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# Saxenda® demonstrated similar efficacy and safety profile across obesity severity stages

**VANCOUVER, May 3, 2016 /CNW/** - Today, pooled results from the SCALE™ Obesity and Prediabetes, and SCALE™ Diabetes trials were presented at the 13th International Congress on Obesity (ICO). This post-hoc analysis demonstrated that at 56 weeks, people with obesity or who were overweight with comorbidities and treated with Saxenda®, as an adjunct to a reduced-calorie diet and increased physical activity, had a generally consistent effect on weight loss and certain weight related risk factors across baseline Edmonton Obesity Staging System (EOSS) scores.[1] The EOSS is a disease staging system, which ranks severity of obesity based on clinical assessment of weight-related health problems, mental health and physical function.[2]

At 56 weeks, greater weight loss was seen in people with obesity or who were overweight, with or without type 2 diabetes, treated with Saxenda® compared to placebo consistently across all baseline EOSS scores.[1] Additionally, improvements in cardiometabolic risk factors (including bA1c, systolic blood pressure (SBP) and lipid parameters) and physical function were greater in those treated with Saxenda® compared to placebo, again, consistently across all baseline EOSS scores.[1]

or this analysis, individuals were assigned a baseline EOSS score ranging from 0-4, based on the available data on obesity-related comorbidities. An EOSS score of 0 indicated no obesity-related comorbidities or risk factors, whereas a score of 4 indicated severe disability due to obesity-related comorbidities or risk factors.

ather than using BMI, the traditional measure of obesity, we developed the Edmonton Obesity Staging System as a tool to describe the overall health of people with obesity or who are overweight with the aim of better supporting weight-management decisions in clinical practice. said Dr Arya Sharma, niversity of Alberta, Canada and SCALE™ clinical trial investigator. In this analysis, we saw that Saxenda® led to weight loss and improvements of weight-related comorbidities in people with obesity regardless of the severity of their disease .

Saxenda® was generally well tolerated and observed side effects were in line with previous liraglutide trials.[3] Across EOSS scores, rates of overall adverse events were similar. Pulse rate increased with Saxenda® (1.9–2.6 bpm) vs placebo (-3.9–0.9 bpm treatment difference 2.0–6.5 bpm, p 0.05).[1]

## About obesity

Obesity is a disease that requires long-term management. It is associated with many serious health consequences and decreased life-expectancy.[4,5,6] Obesity-related comorbidities include type 2 diabetes, heart disease, obstructive sleep apnoea (OSA) and certain types of cancer.[5,7,8] It is a complex and multi-factorial disease that is influenced by genetic, physiological, environmental and psychological factors.[9]

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The global increase in the prevalence of obesity is a public health issue that has severe cost implications to healthcare systems. In 2014, 13 per cent of adults, or approximately 600 million adults, were living with obesity.[10] In Canada, approximately 25 per cent of adults, equivalent to approximately 6.5 million people, live with obesity.[11] Estimates of the economic burden of obesity in Canada range from $4.6 billion to $7.1 billion annually.[12]

**About the Edmonton Obesity Staging System (EOSS)**

The EOSS ranks people with obesity on a 5-point scale, based on severity of obesity based on clinical assessment of weight-related health problems, mental health and quality of life:

- EOSS score '0' = no signs of obesity-related risk factors, physical symptoms, psychological symptoms, or functional limitations
- EOSS score '1' = mild obesity-related physical symptoms, psychological, or functional limitations
- EOSS score '2' = presence of established obesity-related comorbidities (such as hypertension, type 2 diabetes, sleep apnoea, osteoarthritis) requiring medical intervention, moderate psychological symptoms or limitations in activities of daily living
- EOSS score '3' = significant obesity-related comorbidities with end-organ damage such as heart failure, stroke, significant psychological symptoms, functional limitations or impairment of well-being
- EOSS score '4' = severe end-stage disease from obesity-related comorbidities, severely disabling psychological symptoms, functional limitations or impairment of well-being[2]

**About Saxenda®**

Saxenda® (liraglutide 3 mg) is a once-daily glucagon-like peptide-1 (GLP-1) analogue with 97 per cent similarity to naturally occurring human GLP-1, a hormone that is released in response to food intake.[13] Like human GLP-1, Saxenda® regulates appetite by increasing feelings of fullness and satiety, while lowering feelings of hunger and prospective food consumption, thereby leading to reduced food intake. As with other GLP-1 receptor agonists, Saxenda® stimulates insulin secretion and lowers glucagon secretion in a glucose-dependent manner.[3] These effects can lead to a reduction of fasting and post-prandial blood glucose. Saxenda® was evaluated in the SCALE™ (Satiety and Clinical Adiposity – Liraglutide Evidence) phase 3 clinical trial program.

In Canada, Saxenda® is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adult patients with an initial body mass index (BMI) of 30 kg/m2 or greater (obese), or 27 kg/m2 or greater (overweight) in the presence of at least one weight-related comorbidity (e.g., hypertension, type 2 diabetes, or dyslipidemia) who have failed a previous weight management intervention.[14]

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Guidance is given in all labels that treatment with Saxenda® should be discontinued if a specific threshold of weight loss has not been achieved after a certain period of time.

**About the SCALE™ clinical development program**
Novo Nordisk's phase 3 development program, called SCALE™, investigates liraglutide 3 mg for weight management. SCALE™ (Satiety and Clinical Adiposity – Liraglutide Evidence) consists of four, placebo-controlled, multinational trials called: SCALE™ Obesity and Prediabetes, SCALE™ Diabetes, SCALE™ Sleep Apnoea and SCALE™ Maintenance. The trials include more than 5,000 people who are overweight (BMI ≥27 kg/m2) with comorbidities such as hypertension, dyslipidaemia, obstructive sleep apnoea (OSA), or type 2 diabetes, or who have obesity (BMI ≥30 kg/m2), with or without comorbidities. The studies all involved a reduced-calorie diet and increased physical activity.

Key results from all trials in the SCALE™ clinical development program have been published, with further data expected to be presented and published throughout 2016.

**About Novo Nordisk**
Novo Nordisk Canada is an affiliate of Novo Nordisk A/S, a global healthcare company with more than 90 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat other serious chronic conditions: hemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 41,000 people in 75 countries and markets its products in more than 180 countries.

Novo Nordisk's company history has deep Canadian roots, with company founders Marie and August Krogh traveling to Toronto in 1922 to meet with Banting, Best, Collip and MacLeod to discuss the insulin preparation. Novo Nordisk would become the first company in Europe to produce insulin in 1923.

Novo Nordisk Canada employs approximately 280 people at its head office in Mississauga and across Canada. The company is listed as one of Canada's Top 100 Employers for 2016 and has also been awarded the distinction of being a Top GTA Employer since 2008. For more information, visit www.novonordisk.ca or follow us on Twitter @NovoNordiskCA.

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