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FDA Approved First Interchangeable Biosimilar - Semglee®

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Hello, and welcome back. I wanted to share some exciting news regarding the FDA approval of the first biosimilar in the United States that has been granted interchangeability status: Semglee®.

Before getting into the specifics on Semglee®, let's take a few minutes to review how biologic medications differ from traditional small molecule drugs. Traditional small molecule drugs exhibit a well-defined structure that can be thoroughly characterized and understood and therefore are relatively easy to chemically synthesize. On the other hand, biologic products are generally derived from living sources such as humans, animals, or microorganisms. These medications have complex structures and therefore may not be able to be fully characterized. Due to this, traditional small molecule drugs are approved under the FDA's NDA (New Drug Application) process and biologics are reviewed and approved under BLAs (Biologic License Applications).

In previous issues of Ron's Clinical Corner, we have spoken about biosimilars, which would be approved under the BLA process. By definition, a biosimilar product is one that is "highly similar to and has no clinically meaningful differences from an existing FDA-approved reference product".¹ In order for a biosimilar to qualify for substitution without prescriber involvement, a product must also be labeled as "interchangeable". To receive this designation, a biosimilar must undergo additional testing and meet further requirements. Until now, there have been no biosimilar medications that have received the interchangeable designation.

Semglee® (insulin glargine, Mylan) is a long-acting insulin product that competes with Lantus® (insulin glargine, Sanofi). Along with submitting the application for

approval, Mylan also filed an application with the FDA seeking interchangeability compared to Lantus®. On July 28, 2021, the FDA approved Semglee® as the first interchangeable biosimilar to Lantus®. This means the product can be substituted by pharmacies when a prescriber writes a prescription for Lantus®. One key thing to remember is that although Semglee® is available on the prescription drug market today, the current formulations (NDCs) are NOT interchangeable with Lantus®.

MYLAN IS IN THE PROCESS OF PREPARING TO LAUNCH NEW NDCS FOR SEMGLEE® IN THE NEXT FEW MONTHS. ONCE THESE NEW NDCS ARE LAUNCHED, WE EXPECT TO HAVE A CLEAR PICTURE OF WHAT THE OVERALL NET COSTS WILL BE FOR THE COMPETING INSULIN GLARGINE PRODUCTS.

In addition, being the first interchangeable product, Semglee® will have 12 months of exclusivity as being the only interchangeable biosimilar to Lantus®.

Speaking of insulin and interchangeable biosimilars, there are currently two products undergoing FDA interchangeability studies compared to Novolog® (insulin aspart), a short-acting insulin. The biosimilar made by Viatris (Mylan) has completed the interchangeability studies and could be approved at any time. Sanofi's biosimilar product, on the other hand, could be available at some point in 2022. Once approved the manufacturers will likely announce their plans for launch along with potential pricing.

Thanks for stopping by and see you next month at the Corner.