press release

Health Canada approves TRESIBA® for children with Type 1 diabetes

Rates of Type 1 diabetes among children and youth on the rise globally[1]

Mississauga, October 1, 2018 — Novo Nordisk Canada Inc. announces TRESIBA® (insulin degludec injection) has received an expanded Health Canada approval for the treatment of pediatric patients (>2 years of age) with Type 1 diabetes mellitus.[2] TRESIBA® is an ultra-long-acting basal insulin which provides a glucose-lowering effect beyond 42 hours.[2]

"For children living with Type 1 diabetes, blood sugar control remains one of the most significant challenges of managing the disease," says Dave Prowten, President and CEO, JDRF. "We are pleased that this announcement means more individuals will have a new treatment option available to assist in combatting this challenge at all stages of the disease."

Diabetes is the most frequently diagnosed endocrine disease occurring in children, and is one of the most common chronic conditions among this group.[3] Annually, 86,000 children develop Type 1 diabetes globally, and Canada has one of the highest incidence rates for children under 14 years of age.[4,1] Hypoglycemia, a side effect of insulin, which is a life-saving treatment, is a particular challenge for children with Type 1 diabetes.[2,4,3]

"With appropriate treatment options available, pediatric patients and their caregivers can manage Type 1 diabetes effectively," says Brian Hilberdink, President, Novo Nordisk Canada Inc. "We're proud to offer this long-acting treatment to pediatric patients and their caregivers to help them best manage their condition and improve glycemic control."

The expanded indication of TRESIBA® follows its first Health Canada approval in August 2017 for the treatment of adults with Type 1 and Type 2 diabetes mellitus. TRESIBA® has been approved for reimbursement for adults with Type 1 and Type 2 diabetes mellitus in Ontario, effective September 27, 2018, Quebec, effective September 27, 2018, Saskatchewan, effective October 1, 2018, Manitoba, effective October 18, 2018, as well as by the Non-Insured Health Benefits Program, effective September 18, 2018.[5,6,7,8,9] TRESIBA® was also the first insulin added to the Register of Innovative Drugs for human use.

About TRESIBA®
TRESIBA® (insulin degludec injection) is a once-daily, ultra-long-acting basal insulin approved in Canada on August 25, 2017 for the once-daily treatment of adults with diabetes mellitus to improve glycemic control.[2] On July 17, 2018, TRESIBA® was also approved in Canada for pediatric patients (>2 years of age) with Type 1 diabetes mellitus.[2] TRESIBA® provides a duration of action beyond 42 hours with a flat and stable glucose-lowering effect.[2,10] It has been shown to provide a lower risk of overall, nocturnal and severe hypoglycemia, and low variability in blood sugar levels versus insulin glargine U100.[2,11] TRESIBA® received its first global regulatory approval in September 2012 and has since been approved in more than 80 countries globally. It is now commercially available in more than 61 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.[2]

About Novo Nordisk
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 obesity, hemophilia, growth disorders and other serious chronic diseases. Headquartered in Denmark, Novo Nordisk employs approximately 41,700 people in 77 countries and markets its products in more than 165 countries. For more information, visit novonordisk.ca, Twitter, YouTube.

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