company announcement

FDA posts briefing materials prior to Advisory Committee meeting for Saxenda® for the treatment of obesity

Bagsværd, Denmark, 9 September 2014 – Novo Nordisk today announced that the US Food and Drug Administration (FDA) has published the briefing documents ahead of the 11 September 2014 Advisory Committee meeting to discuss the New Drug Application (NDA) for Saxenda®, the intended brand name for liraglutide 3 mg for the treatment of obesity.

The briefing documents from Novo Nordisk and the FDA, which will form the basis for the Advisory Committee's discussion, provide an overview of the non-clinical and clinical data for Saxenda® for the management of obesity as an adjunct to diet and physical activity.

The briefing materials can be accessed on the FDA webpage

About FDA 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 drugs to an advisory committee meeting, or alternatively justify why an advisory committee meeting was not requested.

About obesity
Obesity is a disease[1] that requires chronic management. It is associated with serious comorbidities including type 2 diabetes, heart disease, obstructive sleep apnoea (OSA), certain types of cancer and a decreased life expectancy. The risk of morbidity and mortality increases with the severity of obesity. It is a complex and multi-factorial disease that is influenced by genetic, physiological, environmental and psychological factors.

The global increase in the prevalence of obesity is a public health issue that has severe cost implications to healthcare systems. In the US, approximately 35% of adults, or some 100 million people, live with obesity.

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About Saxenda®

Saxenda® (liraglutide 3 mg) is a once-daily glucagon-like peptide-1 (GLP-1) analogue with 97% similarity to naturally occurring human GLP-1, a hormone that is released in response to food intake. Like human GLP-1, Saxenda® regulates appetite and food intake by decreasing hunger and increasing feelings of fullness and satiety after eating. The dual actions of Saxenda® on both appetite and blood glucose regulation (for adults with pre-diabetes or type 2 diabetes) hold therapeutic potential for adults with obesity, both those with and without type 2 diabetes.

Saxenda® is an investigational product and is not approved by the FDA or European Medicines Agency (EMA).

Novo Nordisk is a global healthcare company with more than 90 years of innovation and leadership in diabetes care. The company also has leading positions within haemophilia care, growth hormone therapy and hormone replacement therapy. Headquartered in Denmark, Novo Nordisk employs approximately 40,700 employees in 75 countries, and markets its products in more than 180 countries. Novo Nordisk's B shares are listed on NASDAQ OMX Copenhagen (Novo-B). Its ADRs are listed on the New York Stock Exchange (NVO). For more information, visit novonordisk.com.

Further information

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References

[1] American Medical Association, (AMA). Declaration to classify obesity as a disease. Annual Meeting Report. 19 June 2013.