Viatris and Biocon Biologics have an exclusive collaboration for the development, manufacturing and commercialization of a broad portfolio of biosimilars and insulin analogs. Viatris has exclusive commercialization rights in the U.S., Canada, Australia, New Zealand, the European Union and European Free Trade Association countries. Biocon Biologics has exclusive commercialization rights for Japan and certain emerging markets. Viatris and Biocon Biologics have co-exclusive commercialization rights in the rest of the world.

About Biocon Biologics Ltd.

Biocon Biologics Limited, a subsidiary of Biocon Limited, is a fully integrated global biosimilars organization. It is leveraging cutting-edge science, innovative tech platforms and advanced research & development capabilities to lower treatment costs while improving healthcare outcomes. It has a strong research pipeline of biosimilar molecules across diabetes, oncology, immunology, and other non- communicable diseases. Five molecules from Biocon Biologics' portfolio have been taken from lab to market, in developed markets like United States, EU, Australia, Canada, Japan and key emerging markets. It has many firsts to its credit including the most recent USFDA approval of world's first interchangeable biosimilar, received for its Insulin Glargine. With a team of ~ 4,800 people, Biocon Biologics is committed to transforming healthcare and transforming lives by enabling affordable access to millions of patients' worldwide. Website: www.biocon.com/businesses/biosimilars/ Follow us on Twitter: @BioconBiologics

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. Website: www.biocon.com; Follow-us on Twitter: @bioconlimited

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Forward-Looking Statement:

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.