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Rybelsus® approved in Japan for the treatment of type 2 diabetes

Bagsværd, Denmark, 29 June 2020 - Novo Nordisk today announced that the Japanese Ministry of Health, Labour and Welfare has approved Rybelsus® (oral semaglutide), the first and only oral glucagon-like peptide-1 receptor agonist (GLP-1 RA) in a tablet, for the treatment of adults with type 2 diabetes.

The approval of Rybelsus® in Japan is based on results from the PIONEER clinical trial programme, which involved more than 9,500 adults with type 2 diabetes, including approximately 1,300 adults from Japan. The approved label reflects the Japanese studies, which showed that Rybelsus® 7 mg once daily was comparable to liraglutide 0.9 mg once daily and, in combination with one other oral antidiabetic treatment, Rybelsus® 7 mg once daily was comparable to dulaglutide 0.75 mg once weekly, while Rybelsus® 14 mg once daily resulted in significantly greater reductions in HbA_{1c} than both liraglutide and dulaglutide - the two most widely used injectable GLP-1 receptor agonists in Japan.

“We are very excited about the approval of Rybelsus® in Japan, offering people living with type 2 diabetes the first and only oral GLP-1 in a tablet,” said Mads Krogsgaard Thomsen, executive vice president and chief scientific officer. “Providing people living with type 2 diabetes with efficacious and convenient treatment options is essential, as millions of people are currently not achieving target blood sugar levels on available oral antidiabetic medications.”

Novo Nordisk will now initiate reimbursement negotiations and expects to launch Rybelsus® in Japan thereafter. Novo Nordisk and MSD will be co-promoting Rybelsus® in Japan.

About Rybelsus®

Rybelsus® (oral semaglutide), which has the brand name リベルサス® in Japan, is the first and only oral GLP-1 RA approved for the treatment of type 2 diabetes. It is an analogue of the naturally occurring hormone GLP-1. The approval of Rybelsus® is based on the PIONEER programme, a global clinical development programme that comprises eight global and two Japanese phase 3a trials, encompassing more than 9,500 adults with type 2 diabetes. Rybelsus® is administered orally once daily and is approved for use in three therapeutic dosages, 3 mg, 7 mg and 14 mg in Japan. Rybelsus® has also been approved in the US, the EU, Switzerland and Canada.

Novo Nordisk is a leading global healthcare company, founded in 1923 and headquartered in Denmark. Our purpose is to drive change to defeat diabetes and other serious chronic diseases such as obesity and rare blood and endocrine disorders. We do so by pioneering scientific breakthroughs, expanding access to our medicines and working to prevent and ultimately cure disease. Novo Nordisk employs about 43,100 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, Twitter, LinkedIn, YouTube.

Further information

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