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press release

Saxenda® demonstrated improvements in BMI and body weight in adolescents with obesity

Bagsværd, Denmark, 31 March 2020 – Novo Nordisk today announced that a peer-reviewed journal published the results of a phase 3 trial evaluating the investigational use of Saxenda® (liraglutide 3.0 mg) in adolescents (aged 12–<18) with obesity. The study was accepted for presentation at ENDO 2020, the Endocrine Society's annual meeting in San Francisco, US, and will be published in a supplemental issue of the *Journal of the Endocrine Society*.[1] Saxenda® is currently indicated 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 diet and increased physical activity.[2,3]

The trial was designed to evaluate the efficacy and safety of Saxenda® in this population and achieved its primary endpoint demonstrating that Saxenda®, compared with placebo, was superior in reducing Body Mass Index (BMI) standard deviation score (SDS) at 56 weeks with a -0.22 estimated treatment difference (ETD).[1] BMI-SDS is a measure of relative weight status adjusted for age and gender in children and adolescents.[1,4] The study was a post-marketing requirement of the FDA[5] and the EMA in agreement with Paediatric Investigation Plan (PIP),[6,7] both of which aim to ensure treatments are safe and effective for children and adolescents.

Over the last 20 years, the global prevalence of overweight and obesity in children and adolescents has doubled from 1 in 10 to 1 in 5.[8] However, current treatment options for this population are limited, highlighting a considerable and growing need for additional strategies.[9]

"Most adolescents with obesity are likely to have obesity as adults and are at increased risk for developing other weight-related diseases, which is why it's so important to address weight care and support early on," said Dr Aaron Kelly, Professor of Pediatrics and Co-Director of the Center for Pediatric Obesity Medicine at the University of Minnesota. "Today, treatment options beyond behavioural counselling are limited for adolescents with obesity. Anti-obesity medications could provide a key option as part of a personalised, complete care plan to help them lose weight and keep it off."

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In the trial, following 56 weeks of treatment, there was a difference in change in BMI (kg/m^2) with adolescents in the Saxenda® arm achieving a 4.29% reduction in BMI, compared to a 0.35% increase with placebo. In addition, 43.3% of adolescents treated with Saxenda® had a 5%, or more, reduction in BMI at week 56 (compared to 18.7% on placebo) and 26.1% had a 10%, or more, reduction (compared to 8.1% with placebo).[1]

"We are encouraged by these results and the progress made to provide a treatment option for healthcare professionals caring for adolescents living with obesity," said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk. "It's vital that families affected by obesity have the tools and resources needed to address this health issue. These data add to the extensive evidence for the clinical use and value of Saxenda® and support Novo Nordisk's commitment to improving the lives of people with obesity."

There were no new safety signals identified, and no severe hypoglycaemias were reported, and adverse events were similar to those observed in adults. During the 56-week treatment period, 64.8% of adolescents on Saxenda® reported gastrointestinal adverse events, compared to 36.5% of those receiving placebo. Three adolescents on Saxenda® reported serious adverse events, versus five in the placebo group. A greater number of adolescents discontinued treatment due to adverse events with Saxenda® (10.4%) compared to placebo (0%), primarily related to gastrointestinal side effects.[1]

About the phase 3 trial (NCT02918279)
The trial was a phase 3a randomised, double-blind, placebo-controlled clinical trial investigating the effect of Saxenda® (liraglutide) injection 3.0 mg compared to placebo for weight management in 251 adolescents living with obesity as an adjunct to lifestyle therapy, defined as counselling in healthy nutrition and physical activity for weight loss. The trial included a 12-week run-in of lifestyle therapy, a 56-week treatment period (including dose escalation of 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.[1]

In the trial, the primary endpoint was change from baseline in BMI-SDS at week 56. BMI is a calculation of weight (kg) divided by the square of height in metres. BMI-SDS is a measure of relative BMI status that accounts for age and gender.[1,4]

About Saxenda®
Saxenda® (liraglutide 3.0 mg) is a once-daily glucagon-like peptide-1 (GLP-1) analogue with 97% similarity to naturally occurring human GLP-1,[3,10] a hormone that is released in response to food intake.[11] Like human GLP-1, Saxenda® regulates appetite by increasing feelings of fullness and satiety, while lowering feelings of hunger, thereby leading to reduced food intake.[3,10,12] As with other GLP-1 analogues, Saxenda® stimulates insulin secretion and lowers glucagon secretion in a glucose-dependent manner.[12] 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 patients have been treated with Saxenda® globally.[5]

Saxenda® is currently indicated 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 diet and increased physical activity.[2,3]

About adolescent obesity

Obesity is a chronic disease that is influenced by multiple aspects, including physiological, psychological, genetic, environmental and socioeconomic factors.[13] 80% of adolescents who live with obesity are likely to have obesity as an adult.[14] Adolescents with obesity are also more likely to develop weight-related diseases, like diabetes and cardiovascular diseases, at a younger age.[15] Just like other chronic diseases, obesity requires long-term management.[16-19] The global increase in the prevalence of obesity is a public health issue that has severe cost implications to healthcare systems.[20,21] Globally over 100 million children and adolescents have obesity.[22]

