News Release

FOR IMMEDIATE RELEASE

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EMERGENT BIOSOLUTIONS EXPANDS COMMERCIAL PRODUCT PORTFOLIO WITH FDA APPROVAL OF IXINITY, A RECOMBINANT FACTOR IX TREATMENT FOR HEMOPHILIA B

GAITHERSBURG, Md.—April 30, 2015—Emergent BioSolutions Inc. (NYSE: EBS) today announced that the U.S. Food and Drug Administration (FDA) has approved IXINITY® [coagulation factor IX (recombinant)], an intravenous recombinant human coagulation factor IX therapeutic for the control and prevention of bleeding episodes and for perioperative management in adults and children, ≥12 years of age, with Hemophilia B. Hemophilia B is a bleeding disorder caused by a mutation on the factor IX gene resulting in a deficiency of clotting factor IX in the blood, which controls bleeding.

"Emergent is committed to making a positive impact on the Hemophilia B community, including people living with this chronic bleeding disorder as well as their families, caregivers, and healthcare providers," said Barry Labinger, Executive Vice President and President, Biosciences Division at Emergent BioSolutions. "We believe the community will benefit from additional choices for the management of Hemophilia B, such as IXINITY, as well as the various patient education and support programs we plan to offer."

The approval of IXINITY is based on a global clinical trial in which IXINITY showed a mean incremental recovery of 0.98 IU/dL and a mean terminal half-life of 24 hours. IXINITY is a third-generation[1] treatment with no factor IX inhibitors developed in clinical trials. Simultaneous with this approval, the company is launching the IXINITY IXperience™ Concierge, available at 1-855-IXINITY, which will provide information on IXINITY and other programs designed with the needs of people with Hemophilia B and their community in mind.

"I am very excited about the approval of IXINITY and give my congratulations to Emergent for reaching this wonderful milestone. Our goal for IXINITY was to offer choice to a wider group of patients than ever before and I am proud that Emergent has continued this work," said John Taylor, founder of the Coalition for Hemophilia B and co-founder of Inspiration Biopharmaceuticals, which began development of IXINITY prior to the product being acquired by Emergent through its acquisition of Cangene Corporation.

Clinical Trial Overview

The approval of IXINITY is based on results from a Phase I/III, open-label, uncontrolled, multi-center, global study evaluating safety, efficacy, and pharmacokinetics in previously treated adults and children 12 years of age or older with severe to moderately severe (factor IX level <2%)

Hemophilia B. The pharmacokinetic results (N=32) showed that IXINITY achieved similar pharmacokinetic behavior as nonacog alfa, another licensed recombinant coagulation factor IX product. Subjects (N=68) received IXINITY either as routine or on-demand treatment of bleeding episodes. Fifty-five (55) subjects received IXINITY for >50 exposure days and 45 received IXINITY for > 100 exposure days. No significant reduction in steady state factor IX levels or alteration in pharmacokinetic behavior occurred over time. The median duration of treatment on study was 16.2 months (range 2.4-39.6) for the routine treatment regimen and 14.1 months (range 2.3-36.9) for the on-demand treatment regimen. In the studies, a total of 508 bleeding episodes were treated with IXINITY, of which 286 bleeds were recorded for subjects treated with the routine treatment regimen and 222 in the on-demand regimen. A majority of the bleeds, 84%, were resolved by one or two infusions of IXINITY. Hemostatic efficacy at resolution of a bleed was rated by the subjects as excellent or good in 84% of all treated bleeding episodes. Excellent was defined as a dramatic response with abrupt pain relief and clear reduction in joint or hemorrhage site size; good was defined as pain relief or reduction in hemorrhage site size that may have required an additional infusion for resolution. In addition, administration of IXINITY resulted in hemostasis in study participants who underwent major surgical procedures.

