company announcement

Wegovy® approved in the US for cardiovascular risk reduction in people with overweight or obesity and established cardiovascular disease

Bagsværd, Denmark, 8 March 2024 – Novo Nordisk today announced that the US Food and Drug Administration (FDA) has approved a label expansion for Wegovy® based on a supplemental New Drug Application (sNDA) for the indication of reducing risks of major adverse cardiovascular events (MACE) including cardiovascular death, non-fatal heart attack (myocardial infarction) or non-fatal stroke in adults with either overweight or obesity and established cardiovascular disease (CVD).

The approval is based on the SELECT cardiovascular outcomes trial, which demonstrated that Wegovy® statistically significantly reduced the risk of MACE by 20% compared to placebo when added to standard of care. The exact mechanism of cardiovascular risk reduction has not been established.

The findings from SELECT also showed that over a period of up to five years, risk reductions in MACE were achieved regardless of baseline age, sex, race, ethnicity, body mass index (BMI) and level of renal function impairment. In addition, the label is updated to include data from SELECT showing a risk reduction in cardiovascular death by 15% and a risk reduction of death from any cause by 19%, both compared to placebo[1]. Further, additional clinical data from SELECT are included in the label.

"We are very pleased that Wegovy® is now approved in the US as the first therapy to help people manage their weight and reduce cardiovascular risks," said Martin Holst Lange, executive vice president and head of Development at Novo Nordisk. “This approval is an important milestone for people living with obesity and cardiovascular disease, as the SELECT data demonstrated that Wegovy® has the potential to prolong lives by addressing some of the leading causes of preventable deaths by reducing the risks of cardiovascular events.”

[1] Cardiovascular death superiority not confirmed (hazard ratio: 0.85 (0.71;1.01)). Death by any cause not statistically significant based on the prespecified testing hierarchy (hazard ratio: 0.81 (0.71; 0.93)).

Novo Nordisk A/S
Investor Relations

Novo Alle 1
2880 Bagsværd
Denmark

Telephone:
+45 4444 8888

www.novonordisk.com
CVR no: 24 25 67 90

Novo Nordisk has also filed for a label expansion in the EU, and a decision is expected in 2024.

About obesity and cardiovascular disease

Obesity is a chronic disease that requires long-term management. It is associated with many serious health consequences and decreased life expectancy. Obesity-related complications are numerous and include type 2 diabetes, chronic kidney disease, non-alcoholic fatty liver disease, cancer and an increased risk of CVD, including heart attack and stroke, high levels of blood sugar, cholesterol, blood pressure and inflammation.

About the SELECT trial

SELECT was a randomised, double-blind, parallel-group, placebo-controlled trial designed to evaluate the efficacy of semaglutide 2.4 mg versus placebo as an adjunct to standard of care for prevention of MACE in people with established CVD with overweight or obesity with no prior history of diabetes over a period of five years. People included in the trial were aged ≥45 years with a BMI ≥27 kg/m^2.

The primary objective of the SELECT trial was to demonstrate the superiority of semaglutide 2.4 mg compared to placebo with respect to reducing the incidence of three-point MACE consisting of cardiovascular death, non-fatal heart attack (myocardial infarction) or non-fatal stroke. Key secondary objectives were to compare the effects of semaglutide 2.4 mg to placebo regarding mortality, heart failure, cardiovascular risk factors, including glucose metabolism, body weight and kidney function. The trial enrolled 17,604 adults and was conducted in 41 countries at more than 800 investigator sites. SELECT was initiated in 2018.

The SELECT data were presented at the American Heart Association (AHA) annual meeting in November 2023 and published in the New England Journal of Medicine (NEJM).

About Wegovy® (semaglutide 2.4 mg)

Following the US label update, Wegovy® is now indicated in combination with a reduced calorie diet and increased physical activity to reduce the risk of MACE in adults with established cardiovascular disease and either obesity or overweight, as well as to reduce excess body weight and maintain weight reduction long term in adults and paediatric patients aged 12 years and older with obesity and in adults with overweight in the presence of at least one weight-related comorbid condition.

Wegovy® has also been launched in Denmark, Norway, Germany, the UK, Iceland, Switzerland, UAE and Japan. Here Wegovy® is indicated as an adjunct to a reduced calorie diet and increased physical activity for chronic weight management in adults with a BMI of 30 kg/m^2 or greater (obesity), adults with a BMI of 27 kg/m^2 or greater (overweight) in the presence of at least one

weight-related comorbid condition, and in Denmark, Norway, Germany, UK, Iceland, and UAE, also for paediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater for age and gender (obesity).

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 serious chronic diseases, built upon our heritage in diabetes. We do so by pioneering scientific breakthroughs, expanding access to our medicines, and working to prevent and ultimately cure disease. Novo Nordisk employs about 63,400 people in 80 countries and markets its products in around 170 countries. Novo Nordisk's B shares are listed on Nasdaq Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com, Facebook, Instagram, X, LinkedIn and YouTube.

Contact for further information:

Media:

Ambre James-Brown
+45 3079 9289
abmo@novonordisk.com

Liz Skrbkova (US)
+1 609 917 0632
lzsk@novonordisk.com

Investors:

Daniel Muusmann Bohsen
+45 3075 2175
dabo@novonordisk.com

Jacob Martin Wiborg Rode
+45 3075 5956
jrde@novonordisk.com

David Heiberg Landsted
+45 3077 6915
dhel@novonordisk.com

Mark Joseph Root (US)
+1 848 213 3219
mjhr@novonordisk.com

Sina Meyer
+45 3079 6656
azey@novonordisk.com

Frederik Taylor Pitter
+45 3075 8259
fptr@novonordisk.com