

Biocon, Mylan launch Semglee in US to expand access for diabetic patients

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Semglee is available in vial and pen presentations at a 65% discounted list price



Biocon Biologics India Ltd., a fully integrated biosimilars company and a subsidiary of Biocon Ltd. (BIOCON), and Mylan N V (MYL), recently announced the U.S. launch of Semglee™ (insulin glargine injection) in a vial and pre-filled pen presentations, approved to help control high blood sugar in adult and pediatric patients with type 1 diabetes and adults with type 2 diabetes.

It is not recommended for the treatment of diabetic ketoacidosis. Semglee, which received final approval from the U.S. Food and Drug Administration (FDA), has an identical amino acid sequence to Sanofi's Lantus® and is approved for the same indications.

To encourage broad patient access to this important medicine, Mylan is offering Semglee at a wholesale acquisition cost (WAC) of \$147.98 per package of five (5) 3ml pens and \$98.65 per 10ml vial, representing the lowest WAC for any long-acting insulin glargine on the market. The list price of Semglee pen is equivalent to the Lantus launch price in 2007, and the Semglee vial is listed at Lantus's 2010 pricing.

Eligible patients may also qualify for patient assistance and/or a co-pay card, similar to other medications in this class. Additionally, Mylan has submitted to FDA all necessary documentation to request approval of Semglee as a biosimilar to Lantus under the 351(k) pathway and remains confident in seeking an interchangeability designation.