During the clinical study, a total of 14 adverse reactions were reported among 6 of the 77 subjects. The most common adverse drug reaction, observed in 2.6% of subjects in clinical trials, was headache. Other adverse reactions reported included asthenia (weakness), apathy (lack of feeling, emotion, interest, or concern), depression, dysgeusia (taste alteration), hemophilia, influenza (flu), injection site discomfort, lethargy (lack of energy) and skin rash. No subjects developed inhibitors (antibodies that interfere with activity of therapy). There were no reports of thrombotic events or allergic reactions.

About Hemophilia B

Hemophilia B is a congenital bleeding disorder caused by a deficiency of coagulation factor IX. It affects approximately 1:25,000 male births, with approximately 4,000 persons affected in the U.S. The clinical spectrum may include spontaneous or trauma-induced bleeding into joints, muscles, and soft tissues, resulting in joint damage, reduction in mobility and severe arthritis, all of which negatively impact health-related quality of life. The primary aim of care is to prevent and treat bleeding by replacement with the deficient clotting factor.

About IXINITY

IXINITY is indicated for the control and prevention of bleeding episodes and for perioperative management for adults and children ≥12 years of age with Hemophilia B. IXINITY is not indicated for induction of immune tolerance in patients with Hemophilia B. IXINITY contains recombinant coagulation factor IX (trenonacog alfa). Trenonacog alfa is a purified single chain glycoprotein derived from Chinese hamster ovary (CHO) cells and has an amino acid sequence that is comparable to the Thr148 allelic form of plasma-derived factor IX. No human or animal proteins are added during any stage of manufacturing or formulation of IXINITY. The recombinant factor IX is purified by a chromatography purification process. The process includes three validated steps for virus inactivation and removal. The process also includes a validated manufacturing step to reduce the presence of CHO proteins in the final drug product.

Indications and Important Risk Information

IXINITY [Coagulation Factor IX (Recombinant)] Lyophilized Powder for Solution for Intravenous Injection is a coagulation factor IX (recombinant) indicated in adults and children ≥ 12 years of age with Hemophilia B for control and prevention of bleeding episodes, and for perioperative management. IXINITY is not indicated for induction of immune tolerance in patients with Hemophilia

B. IXINITY is contraindicated in patients who have known hypersensitivity to IXINITY or its excipients, including hamster protein.

Hypersensitivity reactions, including anaphylaxis, may occur following IXINITY administration. Discontinue use of IXINITY if hypersensitivity symptoms occur, and initiate appropriate treatment. Regularly evaluate patients for the development of factor IX inhibitors by appropriate clinical observations and laboratory tests. If expected factor IX activity plasma levels are not attained, or, if bleeding is not controlled as expected with a certain dose, perform an assay that measures factor IX inhibitor concentration. An association between the occurrence of a factor IX inhibitor and allergic reactions has been reported. Individuals with factor IX inhibitors may be at increased risk of severe hypersensitivity reactions or anaphylaxis if re-challenged.

Nephrotic syndrome may occur with IXINITY. Nephrotic syndrome has been reported following attempted immune tolerance induction in Hemophilia B patients with factor IX inhibitors and a history of allergic reactions. Thromboembolism may occur when using IXINITY (e.g., pulmonary embolism, venous thrombosis, and arterial thrombosis). Patients may develop hypersensitivity to hamster (CHO) protein as IXINITY contains trace amounts. The most common adverse drug reaction observed in >2% of patients in clinical trials was headache.

Please see full Prescribing Information at www.IXINITY.com.

About Emergent BioSolutions
Emergent BioSolutions is a global specialty biopharmaceutical company seeking to protect and enhance life by offering specialized products to healthcare providers and governments to address medical needs and emerging health threats. Additional information about the company may be found at www.emergentbiosolutions.com. Follow us @emergentbiosolu.

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1. A third-generation product is defined by the National Hemophilia Foundation Medical and Scientific Advisory Council as recombinant factor IX (rFIX) produced in Chinese hamster ovary cells; no human or animal plasma-derived proteins are used in the manufacturing process.

Cangene Corporation, a subsidiary of Emergent BioSolutions, Inc., Winnipeg, MB, R3T 5Y3, Canada.
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