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Novo Nordisk' Victoza gets FDA nod to treat type 2 diabetes

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The update is based on results from the global ELLIPSE trial, the first phase 3 trial completed in over a decade in children and adolescents with type 2 diabetes

Novo Nordisk has announced that the U.S. Food and Drug Administration (FDA) has approved an expanded indication for Victoza® (liraglutide) injection to lower blood sugar along with diet and exercise in children and adolescents aged 10-17 years with type 2 diabetes. As the first glucagon-like peptide-1 (GLP-1) receptor agonist approved for children and adolescents with type 2 diabetes, Victoza® provides this population with a new treatment option beyond metformin and insulin for the first time in 19 years. Victoza® was first approved in the U.S. in 2010 as an adjunct to diet and exercise to improve glycemic control in adults with type 2 diabetes.

The update is based on results from the global ELLIPSE trial, the first phase 3 trial completed in over a decade in children and adolescents with type 2 diabetes. In this study, patients aged 10 to 17 were randomized to receive liraglutide up to 1.8 mg/day or placebo, in combination with metformin with or without basal insulin over a 26-week double-blinded period followed by a 26-week open-label extension period.

"We are delighted with the label expansion for Victoza®, which now includes an indication for use in children and adolescents with type 2 diabetes in the U.S. - this is a landmark approval as the first-ever GLP-1 receptor agonist approved for this population," commented Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "The prevalence of type 2 diabetes in the U.S. is ever increasing and we are seeing a higher number of diagnoses in children and adolescents, for whom there are limited treatment choices. Victoza® will provide a new option for clinicians treating this challenging disease, helping to address the growing need for this population."