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News Release

Not intended for U.S. and UK Media

Bayer Receives FDA Approval for Kovaltry® for the Treatment of Children and Adults with Hemophilia A

Leverkusen, March 17, 2016 – The U.S. Food and Drug Administration today approved Bayer's Kovaltry® antihemophilic factor VIII (recombinant) for the treatment of hemophilia A in children and adults. Kovaltry is an unmodified, full-length recombinant factor VIII product. The approval is based on results from the LEOPOLD clinical trials, which demonstrated that Kovaltry controls bleeds, and reduces frequency of bleeding episodes with routine prophylaxis in children and adults with hemophilia A when used two or three times per week.

"We are proud that, based on our comprehensive development program, physicians can now consider twice weekly prophylactic treatment with Kovaltry among the treatment options," said Dr. Joerg Moeller, member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Development. "At Bayer we have been developing and producing treatments for hemophilia A for more than two decades."

Bayer recently received approval of Kovaltry in Europe and Canada. Bayer is pursuing regulatory approvals of Kovaltry for the treatment of hemophilia A in further markets across the world.

The approvals of Kovaltry build upon Bayer's growing hematology portfolio which also includes Kogenate® Bayer, a product currently on the market in more than 70 countries, as well as a long-acting recombinant factor VIII pipeline candidate. Bayer is also pursuing alternative treatment approaches in preclinical and early clinical development, such as factor VIII gene therapy and inhibition of tissue factor pathway inhibitor (TFPI) in hemophilia, as well as in other blood disorders.

About LEOPOLD
The LEOPOLD (Long-Term Efficacy Open-Label Program in Severe Hemophilia A Disease) Clinical Development Program consists of three multinational clinical trials designed to evaluate the pharmacokinetics, efficacy and safety of Kovaltry in subjects with severe hemophilia A (<1% FVIII:C). The combined trials evaluated Kovaltry in more than 200 children and adults with severe hemophilia A from 60 sites in 25 countries worldwide.

About Hemophilia
Hemophilia affects approximately 400,000 people around the world and is a largely inherited disorder in which one of the proteins needed to form blood clots is missing or reduced. Hemophilia A is the most common type of hemophilia where factor VIII is missing or reduced. Hemophilia A affects 1 in 10,000 males, including more than 30,000 in Europe, and 16,000 in the U.S. today. Over time, hemophilia A can cause prolonged or spontaneous bleeding, especially into the joints, muscles or internal organs.

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 quality of life. 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.com.

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Forward-Looking Statements

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