DEVOTE headline results

Investor conference call
30 November 2016
Forward-looking statements

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Important drug information

• Victoza® (liraglutide 1.2 mg & 1.8 mg) is approved for the management of type 2 diabetes only
• Saxenda® (liraglutide 3 mg) is approved in the US and EU for the treatment of obesity only
DEVOTE trial conducted to fulfil regulatory requirements for Tresiba® and Ryzodeg® 70/30 in the US

Regulatory review timeline of Tresiba® and Ryzodeg® 70/30 in the US

29 Sep 2011: NDA for insulin degludec and insulin degludec/insulin aspart filed with the FDA

8 Feb 2013: Novo Nordisk receives CRL

26 Mar 2015: Novo Nordisk decides to resubmit insulin degludec and insulin degludec/insulin aspart based on DEVOTE interim analysis

25 Sep 2015: The FDA approves Tresiba® and Ryzodeg® 70/30

23 Sep 2016: Submission of SWITCH results to the FDA

29 Jan/23 Feb 2016: Announcement of SWITCH headline results

29 Nov 2016: Announcement of DEVOTE headline results

Timeline

NDA: New Drug Application; CRL: Complete Response Letter
DEVOTE was designed to investigate the CV safety of Tresiba® versus insulin glargine U100 in type 2 diabetes

**DEVOTE trial design**

- **7,637 patients with type 2 diabetes**

- **Tresiba® once daily (blinded vial) + standard of care**

- **Insulin glargine U100 once daily (blinded vial) + standard of care**

- **Event driven trial (To be concluded at 633 events)**

**Trial objective**
- To investigate the cardiovascular safety of Tresiba®

**Trial endpoints**

- **Primary endpoint: 3-point MACE**
  - Time from randomisation to first occurrence of a major adverse cardiovascular event (MACE) defined as either:
    - cardiovascular death,
    - non-fatal myocardial infarction, or
    - non-fatal stroke

- **Key secondary confirmatory endpoints**
  - Rate of severe hypoglycaemia episodes
  - Proportion of subjects with one or more severe hypoglycaemia episodes
  - Rate of nocturnal severe hypoglycaemia episodes

**CV**: Cardiovascular

Key inclusion criteria: Adults above 50 years with type 2 diabetes and established cardiovascular disease, or above 60 years with multiple cardiovascular risk factors; Hba\(_1\)c ≥7.0% or Hba\(_1\)c <7.0% and current basal insulin therapy ≥20 units per day; treatment with ≥1 oral or injectable anti-diabetic drug(s)
### Cardiovascular outcomes and general safety

**3-point MACE (Primary endpoint)**
- Non-inferiority demonstrated with a hazard ratio of 0.91 in favour of Tresiba® relative to insulin glargine U100 with no statistically significant difference between the two treatments

**General safety**
- Tresiba® appeared to have a safe and well-tolerated profile consistent with previous trials conducted with Tresiba®

### Severe hypoglycaemia

**Severe hypoglycaemia**
- Compared to insulin glargine U100, Tresiba® demonstrated a superior and statistically significant:
  - 40% reduction in the overall rate of severe hypoglycaemia episodes
  - 27% reduction in the proportion of subjects with one or more severe hypoglycaemia episodes

**Nocturnal severe hypoglycaemia**
- Tresiba® demonstrated a superior and statistically significant 54% reduction compared to insulin glargine U100 in the rate of nocturnal severe hypoglycaemia episodes

### Next steps
- Presentation of detailed results at a scientific meeting and submission to regulatory authorities in the first half of 2017

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CV: Cardiovascular; IGlar 100: insulin glargine U100; MACE: Major adverse cardiovascular event; 3-point MACE comprises cardiovascular death, non-fatal myocardial infarction and non-fatal stroke; expanded MACE comprises unstable angina in addition to 3-point MACE
Investor contact information

Share information
Novo Nordisk’s B shares are listed on the stock exchange in Copenhagen under the symbol ‘NOVO B’. Its ADRs are listed on the New York Stock Exchange under the symbol ‘NVO’. For further company information, visit Novo Nordisk on the internet at: novonordisk.com

Upcoming events
- 02 Feb 2017  Financial statement for 2016
- 23 Mar 2017  Annual General Meeting 2017
- 03 May 2017  Financial statement for the first three months of 2017
- 09 Aug 2017  Financial statement for the first half of 2017
- 01 Nov 2017  Financial statement for the first nine months of 2017

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