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 42,700 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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References

1. Kelly A, Auerbach P, Barrientos-Perez M. Liraglutide for weight management in pubertal adolescents with obesity: a randomized controlled trial. Journal of the Endocrine Society. Volume 4, Issue supplement 1. April–May 2020.
2. FDA. Saxenda® (liraglutide 3 mg) US Prescribing Information. Available at: http://www.novo-pi.com/saxenda.pdf. Last accessed: March 2020.
3. EMA. Saxenda® (liraglutide 3 mg) summary of product characteristics. Available at: https://www.ema.europa.eu/en/documents/product-information/saxenda-epar-product-information_en.pdf Last accessed: March 2020.
4. US Preventive Task Force, Grossman D, Bibbins-Domingo K*, et al.* Screening for Obesity in Children and Adolescent: US Preventive Services Task Force Recommendation Statement. *JAMA*. 2017; 317:2417–2426.
5. Novo Nordisk. Data on file.
6. EMA. Paediatric investigation plans. Available at: https://www.ema.europa.eu/en/human-regulatory/research-development/paediatric-medicines/paediatric-investigation-plans Last accessed: March 2020.
7. EMA. On the acceptance of a modification of an agreed paediatric investigation plan for liraglutide (Saxenda). Available at: https://www.ema.europa.eu/en/documents/pip-decision/p/0154/2016-ema-decision-15-june-2016-acceptance-modification-agreed-paediatric-investigation-plan_en.pdf. Last accessed: March 2020.
8. UNICEF. The state of the world's children 2019. Available at: https://www.unicef.org/media/60806/file/SOWC-2019.pdf. Last accessed: March 2020.
9. Cardel M, Jastreboff A and Kelly A. Treatment of Adolescent Obesity in 2020. *Journal of the American Medical Association*. 2019; 322:1707–1708.
10. Novo Nordisk Canada. Saxenda® (liraglutide 3 mg) Canada Product Monograph. 12 July 2017. Available at: http://www.novonordisk.ca/content/dam/Canada/AFFILIATE/www-novonordisk-ca/OurProducts/PDF/Saxenda_PM_English.pdf. Last accessed: March 2020.
11. Orskov C, Wettergren A and Holst JJ. Secretion of the incretin hormones glucagon-like peptide-1 and gastric inhibitory polypeptide correlates with insulin secretion in normal man throughout the day. *Scandinavian Journal of Gastroenterology*. 1996; 31:665–670.
12. van Can J, Sloth B, Jensen CB*, et al.* Effects of the once-daily GLP-1 analog liraglutide on gastric emptying, glycemic parameters, appetite and energy metabolism in obese, non-diabetic adults. *International journal of Obesity*. 2014; 38:784–793.
13. National Institutes of Health. Clinical Guidelines On The Identification, Evaluation, And Treatment Of Overweight And Obesity In Adults. Available at: http://www.nhlbi.nih.gov/guidelines/obesity/ob_gdlns.pdf. Last accessed: March 2020.
14. Lifshitz F. Obesity in Children. *J Clin Res Pediatr Endocrinol*. 2008; 1:53–60.
15. WHO. Childhood overweight and obesity. Available at: https://www.who.int/dietphysicalactivity/childhood/en/. Last accessed: March 2020.
16. EASO. 2015. 2015 Milan Declaration: A Call to Action on Obesity. Available at: https://easo.org/2015-milan-declaration-a-call-to-action-on-obesity/. Last accessed: March 2020.

17. American Medical Association. A.M.A Adopts New Policies on Second Day of Voting at Annual Meeting. Obesity as a Disease. Available at: http://news.cision.com/american-medical-association/r/ama-adopts-new-policies-on-second-day-of-voting-at-annual-meeting,c9430649. Last accessed: March 2020.
18. Bray GA, Kim KK, Wilding JPH*, et al.* Obesity: a chronic relapsing progressive disease process. A position statement of the World Obesity Federation. *Obes Rev*. 2017; 18:715–723.
19. The Obesity Society. The Obesity Society Updates Position on Obesity. New Statement Focuses on Obesity as a Chronic Disease. Available at: https://www.prnewswire.com/news-releases/the-obesity-society-updates-position-on-obesity-300769218.html Last accessed: March 2020.
20. World Health Organization. Obesity and Overweight Factsheet no. 311. Available at: http://www.who.int/mediacentre/factsheets/fs311/en/. Last accessed: March 2020.
21. Cawley J, Meyerhoefer C, Biener A*, et al.* Savings in Medical Expenditures Associated with Reductions in Body Mass Index Among US Adults with Obesity, by Diabetes Status. *Pharmacoeconomics*. 2015; 33:707–722.
22. The GBD 2015 Obesity Collaborators. Health Effects of Overweight and Obesity in 195 Countries over 25 Years. *New England Journal of Medicine*. 2017; 377:13–27.