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Investor News

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Bayer Receives Approval for Kovaltry® for the Treatment of Hemophilia A in Japan

Leverkusen, Germany, March 29, 2016 – Bayer has received approval from the Ministry of Health, Labour and Welfare (MHLW) in Japan for Kovaltry®, a full-length unmodified, recombinant factor VIII product for the treatment of hemophilia A. The approval is based on results from the LEOPOLD clinical trials, which demonstrated that Kovaltry controls and prevents bleeding in children, adolescents and adults with hemophilia A.

“The approval of Kovaltry in Japan is an important example of Bayer’s long-standing and continued commitment to the Hemophilia community,” said Dr. Joerg Moeller, member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Development. “We are proud that Kovaltry, which demonstrated efficacy as a two or three-times per week prophylactic treatment, will provide flexibility to tailor the treatment to the specific needs of people living with hemophilia A.”

Kovaltry is already approved in Canada, the US, and the EU. Bayer is pursuing regulatory approvals of Kovaltry for the treatment of hemophilia A in further markets across the world.

The approval of Kovaltry builds upon Bayer’s growing hematology portfolio which also includes Kogenate® Bayer, a product currently on the market in more than 70 countries globally, 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 and 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 about 5,000 in Japan. 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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