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BACKGROUNDER

ALPROLIX™

FOR MEDIA ONLY

About ALPROLIX: Enabling Prophylactic Infusions Starting at Least a Week Apart

ALPROLIX™ [Coagulation Factor IX (Recombinant), Fc Fusion Protein] is a recombinant coagulation factor therapy approved in the United States for the control and prevention of bleeding episodes, perioperative (surgical) management and routine prophylaxis (protection) in adults and children with hemophilia B. ALPROLIX is not indicated for immune tolerance induction therapy, which is a treatment for people with inhibitors (neutralizing antibodies that may interfere with the activity of the therapy). The approval of ALPROLIX is the first significant advance in hemophilia B treatment in more than 17 years. ALPROLIX is the only therapy that can reduce bleeding episodes with prophylactic (protective) infusions starting at least a week apart.

ALPROLIX was developed by fusing factor IX to the Fc portion of immunoglobulin G subclass 1, or IgG_1 (a protein commonly found in the body). It is believed that this enables ALPROLIX to use a naturally occurring pathway to prolong the time the therapy remains in the body. While Fc fusion has been used to develop medicines for more than 15 years, Biogen Idec is the only company to apply it in hemophilia.

Clinical Profile

In the largest Phase 3 registrational study in hemophilia B ever completed (involving 123 adults and adolescents), called B-LONG, ALPROLIX was found to be safe and effective in:

- The control and prevention of bleeding episodes
- Perioperative management
- Routine prophylaxis

This study did not evaluate ALPROLIX as an immune tolerance induction therapy in people with inhibitors.

The overall median annualized bleeding rate (ABR), or projected rate of bleeding episodes per year, reported in the study was 3.0 for the weekly prophylaxis arm, with spontaneous bleeding episodes averaging 1.04 per year. In the individualized-interval prophylaxis arm, the overall median ABR was 1.4, with spontaneous bleeding episodes averaging 0.88 per year. This arm's dosing interval started at once every 10 days. More than 90 percent of bleeding episodes in the study were controlled by a single infusion of ALPROLIX.

ALPROLIX was generally well tolerated. No inhibitors were detected and no events involving serious allergic reactions were reported in any study participant. Across routine prophylaxis and on-demand therapy arms, adverse reactions were reported in 8.4 percent of participants. Common adverse reactions (incidence greater than or equal to 1 percent) were headache and oral paresthesia (abnormal sensation in the mouth), which were each reported in two study participants.

Biogen Idec is conducting a Phase 3 study of ALPROLIX in children under the age of 12 called Kids B-LONG, and B-YOND, an extension study to evaluate the therapy's long-term safety and efficacy.

An interim analysis from Kids B-LONG demonstrated that in 23 children under the age of 12 years old who received ALPROLIX, no inhibitors were detected and ALPROLIX's extension of half-life (a measure of

the time therapy remains in the body) was consistent with data reported in adults and adolescents. This interim data, along with the B-LONG study results, supported the U.S. approval of ALPROLIX in children.

About Hemophilia B

Hemophilia B is a rare, chronic, genetic disorder in which the ability of a person's blood to clot is impaired. It is caused by having substantially reduced or no factor IX activity, which is needed for normal blood clotting. Hemophilia B occurs in about one in 25,000 male births annually, and more rarely in females.[1] Approximately 4,000 people in the United States have hemophilia B. According to the World Federation of Hemophilia, an estimated 400,000 people are living with hemophilia and about 28,000 people are currently diagnosed with hemophilia B worldwide.[2] People with hemophilia B experience prolonged bleeding episodes that can cause pain, irreversible joint damage and life-threatening hemorrhages. Prophylactic infusions of factor IX can temporarily replace the missing clotting factor that is needed to control bleeding and prevent new bleeding episodes. The Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation (NHF) recommends prophylaxis as the optimal therapy for people with severe hemophilia B. Based on NHF guidelines, traditional hemophilia B therapy can require prophylactic infusions two or more times a week.

ALPROLIX Global Regulatory Status

ALPROLIX was approved in Canada in March 2014 for the control and prevention of bleeding episodes and routine prophylaxis in adults and children aged 12 and older with hemophilia B. The therapy was approved in the United States in March 2014 for the control and prevention of bleeding episodes, perioperative management and routine prophylaxis in adults and children with hemophilia B. ALPROLIX is not indicated for immune tolerance induction therapy, which is a treatment for people with inhibitors. Regulatory applications for ALPROLIX are currently under review in several countries including Australia and Japan.

Biogen Idec and Swedish Orphan Biovitrum (Sobi) are partners in the development and commercialization of ALPROLIX for hemophilia B. Biogen Idec leads development, has manufacturing rights, and has commercialization rights in North America and all other regions in the world excluding the Sobi territory. Sobi has the right to opt in to assume final development and commercialization in Europe, Russia, the Middle East and Northern Africa**.**

Important Safety Information

Do not use ALPROLIX if you are allergic to ALPROLIX or any of the other ingredients in ALPROLIX.

Tell your healthcare provider if you have or have had any medical problems, take any medicines, including prescription and non-prescription medicines, supplements, or herbal medicines, have any allergies and all your medical conditions, including if you are pregnant or planning to become pregnant, are breastfeeding, or have been told you have inhibitors (antibodies) to factor IX.

Allergic reactions may occur with ALPROLIX. Call your healthcare provider or get emergency treatment right away if you have any of the following symptoms: difficulty breathing, chest tightness, swelling of the face, rash, or hives.

Your body can also make antibodies called, "inhibitors" against ALPROLIX, which may stop ALPROLIX from working properly.

ALPROLIX may increase the risk of formation of abnormal blood clots in your body if you have risk factors for developing clots.

Common side effects of ALPROLIX include headache and abnormal sensation of the mouth. These are not all the possible side effects of ALPROLIX. Talk to your healthcare provider right away about any side effect that bothers you or does not go away, and if bleeding is not controlled using ALPROLIX.

You are encouraged to report negative side effects of prescription drugs to the FDA. Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see www.ALPROLIX.com for full Prescribing Information.

For more information on ALPROLIX clinical studies, visit www.ALPROLIX.com or www.ClinicalTrials.gov.

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[1] National Hemophilia Foundation. Hemophilia B. http://www.hemophilia.org/NHFWeb/MainPgs/MainNHF.aspx?menuid=181&contentid=46&rptname=bleeding. Accessed January 09, 2014.
[2] World Federation of Hemophilia. Annual Global Survey 2012. http://www1.wfh.org/publications/files/pdf-1574.pdf. Accessed January 28, 2014.