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press release

FDA approves Saxenda® for the treatment of obesity in adolescents aged 12-17

Saxenda® (liraglutide) injection 3 mg becomes the first FDA-approved therapy to treat obesity in adolescents in more than a decade

Plainsboro, New Jersey, US, December 4, 2020 – Novo Nordisk today announced that the U.S. Food and Drug Administration (FDA) approved an updated label for Saxenda® (liraglutide) injection 3 mg for use in the treatment of obesity in adolescents (12–17 years) with a body weight above 60 kg and an initial body mass index (BMI) corresponding to 30 kg/m^2 or greater for adults, as an adjunct to reduced-calorie meals and increased physical activity. Saxenda® was approved in 2014 for chronic weight management in adults with a BMI ≥30 kg/m^2, or ≥27 kg/m^2 with at least one weight-related comorbidity, as an adjunct to a reduced calorie meal plan and increased physical activity.[1]

Over the last 20 years, the global prevalence of children and adolescents with excess weight has doubled from 1 in 10 to 1 in 5.[2] Research also shows that when both parents have excess weight, 80% of their children will have obesity.[3] However, current treatment options for this population are limited, highlighting a considerable and growing need for additional treatment strategies.[4]

"New options to treat adolescents who live with obesity can bring much-needed hope to families and help address this growing epidemic," said Dr. Aaron Kelly, Professor of Pediatrics and co-director of the Center for Pediatric Obesity Medicine at the University of Minnesota. "With up to 90 percent of adolescents with obesity likely to have it as adults and thus at increased risk for developing weight-related complications, it's important to address weight care and offer support early on.[3,5] I'm encouraged that healthcare providers now have another

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tool in developing a personalized, complete care plan to help adolescents lose weight and keep it off."

The safety and efficacy of Saxenda® as a treatment for adolescents with obesity is supported by data from a phase 3a trial published earlier this year in the *New England Journal of Medicine*. The 56-week clinical trial investigated the effects of Saxenda® compared to placebo for weight management in 251 patients aged 12-17 living with obesity as an adjunct to lifestyle therapy, defined as counselling in healthy nutrition and physical activity for weight loss. In the trial, the primary endpoint was change from baseline in Body Mass Index (BMI) Standard Deviation Score (SDS) at week 56.[6]

The data demonstrated a significant reduction in BMI-SDS, as well as reductions in BMI, mean body weight, and other weight-related endpoints vs. placebo in adolescents with obesity when using Saxenda® as an adjunct to lifestyle therapy. Adverse events seen in an adolescent population were similar to those observed in adults. The most common adverse reactions were gastrointestinal events, including nausea, vomiting and diarrhea.[6]

"The rise in adolescent obesity is contributing to a public health crisis, and it poses a real challenge for healthcare professionals due to the limited treatment options available," said Mads Krogsgaard Thomsen, executive vice president and chief scientific officer of Novo Nordisk. "We are proud to be able to offer a new treatment option for adolescents with obesity and their families in the US, as the FDA approval marks another significant milestone for Saxenda®."

What is Saxenda®?

Saxenda® (liraglutide) injection 3 mg is an injectable prescription medicine used for adults with excess weight (BMI ≥27) who also have weight-related medical problems or obesity (BMI ≥30), and children aged 12-17 years with a body weight above 132 pounds (60 kg) and obesity to help them lose weight and keep the weight off. Saxenda® should be used with a reduced calorie diet and increased physical activity.

- Saxenda® and Victoza® have the same active ingredient, liraglutide, and should not be used together or with other GLP-1 receptor agonist medicines.
- It is not known if Saxenda® is safe and effective when taken with other prescription, over-the-counter medicines, or herbal weight-loss products.

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- It is not known if Saxenda® is safe and effective in children under 12 years of age.
- It is not known if Saxenda® is safe and effective in children aged 12 to 17 years with type 2 diabetes.

Important Safety Information

Do not share your Saxenda pen with others even if the needle has been changed. You may give other people a serious infection or get a serious infection from them.

