

company announcement

Novo Nordisk receives Complete Response Letter in the US for once-weekly basal insulin icodec

Bagsværd, Denmark, 10 July 2024 – Novo Nordisk today announced that the US Food and Drug Administration (FDA) has issued a Complete Response Letter (CRL) covering the Biologics License Application for once-weekly basal insulin icodec for the treatment of diabetes mellitus.

In the letter, the FDA has requests related to the manufacturing process and the type 1 diabetes indication before the review of the application can be completed. Novo Nordisk is evaluating the content of the CRL and will work closely with the FDA to fulfil the requests. Novo Nordisk does not expect to be able to fulfil the requests during 2024.

“We believe in the potential of once-weekly basal insulin icodec for those living with diabetes who require basal insulin therapy,” said Martin Lange, executive vice president for Development at Novo Nordisk. “We will work closely with the FDA to identify the next steps needed to complete the review so we can provide this novel treatment option to adults living with diabetes”.

Novo Nordisk submitted the application for insulin icodec to the FDA in April 2023. In May 2024, an FDA Endocrinologic and Metabolic Drugs Advisory Committee meeting was convened with a panel of independent scientific experts to discuss the benefit-risk of once-weekly basal insulin icodec in type 1 diabetes. The panel determined that the data available were not sufficient to conclude on a positive benefit-risk in type 1 diabetes. The Advisory Committee did not discuss the use of once-weekly insulin icodec in type 2 diabetes.

Insulin icodec is approved under the brand name Awiqli® in the EU, Canada, Australia, Japan and Switzerland for the treatment of both type 1 and type 2 diabetes and in China for the treatment of type 2 diabetes.

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](https://www.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 Melvold Gjørund

+45 3077 5649

idmg@novonordisk.com

Mark Joseph Root (US)

+1 848 213 3219

mjhr@novonordisk.com