company announcement

Novo Nordisk receives US FDA approval for Tresiba® and Ryzodeg® 70/30

Bagsværd, Denmark, 25 September 2015 – Novo Nordisk today announced that the US Food and Drug Administration (FDA) has approved Tresiba® and Ryzodeg® 70/30 for the treatment of diabetes mellitus in adults after review of the class II resubmissions of the New Drug Applications (NDAs).

Tresiba®, the approved brand name for insulin degludec, is a once-daily new-generation basal insulin analogue with a half–life of 25 hours and a duration of action of at least 42 hours. In 'treat-to-target' studies comparing Tresiba® to insulin glargine, people using Tresiba® achieved similar reduction in long-term blood glucose (HbA_{1c}), numerically greater fasting plasma glucose reduction, while using numerically lower doses of insulin in a majority of the studies. Furthermore, the studies demonstrated that Tresiba® is the first basal insulin to offer people with diabetes the possibility of injecting their basal insulin at any time of the day with the option to adjust the time of injection.

Ryzodeg® 70/30, the approved brand name for insulin degludec/insulin aspart, contains insulin degludec in a soluble co-formulation with insulin aspart. Ryzodeg® 70/30 can be administered once or twice daily with any main meal. In a 'treat-to-target' study supporting the new drug application where Ryzodeg® 70/30 was compared to NovoLog® Mix 70/30, Ryzodeg® 70/30 showed equivalent reductions in HbA_{1c}.

Novo Nordisk expects to launch Tresiba® in the US during the first quarter of 2016. Tresiba® will be available in the FlexTouch® device and be offered in two concentrations enabling maximum doses of 80 units and 160 units per injection, respectively.

On 26 March 2015, Novo Nordisk announced the decision to submit the class II resubmissions of the NDAs following the completion of the interim analysis of the cardiovascular outcomes trial for insulin degludec, DEVOTE. In order to preserve the integrity of the ongoing DEVOTE trial, only a small dedicated team within Novo Nordisk has access to the data. Novo Nordisk management does not have access to the results of the interim analysis. The trial is still expected to have accrued the prespecified number of major adverse cardiovascular events (MACE) for the full trial analysis in mid-2016.

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"We are very happy with FDA's decision to approve Tresiba® and Ryzodeg® 70/30 as we believe these products offer significant benefits and important treatment options for people with type 1 and type 2 diabetes", said Lars Rebien Sørensen, president and chief executive officer of Novo Nordisk. "The approvals mark an important milestone for Novo Nordisk and we look forward to making Tresiba® available for people in the US".

Reflecting a separate action, Novo Nordisk today also announced that a New Drug Application for Xultophy®, the first once-daily single-injection combination of Tresiba® (insulin degludec) and Victoza® (liraglutide), has been submitted to the FDA. The submission is expected to be reviewed under US FDA's Prescription Drug User Fee Act V (PDUFA V).

Conference call
On 28 September 2015 at 8.00 am CEST, corresponding to 2.00 am EDT, a conference call for investors will be held. Investors will be able to listen in via a link on the investor section of novonordisk.com.

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 39,700 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

Further information

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