

Rezvoglar™ (insulin glargine-aglr) – New biosimilar approval

- On December 20, 2021, the <u>FDA announced</u> the approval of Eli Lilly's <u>Rezvoglar (insulin glargine-aglr)</u>, a biosimilar to Sanofi's <u>Lantus</u> (insulin glargine).
 - This is the second biosimilar approval for Lantus. Viatris/Biocon Biologics' <u>Semglee[®] (insulin glargine-yfgn)</u> was approved on July 28, 2021 as the first *interchangeable* biosimilar to Lantus. Semglee launched on November 16, 2021.
- Rezvoglar, Semglee and Lantus share the same indication: to improve glycemic control in adults and pediatric patients with type 1 diabetes mellitus and in adults with type 2 diabetes mellitus.
 - Rezvoglar, Semglee and Lantus are not recommended for treating diabetic ketoacidosis.
- The approval of Rezvoglar as biosimilar to Lantus is based on evidence that showed the products
 are highly similar and that there are no clinically meaningful differences between Rezvoglar and
 Lantus in terms of safety, purity and potency.
 - Rezvoglar has not been granted interchangeable status; therefore, a patient would need a
 prescription from a health care prescriber written specifically for Rezvoglar.
- Eli Lilly's launch plans for Rezvoglar are pending. Rezvoglar will be available as 100 mg/mL solution in a 3 mL single-patient-use KwikPen® prefilled pen.



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