What is the most important information I should know about Saxenda®?
Serious side effects may happen in people who take Saxenda®, including:

Possible thyroid tumors, including cancer. Tell your health care professional if you get a lump or swelling in your neck, hoarseness, trouble swallowing, or shortness of breath. These may be symptoms of thyroid cancer. In studies with rats and mice, Saxenda® and medicines that work like Saxenda® caused thyroid tumors, including thyroid cancer. It is not known if Saxenda® will cause thyroid tumors or a type of thyroid cancer called medullary thyroid carcinoma (MTC) in people.

Do not use Saxenda® if you or any of your family have ever had MTC, or if you have an endocrine system condition called Multiple Endocrine Neoplasia syndrome type 2 (MEN 2).

Who should not use Saxenda®?
Do not use Saxenda® if:
- you or any of your family have ever had MTC or if you have MEN 2.
- you are allergic to liraglutide or any of the ingredients in Saxenda®.
- you are pregnant or plan to become pregnant. Saxenda may harm your unborn baby.

Before taking Saxenda®, tell your health care provider about all of your medical conditions, including if you:
- are taking certain medicines called GLP-1 receptor agonists.
- have severe problems with your stomach, such as slowed emptying of your stomach (gastroparesis) or problems with digesting food.
- have or have had problems with your pancreas, kidneys or liver.
- have or have had depression or suicidal thoughts, or mental health issues.
- are breastfeeding or plan to breastfeed. It is not known if Saxenda® passes into your breast milk. You and your health care provider should decide if you will use Saxenda® or breastfeed.

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Tell your health care provider about all the medicines you take, including prescription, over-the-counter medicines, vitamins, and herbal supplements. Saxenda® slows stomach emptying and can affect medicines that need to pass through the stomach quickly. Saxenda® may affect the way some medicines work and some other medicines may affect the way Saxenda® works. Tell your health care provider if you take diabetes medicines, especially insulin and sulfonylurea medicines.

How should I use Saxenda®?

- Inject your dose of Saxenda® under the skin (subcutaneously) in your stomach area (abdomen), upper leg (thigh), or upper arm, as instructed by your health care provider. **Do not inject into a vein or muscle.**

What are the possible side effects of Saxenda®?

Saxenda® may cause serious side effects, including:

- **inflammation of the pancreas (pancreatitis).** Stop using Saxenda® and call your healthcare provider right away if you have severe pain in your stomach area (abdomen) that will not go away, with or without vomiting. You may feel the pain from your stomach area (abdomen) to your back.
- **gallbladder problems.** Saxenda® may cause gallbladder problems, including gallstones. Some gallbladder problems need surgery. Call your health care provider if you have any of the following symptoms: pain in your upper stomach (abdomen), fever, yellowing of your skin or eyes (jaundice), or clay-colored stools.
- **increased risk of low blood sugar (hypoglycemia) in adults with type 2 diabetes who also take medicines to treat type 2 diabetes such as sulfonylureas or insulin.**
- **risk of low blood sugar (hypoglycemia) in children who are 12 years of age and older without type 2 diabetes.**
- Signs and symptoms of low blood sugar may include: shakiness, sweating, headache, drowsiness, weakness, dizziness, confusion, irritability, hunger, fast heartbeat, and feeling jittery. You should check your blood sugar before you start taking Saxenda® and while you take Saxenda®.
- **increased heart rate.** Saxenda® can increase your heart rate while you are at rest. Your health care provider should check your heart rate while you take Saxenda®. Tell your health care professional if you feel your heart racing or pounding in your chest and it lasts for several minutes.
- **kidney problems (kidney failure).** Saxenda® may cause nausea, vomiting, or diarrhea leading to loss of fluids (dehydration). Dehydration may cause kidney failure, which can lead to the need for dialysis. This can happen in people who have never had kidney problems before. Drinking plenty of fluids may reduce your chance of dehydration. Call your health care provider right away if you have nausea, vomiting, or diarrhea that does not go away, or if you cannot drink liquids by mouth.

