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ASIA EDITION

'Biocon Biologics to work with RSSDI to train ~400 HCPs in India'

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The year 2021 marks the 100th year of Insulins discovery and As India's largest biopharma company and third largest global insulins player, Biocon Biologics has been keeping up with its commitment to enable and expand affordable access to insulins through its world-class biosimilar Insulins portfolio to people with diabetes, Biocon Biologics has made India proud by being the first company from India to obtain USFDA approval for the world's first 'interchangeable biosimilar' for its insulin Glargine which has been launched in the US recently. Dr Sandeep Athalye, CMO, Biocon Biologics, Bengaluru, talks about this momentous breakthrough and the way ahead for Biocon Biologics in the insulin market.

What additional scientific data did you have to submit to the US FDA for obtaining interchangeable biosimilar approval for your biosimilar Insulin Glargine?

The US FDA has set a high scientific bar for granting interchangeability status, with biosimilar developers required to establish a very high level of similarity for physicochemical attributes at molecule level as well as highly similar functional assay results compared to the reference product. An additional switching study may also be required that evaluates patient safety and immunogenicity when they switch between reference to biosimilar and back to reference product. Biocon Biologics-Viatris conducted the INSTRIDE-3 study to assess the efficacy, changes in insulin dose, safety and immunogenicity when patients with Type 1 diabetes were switched between Lantus and its biosimilar Insulin Glargine multiple times. The results of the study showed equivalent efficacy, safety and immunogenicity, demonstrating that patients taking the reference Insulin Glargine (Lantus) can safely switch to Biocon Biologics' biosimilar Insulin Glargine.

The results of the switching study and the subsequent FDA interchangeable approval have boosted the confidence of health care providers and patients in the safety and effectiveness of our product. In addition, it provides greater convenience for retail pharmacists. Already, our interchangeable product has been included in the National Formularies of two leading Pharmacy Benefit Managers (PBMs) in the U.S., Express Scripts and Prime Therapeutics, which together have a reach of

over 60 million members.

The launch of our interchangeable biosimilar Insulin Glargine in the U.S. by our partner Viatris is a landmark event and along with the recent formulary listings, we believe it will allow us to improve accessibility, availability and adoption of biosimilars in the US for the benefit of patients and the overall healthcare system

What makes your biosimilar Insulin Glargine unique?

As an innovation-led company, Biocon Biologics uses its proprietary yeast platform based on Pichia pastoris to manufacture a wide portfolio of biosimilar insulins, including recombinant human Insulin (rh-Insulin), Insulin Glargine and Insulin Aspart. The development in Pichia is unique as it offers rapid cell growth and high expression levels of the protein. The protein folding is neat and is naturally secreted from the cell unlike in E-coli derived insulin. Our purification processes and large scale manufacturing offers scalability, quality and affordability. This unique technology will allow us to reach diabetes patients worldwide and be a leader in providing affordable access to patients.

Glargine was launched as Basalog in India in 2009.

Our global development programme enabled us to get our biosimilar Insulin Glargine approved and launched in Japan in 2016. We received regulatory approval for biosimilar Insulin Glargine (Semglee) in the US through our partner Viatris, which commercialised the product there in August 2020. It is the third biosimilar approved by the FDA through the Viatris-Biocon Biologics collaboration. Our biosimilar Insulin Glargine was commercialised in several countries in Europe in 2018 after EMA approval.

How is Biocon Biologics expanding access to Insulin Glargine, Basalog, for people with diabetes in India?

The launch of Insulin Glargine, Basalog, in 2009 provided people with diabetes in India with an advanced, affordable insulin analogue. Since then, we have been offering different presentations of the therapy, including vials, refills, reusable insulin pens and disposable insulin pens, to provide a comprehensive diabetes-management solution and ensure ease of use for people with diabetes in India.

Biocon Biologics has now partnered with RSSDI to launch a Comprehensive Care Programme, BRIDGE-1, for young Type 1 diabetes patients. India has over 1 million children with Type 1 diabetes, as per IDF Diabetes Atlas 2019. To address the needs of Type 1 diabetes management in children in a holistic manner, Biocon Biologics will work together with the Research Society for the Study of Diabetes in India (RSSDI) to identify and train ~400 healthcare professionals (HCPs) in different districts across the country. We will also enable these HCPs with a free supply of our insulins to treat over 1,000 children from marginalised communities. Additionally, we will work with RSSDI to develop specific training material for these identified physicians, who will further engage with their peers and the community at large in their respective districts to enable better Type 1 diabetes management. Biocon Biologics will provide on-ground facilitation to support these training programmes.

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