

company announcement

Rybelsus® (oral semaglutide) recommended for approval for the treatment of adults with type 2 diabetes by the European regulatory authorities

Bagsværd, Denmark, 31 January 2020 - Novo Nordisk today announced that the Committee for Medicinal Products for Human Use (CHMP) under the European Medicines Agency (EMA) has adopted a positive opinion, recommending marketing authorisation for Rybelsus® (oral semaglutide) for the treatment of adults with insufficiently controlled type 2 diabetes to improve glycaemic control as an adjunct to diet and exercise.

The CHMP recommends Rybelsus® to be indicated as monotherapy when metformin is considered inappropriate, as well as in combination with other medicinal products for the treatment of type 2 diabetes. The label also refers to clinical trial results with respect to combination with other diabetes medications, effects on glycaemic control, cardiovascular events and the populations studied.

"We are very excited about the positive opinion for Rybelsus®, as it is the first and only GLP-1 in a tablet, and we believe it has the potential to set a new standard for the treatment of type 2 diabetes in the EU," said Mads Krogsgaard Thomsen, executive vice president and chief science officer. "A high proportion of people with type 2 diabetes does not achieve target blood sugar levels, which underpins the need for new and more efficacious solutions to better manage their disease."

Novo Nordisk expects to receive final marketing authorisation from the European Commission in the beginning of second quarter of 2020.

About Rybelsus®

Rybelsus® (oral semaglutide) is an analogue of the naturally occurring hormone GLP-1, and it is the world's first and only GLP-1 in a tablet. Rybelsus® is approved in the US and it is indicated as an adjunct to diet and exercise to improve glycaemic control in adults with type 2 diabetes. It is administered once daily and is approved for use in two therapeutic dosages, 7 mg and 14 mg in the US.

Novo Nordisk is a global healthcare company with more than 95 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat obesity, haemophilia, growth disorders and other serious chronic diseases. Headquartered in Denmark, Novo Nordisk employs approximately 42,200 people in 80 countries and markets its products in more than 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, Twitter, LinkedIn, YouTube.

Further information

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