

# company announcement

## **Novo Nordisk receives Refusal to File letter for once-weekly semaglutide 2.0 mg for the treatment of type 2 diabetes**

**Bagsværd, Denmark, 22 March 2021** – Novo Nordisk today announced that the US Food and Drug Administration (FDA) has issued a Refusal to File letter covering the label expansion application for once-weekly semaglutide 2.0 mg for the treatment of type 2 diabetes which was filed on 20 January 2021. A refusal to file letter is received when the FDA determines additional information is required to review a complete application.

In the letter, FDA has requested additional information including data relating to a proposed new manufacturing site. While additional information needs to be included in the resubmission, Novo Nordisk believes the already completed clinical trial programme will be sufficient for approval of the label expansion application.

Novo Nordisk expects to resubmit the application to FDA during the second quarter of 2021.

### **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 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 45,000 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](http://novonordisk.com), [Facebook](#), [Twitter](#), [LinkedIn](#), [YouTube](#).*

### **Further information**

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