press release

Wegovy® recommended by the European regulatory authorities for label update to reflect reduced heart failure symptoms and improved physical function

- Wegovy® (semaglutide 2.4 mg) is the first obesity medication to receive a positive opinion recommending a label update that reflects reduced symptoms and improved physical limitations and exercise function in people with obesity-related heart failure with preserved ejection fraction (HFpEF).

- The positive opinion is based on results from the STEP HFpEF and STEP HFpEF-DM trials, which showed that Wegovy® is an effective therapy compared to placebo for people with obesity-related HFpEF. [1,2]

Bagsværd, Denmark, 19 September 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 in the European Union (EU). The label update incorporates data showing that Wegovy®, when added to standard of care, can reduce heart failure-related symptoms and improve physical limitations and exercise function in people with obesity-related HFpEF, with or without type 2 diabetes. [1,2]

The positive opinion is based on the results from the STEP HFpEF and STEP HFpEF-DM trials conducted in people with obesity-related HFpEF, with or without type 2 diabetes. [1,2] In both trials, Wegovy® demonstrated greater reductions in heart failure-related symptoms and greater improvements in physical limitations, as measured by the patient-reported Kansas City Cardiomyopathy Questionnaire Clinical Summary Score (KCCQ-CSS), alongside greater weight loss compared to placebo. [1,2] The beneficial effects were consistent regardless of baseline age, sex, race, ethnicity, body mass index (BMI), region, systolic blood pressure, left ventricular ejection fraction, and concomitant heart failure therapy.[1,2]

The label update also incorporates data which showed that participants receiving Wegovy® achieved a greater increase in exercise function, as measured by the difference in 6-minute walking distance (6MWD) from baseline to week 52, compared to those receiving placebo. [1,2]

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"The recommendation to update the EMA label for Wegovy® is an important step forward for people with obesity-related HFpEF who currently have limited treatment options. Wegovy® improves patients' health-related quality of life, enabling them to live a life with greater functionality to conduct daily activities. These data further add to the body of evidence for the semaglutide molecule," said Martin Holst Lange, executive vice president and head of Development at Novo Nordisk.

The recommendation to incorporate the data from the STEP HFpEF trials adds to the recent Wegovy® EMA label update that included data from the SELECT landmark trial to reflect risk reduction of heart attack, stroke and cardiovascular death. [3]

With the positive opinion from the CHMP, Novo Nordisk expects implementation of the EU label update shortly, following a linguistic review process by the EMA. As communicated earlier this year, Novo Nordisk will resubmit to the US Food & Drug Administration for inclusion of data from the STEP HFpEF trials in the Wegovy® label in the US in 2025.

About HFpEF and obesity

Heart failure affects at least 64 million people worldwide and is especially prevalent in those with obesity and/or type 2 diabetes.[3] Heart failure with preserved ejection fraction (HFpEF) is now the most common form of heart failure, comprising approximately 50% of all heart failure cases.[4,5] Obesity is considered a key driver in the development and progression of HFpEF.[6] Approximately 80% of people with HFpEF live with overweight or obesity, which is associated with symptoms including shortness of breath, swollen legs and feet and trouble exercising.[7,8] This can lead to poor quality of life due to the greater symptom burden and worse physical functioning.[9] Despite therapeutic advances in HFpEF, significant unmet needs persist.[10]

