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

Bagsværd, Denmark, December 5, 2020 – Novo Nordisk 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 a reduced-calorie diet and increased physical activity. Saxenda® was approved by the FDA 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 diet 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, about 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% 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 tool in developing a personalised, 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

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CVR no:
24 25 67 90

Veeva ID: HQ20SX00093
Approval date: 5 December 2020

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 diarrhoea.[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®."

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–<18 years) living with obesity as an adjunct to lifestyle therapy. 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. 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 programme. Since launch in 2015, more than 1.5 million adult patients have been treated with Saxenda® globally.[7]

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 at least one weight-related comorbidity, as an adjunct to a reduced-calorie diet and increased physical activity.[1]

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About obesity
Obesity is a chronic and progressive disease that requires long-term medical management.[9, 10] One common 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, behaviour 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 hospitalisation 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]

About Novo Nordisk

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders. We do so by pioneering scientific breakthroughs, expanding access to our medicines and working to prevent and ultimately cure disease. Novo Nordisk employs about 44,000 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube.

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