
Novo Nordisk receives positive opinion from European drug authorities Fiasp® (rapid-acting insulin aspart) for the treatment of diabetes

November 11, 2016 07:25ET | Source: Novo Nordisk A / S

Bagsvaerd, November 11, 2016 - Novo Nordisk today announced that the Committee for Human Medicinal Products (CHMP) of the European Medicines Agency (EMA) has issued a favorable opinion on the use of Fiasp® (rapid-acting insulin aspart), recommending marketing authorization for treatment of adults with type 1 and type 2 diabetes.

CHMP recommends that Fiasp®, the intended trademark for fast-acting insulin aspart, is indicated for use as boluskomponenten in basal-bolus therapy in combination with basal insulin and continuous subcutaneous infusion via an insulin pump. Novo Nordisk has developed Fiasp® as a meal insulin with an earlier and greater glucose lowering effect than NovoRapid® (insulin aspart).

"We believe that Fiasp® represents an important evolution in meal insulin, which can address the unmet medical needs of people who have a need for better regulation of blood sugar levels around mealtimes or greater dosing flexibility," says Mads Krogsgaard Thomsen, chief science development in Novo Nordisk.

Novo Nordisk expects to receive final marketing authorization from the European Commission in the first quarter of 2017.

About Fiasp®

Fiasp® (fast-acting insulin aspart) is a meal insulin for improved control of blood glucose increase after meals, and are designed for treatment of humans with type 1 and type 2 diabetes, as well as to the pump therapy. Fiasp® is insulin aspart (NovoRapid®) in a new formulation, which added two new adjuvants to ensure early and rapid absorption, which means that the insulin works faster. The evaluation of Fiasp® was based on the Phase 3 clinical program 'onset', which includes four studies involving more than 2,100 people with type 1 and type 2 diabetes.

This is a translation of the original English announcement. In the event of discrepancies between the Danish and the English version, the English force.

More info

Media:

Katrine Sperling

+45 3079 6718 krsp@novonordisk.com

investors:

Peter Ankersen Hugrefte +45 3075 9085 phak@novonordisk.com
Hanna Ögren +45 3079 8519 haoe@novonordisk.com
Anders Mikkelsen +45 3079 4461 armk@novonordisk.com
Melanie Raouzeos +45 3075 3479 mrz@novonordisk.com

Company Announcement no. 78/2016

Attachments:

<http://www.globenewswire.com/NewsRoom/AttachmentNg/dcc93dca-a16b-4b14-8197-4866ed3535f5>

Newswire Distribution Network & Management

- [Home](#)
- [News Room](#)
- [RSS Feeds](#)
- [Legal](#)
- [Contact Us](#)

ABOUT US

GlobeNewswire, a Nasdaq company, is one of the world største newswire distribution networks, Specializing in the delivery of corporate press releases financial disclosures and multimedia content for media, investment community, individual investors and the general public.

CONTACT US

Corporate Headquarters

2321 Rosecrans Avenue.
Suite 2200
El Segundo, CA 90245
Phone: (800) 307-6627
Fax: (800) 307-3567

European Headquarters

Woolgate Exchange,
25 Basinghall Street,
London EC2V 5HA
UK
Phone: +1 866-465-8454

© 2016 GlobeNewswire, Inc. All Rights Reserved.