

HEALTH CANADA APPROVES TRESIBA[®], A NEW BASAL INSULIN FOR TYPE 1 AND 2 DIABETES

The new once-daily, ultra-long-acting insulin provides a glucose-lowering effect beyond 42 hours

Mississauga, Ontario, Canada – August 28, 2017 – Novo Nordisk today announced that Health Canada has approved Tresiba[®] (insulin degludec injection), a new basal insulin for the once-daily treatment of adults with diabetes mellitus to improve glycemic control.¹ Tresiba[®] is the first insulin to be added to Canada's national Register of Innovative Drugs by Health Canada since the register was established in 2006.

Tresiba[®] has been shown to have low risk of overall, nocturnal and severe hypoglycemia.² Hypoglycemia, or low blood sugar, is the most common adverse effect associated with insulin therapy, with symptoms that can vary from confusion and numbness to seizures and even death in severe cases.³

"Maintaining blood glucose control with insulin treatment is critical but it can also be challenging for healthcare professionals and people living with diabetes due to the risk of hypoglycemia," said Rick Blickstead President and CEO, Diabetes Canada. "Canadians living with diabetes are looking for treatment options that provide greater flexibility and better enable them to live a life free from diabetes-related complications, like hypoglycemia."

"Health Canada's approval of Tresiba[®] provides physicians with a new ultra-long-acting option for their patients that can help to improve glycemic control," said Brian Hilberdink, President, Novo Nordisk Canada Inc. "In 1923, our founders began a journey to change diabetes and now, almost 100 years past the discovery of insulin in Canada, we continue in our commitment to prevent, treat and ultimately cure diabetes. We are proud to bring this innovation to Canadians and we hope it will help improve the lives of people living with diabetes in Canada. We intend to bring this innovation to Canadians in October 2017."

About Tresiba[®]

Tresiba[®] (insulin degludec injection) is a once-daily, ultra-long-acting basal insulin approved in Canada for the once-daily treatment of adults with diabetes mellitus to improve glycemic control. Tresiba[®] provides a duration of action beyond 42 hours.⁴ It provides low day-to-day variability and a low risk of overall, nocturnal and severe hypoglycemia.² On occasions, when administration at the same time of day is not possible, Tresiba[®] allows for flexibility in day-to-day dosing time with a minimum of eight hours between injections.¹ Tresiba[®] received its first regulatory approval in September 2012 and has since been approved in more than 80 countries globally. It is now commercially available in more than 50 countries.

Hypoglycemia is the most common adverse reaction of all insulin preparations, including Tresiba[®]. The most common side effects found with Tresiba[®] are hypoglycemia, allergic reactions, injection site reactions, lipodystrophy, pruritus, rash, edema and weight gain.¹

About Novo Nordisk Canada

Novo Nordisk Canada Inc. is an affiliate of Novo Nordisk A/S, 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: hemophilia, growth disorders and obesity.

Headquartered in Denmark, Novo Nordisk employs approximately 41,400 employees in 77 countries, and markets its products in more than 165 countries.

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Further information

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References:

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- ³ Diabetes Canada. Canadian Diabetes Association Clinical Practice Guidelines – Hypoglycemia. Available at [http://www.canadianjournalofdiabetes.com/article/S1499-2671\(13\)00023-3/pdf](http://www.canadianjournalofdiabetes.com/article/S1499-2671(13)00023-3/pdf). Accessed: July 2017
- ⁴ Haahr H, Heise T. A review of the pharmacological properties of insulin degludec and their clinical relevance. *Clin Pharmacokinet.* 2014;53:787-800.