press release

Novo Nordisk launches Rebinyn®, a new, long-acting treatment for patients with hemophilia B in Canada

Mississauga, Canada, April 11, 2018 – Today, in Canada, Novo Nordisk announced the launch and availability of Rebinyn® (Coagulation Factor IX (Recombinant), pegylated), an anti-hemophilic factor indicated in adults and children with hemophilia B (congenital factor IX deficiency or Christmas disease) for control and prevention of bleeding episodes and control and prevention of bleeding in the perioperative setting. Rebinyn® is also indicated in patients 18 years and above with hemophilia B for routine prophylaxis to prevent or reduce the frequency of bleeding episodes.[1]

Hemophilia is an inherited bleeding disorder affecting the blood's ability to clot. It can affect people from all races and ethnic origins. Hemophilia B is very rare, affecting just 1 in 50,000 people, or about 600 Canadians.[2]

"Canadians with joint damage caused by hemophilia live with pain and with limited ability to participate in simple, everyday activities like playing sports or being active," says Dr. Jerry Teitel MD, FRCP and Medical Director, St. Michael's Hospital Hemophilia Treatment Centre. "The approval of Rebinyn® offers patients a new, long-acting treatment option that will help to prevent this kind of disability, and that will provide effective control of bleeding when it does occur."

Rebinyn® has a half-life five times longer than standard FIX products and a significantly improved pharmacokinetic (PK) profile.[3] For patients, this means less frequent dosing, helping to alleviate the impact of hemophilia B, and improving the quality of life for both them and their families.[4]

"The Canadian Hemophilia Society advocates for access to the widest possible range of coagulation therapies and welcomes the introduction of Rebinyn® in Canada," said Paul Wilton, the Society's president.

The approval of Rebinyn® was granted based on the results from the paradigm™ clinical trial program, where 115 previously treated children and adults with hemophilia B were treated with Rebinyn®. Rebinyn® was found to be efficacious in routine prophylaxis, treatment of bleeding (breakthrough and on-demand),[5] and in prevention of bleeding during surgery in adults and adolescents (>12y).[6] The most common adverse reactions (may affect up to 1 in 10 people) were injection site reactions (3.5 per cent) and itching or pruritus (2.6 per cent).[7]

Patients receiving Rebinyn® in the phase 3 study program, paradigm™, achieved consistently higher FIX activity levels than those previously reported with standard FIX products. Once-weekly administration of 40 IU/kg Rebinyn® for prophylaxis in adults maintained a mean FIX activity trough level of 29 per cent,[1] resulting in a median annualized spontaneous bleeding rate (AsBR) of 0.0 and a resolution of majority of target joints.[8] Furthermore, these patients reported an improvement in their quality of life during the trial.[9]

About Rebinyn®

Rebinyn® is a glycopegylated recombinant factor IX (rFIX) administered by intravenous bolus injection. Pegylated products have been approved in hemophilia A[10] and other therapeutic areas.[11,12] Rebinyn® reduces bleeding frequency and has the potential to prevent further bleeds in target joints with less frequent injections for adult patients on prophylaxis,[13] due to a half-life that is five times longer than standard rFIX.[14] Rebinyn® has also received regulatory approval in the EU and the United States. Rebinyn® is available through Canadian Blood Services, and therefore, currently not available in Quebec.

About paradigm™

The paradigm™ clinical trial program comprises several trials that studied the safety, efficacy, PK profile and immunogenicity of Rebinyn® in adult and adolescent populations. The use of Rebinyn® for prophylaxis, on-demand treatment of bleeding and surgery was evaluated. In addition, a trial in previously untreated patients (PUPs) is ongoing.

paradigm™1 PK trial (16 people treated) – a single dose-escalation trial evaluating the safety and PK of Rebinyn®, compared with marketed recombinant and plasma-derived FIX products. Rebinyn® demonstrated a twofold increase in recovery, higher activity levels and a fivefold prolongation of half-life, compared with existing treatment, meaning that Rebinyn® can be incorporated into a once-weekly dosing schedule.[15]

paradigm™2 pivotal trial (74 people treated) – a 52-week, single-blinded, randomised trial evaluating safety, efficacy and PK of Rebinyn® in adults and adolescents undergoing routine prophylaxis and treatment of bleeds. Once-weekly prophylaxis with 40 IU/kg Rebinyn® appeared to have a beneficial safety profile and showed a median spontaneous ABR of 0.0. Furthermore, 97 per cent of breakthrough bleeds were treated successfully.[16]

paradigm™3 surgery trial (11 people treated) – a dedicated trial evaluating safety and efficacy during, and after, major surgical procedures.[17] In all patients, a single preoperative dose provided effective hemostatic coverage, and no patient required additional doses on the day of surgery. Additionally, a median of three doses proved sufficient in maintaining hemostasis during the first 2 weeks following the procedure.[18]

paradigm™4 extension trial (71 people treated) – a safety extension trial with longer-term exposure – demonstrated a well-tolerated profile with no inhibitors or other safety signals identified.[19]

paradigm™5 pediatric trial – a trial including 25 pediatric previously treated patients (ages 0–12 years) who received a prophylactic dose of 40 IU/kg once weekly was conducted. The long-term safety of routine prophylaxis in children has not yet been established.[20] An extension of this study is currently ongoing.

paradigm™6 is an ongoing trial investigating the safety and efficacy of Rebinyn® in PUPs.

About Hemophilia in Canada

Hemophilia is a blood disorder characterized by blood that does not clot normally. People with hemophilia do not bleed more profusely or more quickly than other people, however they bleed for a longer time. It's a hereditary condition, passed on from mother to child at the time of conception, and can affect people from all races, colours and ethnic origins. Hemophilia B is very rare, affecting just 1 in 50,000 people, or about 600 Canadians.[21]

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 other serious chronic conditions: hemophilia, growth disorders and obesity. Headquartered in Denmark, Novo Nordisk employs approximately 42,000 people in 77 countries and markets its products in more than 165 countries. For more information, visit novonordisk.com, Facebook, Twitter, LinkedIn, YouTube.

Further information

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