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News Release

Intended for U.S. media only

FDA Approves Bayer's KOVALTRY® Antihemophilic Factor (Recombinant) for the Treatment of Children and Adults with Hemophilia A

Whippany, NJ, March 17, 2016 – The U.S. Food and Drug Administration has approved Bayer's KOVALTRY® Antihemophilic Factor (Recombinant), an unmodified, full-length factor VIII compound for the treatment of hemophilia A in children and adults. The approval is based on results from the LEOPOLD (Long-Term Efficacy Open-Label Program in Severe Hemophilia A Disease) clinical trials, which supported the approval of KOVALTRY for routine prophylaxis to reduce the frequency of bleeding episodes. KOVALTRY can be used two or three times per week in adolescents and adults, and two or three times per week or every other day in children.

"In the LEOPOLD trials, KOVALTRY reduced bleeding episodes in patients with hemophilia A when infused twice to three times per week with routine prophylaxis," said Sanjay P. Ahuja, MD, LEOPOLD investigator and Director, Hemostasis & Thrombosis Center at University Hospitals Rainbow Babies & Children's Hospital and Associate Professor of Pediatrics at Case Western Reserve University School of Medicine in Cleveland, Ohio. "KOVALTRY may offer appropriate patients a twice-weekly prophylaxis dosing option."

Hemophilia A, also known as factor VIII deficiency or classic hemophilia, is a largely inherited bleeding disorder in which one of the proteins needed to form blood clots in the body is missing or reduced. Hemophilia A is the most common type of hemophilia and is

characterized by prolonged or spontaneous bleeding, especially into the joints, muscles or internal organs. It is estimated that 16,000 people are living with hemophilia A in the U.S. today.[i] Treatment of hemophilia A involves infusing replacement factor into a vein.

“Bayer has been committed to providing treatments for hemophilia A for more than 20 years," said Dario Mirski, MD, Bayer's senior vice president and head of medical affairs for the Americas. “We're proud to have used that knowledge to develop KOVALTRY.”

Earlier this year, Bayer received approval of KOVALTRY in Europe and Canada. The company has submitted an application for approval of KOVALTRY in Japan, and plans to file for approval in other countries in the coming months.

“Hemophilia care has changed significantly in recent years, but we have a long way to go to help those living with hemophilia,” said Val Bias, CEO, the National Hemophilia Foundation. “It is vitally important that people are able to choose from a range of treatments, and we applaud Bayer for bringing forth new product options to help people manage their disease.”

About LEOPOLD

The clinical trial program was designed to evaluate KOVALTRY pharmacokinetics, safety, efficacy of prophylaxis, treatment of bleeds and perioperative management in adults, adolescents, and children with severe hemophilia A.

LEOPOLD 1 was a multi-center, open-label, cross-over, uncontrolled study in adolescent and adult (age ≥12 years to <65 years) previously treated patients (PTPs) evaluating the pharmacokinetics, efficacy and safety of routine prophylaxis, and perioperative management of bleeding with KOVALTRY. The annualized bleeding rate (ABR) was the primary efficacy variable.

LEOPOLD 2 was a multi-center, open-label, cross-over, uncontrolled, randomized study in adolescent and adult (age ≥12 years to <65 years) PTPs evaluating the superiority of prophylaxis over on-demand treatment with KOVALTRY over a one-year treatment period. ABR was the primary efficacy variable.

LEOPOLD Kids Part A was a multi-center, open-label, uncontrolled study in pediatric (≤12 years of age) PTPs evaluating the pharmacokinetics, efficacy and safety of routine prophylaxis, and perioperative management of bleeding with KOVALTRY. The primary efficacy variable was annualized number of total bleeds during routine prophylaxis that occurred within 48 hours of previous prophylaxis infusion.

The most frequently reported adverse reactions in the clinical trials (>= 3%) were headache, pyrexia (fever), and pruritus (itchy rash).

KOVALTRY® Indications

- KOVALTRY® is a medicine used to replace clotting factor (Factor VIII or antihemophilic factor) that is missing in people with hemophilia A.
- KOVALTRY® is used to treat and control bleeding in adults and children with hemophilia A. KOVALTRY® can reduce the number of bleeding episodes in adults and children with hemophilia A when used regularly (prophylaxis). Your healthcare provider may give you KOVALTRY® when you have surgery.
- KOVALTRY® is not used to treat von Willebrand Disease.

KOVALTRY® Important Safety Information

- You should not use KOVALTRY® if you are allergic to rodents (like mice and hamsters) or any ingredients in KOVALTRY®
- Tell your healthcare provider if you have heart disease or are at risk for heart disease.
- The common side effects of KOVALTRY® are headache, fever, and itchy rash.
- Allergic reactions may occur with KOVALTRY®. Call your healthcare provider right away and stop treatment if you get tightness of the chest or throat, dizziness, decrease in blood pressure, and nausea.
- Your body can also make antibodies, called “inhibitors,” against KOVALTRY®, which may stop KOVALTRY® from working properly. Consult with your healthcare

provider to make sure you are carefully monitored with blood tests for the development of inhibitors to Factor VIII.

- Tell your healthcare provider about any side effect that bothers you or that does not go away.
- Call your healthcare provider right away if bleeding is not controlled after using KOVALTRY®.

For important risk and use information, please see the full prescribing information.

Recommended Dosing for KOVALTRY®

Individualize the patient's dose based on clinical response.

Adults and adolescents: 20 to 40 IU of KOVALTRY per kg of body weight two or three times per week.

Children ≤12 years old: 25 to 50 IU of KOVALTRY per kg body weight twice weekly, three times weekly, or every other day according to individual requirements

About Bayer Hematology

Hematology at Bayer includes numerous compounds in various stages of development for hemophilia, sickle cell anemia, and other blood and bleeding disorders. Together, these compounds reflect the company's commitment to research and development, prioritizing specific targets for intervention with the potential to improve the way that rare blood and bleeding disorders are treated.

Bayer: Science For A Better Life

Bayer is a global enterprise with core competencies in the Life Science fields of health care and agriculture. Its products and services are designed to benefit people and improve their lives. At the same time, the Group aims to create value through innovation, growth and high earning power. Bayer is committed to the principles of sustainable development and to its social and ethical responsibilities as a corporate citizen. In fiscal 2015, the Group employed around 117,000 people and had sales of EUR 46.3 billion.

Capital expenditures amounted to EUR 2.6 billion, R&D expenses to EUR 4.3 billion. These figures include those for the high-tech polymers business, which was floated on the stock market as an independent company named Covestro on October 6, 2015. For more information, go to www.bayer.us.

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

Please consult your healthcare provider to determine if prescription KOVALTRY® is right for you.

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[i] http://www.cdc.gov/ncbddd/hemophilia/data.html

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