About STEP HFpEF and STEP HFpEF-DM trials

The primary objective of STEP HFpEF and STEP HFpEF-DM trials was to investigate the effects of subcutaneous semaglutide 2.4 mg once-weekly on symptoms, physical function, and body weight compared with placebo in patients with obesity-related HFpEF.[11] STEP HFpEF included 529 people with HFpEF (ejection fraction ≥45%) and obesity (BMI ≥30 kg/m^2),[2] while STEP HFpEF-DM included 616 people with HFpEF (ejection fraction ≥45%), obesity (BMI ≥30 kg/m^2) and type 2 diabetes.[1] Both trials had dual primary endpoints: change in the Kansas City Cardiomyopathy Questionnaire Clinical Summary Score (KCCQ-CSS) from baseline to week 52 and change in body weight from baseline to week 52.[1,2] Key secondary endpoints included change in 6-minute walking distance (6MWD), a hierarchical composite endpoint (all-cause death, heart failure events, changes in KCCQ-CSS and 6MWD from baseline to week 52), and changes in C-reactive protein from baseline (screening) to week 52. [1,2]

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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.[1,2] 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.[1,2] In addition to this, the Wegovy® label (clinical data section) in the EU also reflects data on risk reduction of major adverse cardiovascular events (MACE) in adults with established cardiovascular disease and either overweight or obesity (initial BMI ≥27 kg/m^2) without diabetes.[3]

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 69,000 people in 80 countries and markets its products in around 170 countries. For more information, visit novonordisk.com, Facebook, Instagram, X, LinkedIn and YouTube.

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References

1) Kosiborod MN, Petrie MC, Borlaug BA*, et al.* Semaglutide in Patients with Obesity-Related Heart Failure and Type 2 Diabetes. *N Engl J Med*. 2024; 390:1394-1407.

2) Kosiborod MN, Abildstrom SZ, Borlaug BA*, et al.* Semaglutide in Patients with Heart Failure with Preserved Ejection Fraction and Obesity. *N Engl J Med*. 2023; 389:1069-1084.

3) Borlaug BA, Jensen MD, Kitzman DW*, et al.* Obesity and heart failure with preserved ejection fraction: new insights and pathophysiological targets. *Cardiovasc Res*. 2023; 118:3434-3450.

4) Gurwitz JH, Magid DJ, Smith DH*, et al.* Contemporary prevalence and correlates of incident heart failure with preserved ejection fraction. *Am J Med*. 2013; 126:393-400.

5) Haass M, Kitzman DW, Anand IS*, et al.* Body mass index and adverse cardiovascular outcomes in heart failure patients with preserved ejection fraction: results from the Irbesartan in Heart Failure with Preserved Ejection Fraction (I-PRESERVE) trial. *Circ Heart Fail*. 2011; 4:324-331.

6) Koliaki C, Liatis S and Kokkinos A. Obesity and cardiovascular disease: revisiting an old relationship. *Metabolism*. 2019; 92:98-107.

7) Reddy YNV, Rikhi A, Obokata M*, et al.* Quality of life in heart failure with preserved ejection fraction: importance of obesity, functional capacity, and physical inactivity. *Eur J Heart Fail*. 2020; 22:1009-1018.

8) Gevaert AB, Kataria R, Zannad F*, et al.* Heart failure with preserved ejection fraction: recent concepts in diagnosis, mechanisms and management. *Heart*. 2022; 108:1342-1350.

9) Yap J, Tay WT, Teng TK*, et al.* Association of Diabetes Mellitus on Cardiac Remodeling, Quality of Life, and Clinical Outcomes in Heart Failure With Reduced and Preserved Ejection Fraction. *J Am Heart Assoc*. 2019; 8:e013114.

10) Borlaug BA, Jensen MD, Kitzman DW*, et al.* Obesity and heart failure with preserved ejection fraction: new insights and pathophysiological targets. *Cardiovasc Res*. 2023; 118:3434-3450.

11) ClinicalTrials.gov. Research Study to Look at How Well Semaglutide Works in People Living With Heart Failure, Obesity and Type 2 Diabetes (STEP HFpEF DM). Available at: https://clinicaltrials.gov/ct2/show/NCT04916470. Last accessed: September 2024.

12) European Medicines Agency. Wegovy: EPAR - Product Information. Available at: https://www.ema.europa.eu/en/medicines/human/EPAR/wegovy#product-details. Last accessed: September 2024.

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