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ASIA EDITION

Biocon Malaysia unit receives EU GMP certification

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Biocon's Malaysia Insulin Glargine Manufacturing Facility Receives EU GMP Certification, Provides Fillip to its Capacity



Biocon Ltd , Asia's premier biopharmaceuticals company, Biocon Ltd has announced that it's subsidiary in Malaysia, Biocon Sdn. Bhd., which operates Asia's largest integrated Insulins facility, received the Certificate of GMP compliance from the European Medicines Agency from the representative European inspection authority, Health Products Regulatory Authority (Ireland). This approval expands Biocon's capacities multi-fold with the new large scale devices facility coming up to speed to serve the growing needs of people with diabetes in EU.

The Malaysia site was inspected in May 2019 and the certificate of GMP compliance received now reflects that the agency considers the manufacturing facilities for Drug Substances, Drug Products and Insulin Delivery Devices to be in compliance with the guidelines of Good Manufacturing Practices. Biocon remains committed to highest global standards of Quality and Compliance. Biocon's Malaysia facility is Asia's largest integrated insulins facility and manufactures Drug Substance and Drug Products in vials, cartridges and insulin delivery devices.

The recombinant human Insulin (rh-Insulin) and Insulin Glargine manufactured at this facility are addressing the needs of over 350,000 diabetic patients in Malaysia. Biocon and Mylan's Biosimilar Insulin Glargine Semglee® has previously received Regulatory approval from EMA in March 2018 and has been launched in key European markets by its partner Mylan since Nov 2018.

Biocon has emerged as a leading insulins player globally. The Company has the science, scale, scope, technology and over 15 years of experience in addressing the needs of patients with diabetes, having provided over 2 billion doses of insulins cumulatively, worldwide.

Our range of insulins made at the state-of-the-art Malaysia facility are serving patient populations in EU and several other countries across the globe. Biocon's rh-Insulin is registered in over 40 countries worldwide and has been commercialized in many emerging markets.

The Company’s biosimilar Insulin Glargine has been approved in over 60 countries and is commercialized in several key emerging markets. 2 Biocon through its biosimilars portfolio is committed to serve the needs of patients, people & partners by providing innovative affordable healthcare solutions going beyond the product. Biocon’s Biologics Business started FY20 on a very strong note with a robust revenue growth of 96% at Rs 490 Cr in Q1FY20. This Business aims to impact 2.6 million patient lives in FY20 and aspires to position the company as a global leader.