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- **serious allergic reactions.** Stop using Saxenda® and get medical help right away if you have any symptoms of a serious allergic reaction including swelling of your face, lips, tongue, or throat, fainting or feeling dizzy, very rapid heartbeat, problems breathing or swallowing, or severe rash or itching.
- **depression or thoughts of suicide.** You should pay attention to any mental changes, especially sudden changes, in your mood, behaviors, thoughts, or feelings. Call your health care provider right away if you have any mental changes that are new, worse, or worry you.

The most common side effects of Saxenda® in adults include nausea, diarrhea, constipation, vomiting, injection site reaction, low blood sugar (hypoglycemia), headache, tiredness (fatigue), dizziness, stomach pain, and change in enzyme (lipase) levels in your blood. Additional common side effects in children are fever and gastroenteritis.

Please see Prescribing Information and Medication Guide for Saxenda® at www.novo-pi.com/saxenda.pdf.

About the phase 3 trial (NCT02918279)

The trial investigated the effect of Saxenda® (liraglutide 3.0 mg or maximum tolerated dose) compared to placebo for weight management in 251 adolescents (aged 12 to <18 years) living with obesity as an adjunct to lifestyle therapy.[6] The trial included a 12-week run-in period of lifestyle therapy, a 56-week treatment period (including dose escalation over 4 to 8 weeks) on Saxenda® or placebo and a 26-week follow-up period without Saxenda® or placebo.[6] All participants received lifestyle therapy beginning with the run-in period and during the 56-week treatment period and 26-week follow-up period.[6] The phase 3a trial was a post-marketing requirement of the FDA under the Pediatric Research Equity Act (PREA), which aims to ensure treatments are safe and effective for children and adolescents.[7,8]

About Saxenda®

Saxenda® (liraglutide) injection 3.0 mg is a once-daily glucagon-like peptide-1 (GLP-1) receptor agonist with 97% similarity to naturally occurring human GLP-1, a hormone that is involved in appetite regulation and food intake.[1] Like human GLP-1, Saxenda® is believed to work in areas of the brain involved in appetite regulation, including the hypothalamus.[1] Saxenda® for use in adults with obesity was evaluated in the SCALE (Satiety and Clinical Adiposity – Liraglutide Evidence) clinical trial program. Since launch in 2015, more than 1.5 million patients have been treated with Saxenda® globally.[7]

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Saxenda® is already indicated in the US for chronic weight management in adults with a BMI ≥30 kg/m^2, or ≥27 kg/m^2 with one or more weight-related comorbidities, as an adjunct to a reduced-calorie meal plan and increased physical activity.[1]

About obesity

Obesity is a chronic, progressive and misunderstood disease that requires long-term medical management.[9,10] One key misunderstanding is that this is a disease of willpower, when in fact there is underlying biology that prevents people from achieving long-term weight loss.[11] Obesity is influenced by a variety of factors, including genetics, appetite signals, behavior and the environment.[11] It is a gateway disease and is associated with at least 60 other health conditions.[12] The current COVID-19 pandemic has highlighted that obesity also increases the risk for severe illness and hospitalization due to COVID-19.[13,14] In the United States, more than 42% of adults live with obesity.[15]

About adolescent obesity

Adolescents with obesity are also more likely to develop weight-related diseases, like diabetes and cardiovascular diseases, at a younger age.[16] Just like other chronic diseases, obesity requires long-term management.[9,10] Research shows that when both parents have excess weight, about 80% of their children will have obesity.[3] Globally, more than 124 million children and adolescents have obesity.[17] In the United States, nearly 1 in 5, or about 13.7 million, children and adolescents have obesity.[18,19]

About Novo Nordisk

Novo Nordisk is a global healthcare company that's been making innovative medicines to help people with diabetes lead longer, healthier lives for 95 years. This heritage has given us experience and capabilities that also enable us to help people defeat other serious diseases including obesity, hemophilia and growth disorders. We remain steadfast in our conviction that the formula for lasting success is to stay focused, think long-term and do business in a financially, socially and environmentally responsible way. With U.S. headquarters in New Jersey and production and research facilities in six states, Novo Nordisk employs nearly 6,000 people throughout the country. For more information, visit novonordisk.us, Facebook, Instagram and Twitter.

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