company announcement

European regulatory authority adopts a positive opinion for an update of the Wegovy® label to reflect risk reduction of major adverse cardiovascular events

Bagsværd, Denmark, 25 July 2024 – Novo Nordisk today announced that the European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) has adopted a positive opinion for an update of the Wegovy® (semaglutide 2.4 mg) label to reflect data from the SELECT cardiovascular outcomes trial, demonstrating a risk reduction of major adverse cardiovascular events (MACE) including cardiovascular death, non-fatal heart attack (myocardial infarction) or non-fatal stroke in adults with established cardiovascular disease (CVD) and either overweight or obesity (initial BMI ≥27 kg/m^2) without diabetes.

The SELECT trial demonstrated that Wegovy® statistically significantly reduced the risk of MACE by 20% compared to placebo when added to standard of care. In addition, the findings from SELECT 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. The exact mechanism of cardiovascular risk reduction has not been established but is likely multifactorial.

"We believe that the recommendation to update the EMA label for Wegovy® is a significant milestone for people living with cardiovascular disease and obesity. The SELECT data demonstrated that in addition to helping people manage their weight, Wegovy® has the potential to protect lives by reducing the risks of major adverse cardiovascular events", said Martin Holst Lange, executive vice president and head of Development at Novo Nordisk.

The label update also includes data from the SELECT trial showing a risk reduction in cardiovascular death by 15%, a risk reduction of death from any cause by 19%, and an 18% risk reduction in a heart failure composite endpoint, comprised of cardiovascular death, urgent heart failure visits and hospitalisations for heart failure, all compared to placebo[1].

[1]Cardiovascular death superiority not confirmed (hazard ratio: 0.85; 95% CI (0.71;1.01)). Death by any cause not statistically significant based on the prespecified testing hierarchy (hazard ratio: 0.81; 95% CI: (0.71; 0.93)). Composite heart failure (cardiovascular death, urgent heart failure visits and hospitalisations) not statistically significant based on the prespecified testing hierarchy (hazard ratio: 0.82; 95% CI: (0.71; 0.96)).

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

Following the positive opinion from the CHMP, Novo Nordisk expects implementation of the label update within approximately one month.

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 Wegovy® 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. People included in the trial were aged ≥45 years with a BMI ≥27 kg/m^2 and were followed for a period of up to five years.

The primary objective of the SELECT trial was to demonstrate the superiority of Wegovy® 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 Wegovy® 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 and completed in 2023

About Wegovy® (semaglutide 2.4 mg)
In the EU, Wegovy® is indicated as an adjunct to a reduced calorie diet and increased physical activity for weight management in adults with a BMI of 30 kg/m^2 or greater (obesity), or adults with a BMI of 27 kg/m^2 or greater (overweight) in the presence of at least one weight-related comorbid condition. In the EU, Wegovy® is also indicated for paediatric patients aged 12 years and older with an initial BMI at the 95th percentile or greater for age and gender (obesity) and body weight above 60 kg.

In the US, Wegovy® is 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.

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 66,000 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.

Contacts for further information

Media:

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

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

Investors:

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

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

Sina Meyer
+45 3079 6656
azey@novonordisk.com

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

Ida Schaap Melvold
+45 3077 5649
idmg@novonordisk.com

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