IDegLira receives positive 16-0 vote in favour of approval from FDA Advisory Committee

Bagsværd, Denmark, 24 May 2016 – Novo Nordisk today announced that the Endocrinologic and Metabolic Drugs Advisory Committee (EMDAC) of the US Food and Drug Administration (FDA) voted 16-0, recommending the approval of IDegLira for the treatment of adults with type 2 diabetes. IDegLira is a once-daily, single injection fixed combination of insulin degludec (Tresiba®) and liraglutide (Victoza®) for the treatment of adults with type 2 diabetes.

Based on the data contained in the New Drug Application (NDA) for IDegLira, the FDA asked the panel members to discuss whether Novo Nordisk has provided adequate evidence to establish the efficacy and safety profile of IDegLira for the treatment of adults with type 2 diabetes.

The recommendation for approval was based on data from clinical trials of IDegLira, including the DUAL phase 3 clinical trial programme, which involved more than 3,000 adults with type 2 diabetes. In addition to the DUAL clinical trial programme, both insulin degludec and liraglutide have been studied extensively in separate clinical trial programmes and the products are commercially available across the globe.

“The unanimous recommendation from the Advisory Committee marks an important step towards making IDegLira available to adults with type 2 diabetes in the US. We look forward to working with the FDA as they complete their review of IDegLira,” said Mads Krogsgaard Thomsen, executive vice president and chief science officer of Novo Nordisk.

The NDA for IDegLira was submitted to the FDA in September 2015 under the FDA’s Prescription Drug User Fee Act V (PDUFA V) regulation. In Europe, IDegLira was approved in September 2014 and is marketed under the brand name Xultophy®.

About advisory committee meetings
FDA advisory committees are panels of independent experts who advise the FDA on specific questions raised by the FDA as they consider regulatory decisions. The FDA is not bound by the committee’s recommendation, but it takes its advice into consideration when reviewing new drug applications. According to the FDA Amendment Act of 2007 (FDAAA), the FDA should refer new drugs to an advisory committee meeting, or alternatively justify why an advisory committee meeting was not requested.
About IDegLira
IDegLira is a once-daily, single injection fixed combination product consisting of insulin degludec (Tresiba®), a once-daily new-generation basal insulin analogue, and liraglutide (Victoza®), a once-daily GLP-1 analogue.

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. This heritage has given us experience and capabilities that also enable us to help people defeat other serious chronic conditions: haemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 41,600 people in 75 countries and markets its products in more than 180 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

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