

**PRESS RELEASE**

## **Biocon Biologics' Partner Receives Positive EU CHMP Opinion for Biosimilar Human Insulin for IV Infusion**

### **Celerity Pharmaceuticals Uses Biocon Biologics' Insulin Drug Substance to Develop the Product**

**Bengaluru, India: April 1, 2022:**

**Biocon Biologics Ltd.** (BBL), a subsidiary of Biocon Ltd. (BSE code: 532523, NSE: BIOCON), announced today the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion, recommending the granting of a marketing authorisation for **Inpremia\***, a biosimilar version of *Actrapid (human insulin)*. This is a ready-to-use insulin formulation for intravenous (IV) infusion developed by Celerity Pharmaceuticals LLC (Celerity), using Biocon Biologics' biosimilar human insulin drug substance.

**Inpremia** is formulated as an IV infusion in a flexible plastic container, using human insulin (rDNA origin) 1 U/mL (100 U/100 mL) in 0.9% sodium chloride. Biocon Biologics has developed the drug substance of Inpremia -- insulin human (rDNA), a fast-acting human insulin for injection.

**Inpremia** is a pre-mixed ready-to-use insulin for IV infusion for patients in hospital and other acute care settings. Inpremia would help lower blood glucose by facilitating uptake of glucose into muscle and fat cells and by simultaneously inhibiting glucose output from the liver. This presentation would offer convenience in administration and better patient experience. Once approved, **Inpremia** will be commercialized in the EU by a leading global medical products company.

Biocon Biologics has developed and supplied the US FDA approved biosimilar human insulin drug substance for **Inpremia** and also has supported Celerity by providing relevant data, regulatory and technical expertise throughout the development of the final drug product under a license and supply agreement signed between the two companies.

**Shreehas Tambe, Deputy CEO, Biocon Biologics** said: *"The CHMP's decision to recommend **Inpremia**, an innovative rh-insulin IV formulation developed by our*

*partner, for approval in the EU, is yet another milestone in our mission to broaden access. The positive opinion by CHMP underscores our scientific and technical capabilities in developing and manufacturing a high-quality insulin drug substance that can be formulated to offer multiple drug delivery options to people living with diabetes, globally. This decision further builds on our success with biosimilar Insulin Glargine which is already available in many markets across the EU.”*

**Dan Robins, Ph.D., president, Celerity, said:** *“Obtaining positive CHMP opinion for **Inpremia** is a significant achievement in our continued efforts to introduce medicines in new presentations that help promote clinician efficiency and advance patient care.”*

A biosimilar medicinal product, **Inpremia** is highly similar to the reference product *Actrapid* (human insulin), which was authorised in the EU on 7 October 2002. Data show that **Inpremia** has comparable quality, safety and efficacy to *Actrapid* (human insulin).

**The CHMP positive opinion will be considered by the European Commission. The European Commission decision on the approval is expected later this year.**

Biocon Biologics’ rh-insulin product has been commercialized in almost 40 countries across the world.

*\*Partner’s Brand*

### **About Biocon Biologics Ltd.**

Biocon Biologics Ltd., a subsidiary of Biocon Ltd., is a fully integrated global biosimilars organization. It is leveraging cutting-edge science, innovative tech platforms and advanced research & development capabilities to lower costs of biologics therapies 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 U.S., EU, Australia, Canada, Japan and key emerging markets. It has many firsts to its credit including the most recent U.S. FDA approval of the world’s first interchangeable biosimilar, awarded to its Insulin Glargine, which has been commercialized in the U.S. in 2021. Biocon Biologics has a strategic alliance with Serum Institute Life Sciences to address the inequitable access to life saving vaccines and biologics globally. With a team of ~5000 people, Biocon Biologics is committed to transforming healthcare and transforming lives by enabling affordable access to millions of patients’ worldwide.

**Website:** [www.bioconbiologics.com](http://www.bioconbiologics.com) **Follow us on Twitter:** @BioconBiologics for company updates

## 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](http://www.biocon.com); Follow-us on Twitter: @bioconlimited** for company updates

CONTACTS:	
MEDIA	INVESTORS
<b>Seema Ahuja</b> Sr VP & Global Head of Communications & Corporate Brand, <b>Biocon Biologics &amp; Biocon Group</b> +91 99723 17792 <a href="mailto:seema.ahuja@biocon.com">seema.ahuja@biocon.com</a>	<b>Nikunj Mall</b> Head, Investor Relations, <b>Biocon Biologics</b> +91 998 777 4078 <a href="mailto:nikunj.mall@biocon.com">nikunj.mall@biocon.com</a>

## 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.*