Bayer AG
Investor Relations
51368 Leverkusen
Germany
www.investor.bayer.com

Investor News

Not intended for U.S. and UK Media

Bayer Receives EU Approval of Kovaltry® for Treatment of Hemophilia A

Leverkusen, Germany, February 22, 2016 – Bayer has received approval from the European Commission of Kovaltry® for the treatment of hemophilia A in patients of all age groups. Kovaltry is an unmodified full-length recombinant factor VIII product, that in clinical trials has demonstrated control of bleeds, and protection from bleeds in hemophilia A patients when used prophylactically two or three times per week.

“This approval is the next milestone in our long-term effort to bring new and innovative treatments to the market,” said Dr. Joerg Moeller, member of the Executive Committee of Bayer AG's Pharmaceutical Division and Head of Development. “Bayer has a long-term commitment to the Hemophilia community and we’re excited to introduce Kovaltry as a new treatment option for patients with hemophilia A.”

“Hemophilia treatment has advanced considerably over the past decades; however, there is more that can be done to improve patients’ quality of life,” said Prof. Dr. med. Johannes Oldenburg, Chairman and Director of the Institute of Experimental Hematology and Transfusion Medicine, University Clinic Bonn. “The demonstrated efficacy of two and three times per week prophylactic treatment provides the flexibility to tailor the treatment to the specific need of each person affected by hemophilia A.”

The approval was based on the LEOPOLD (Long-Term Efficacy Open-Label Program in Severe Hemophilia A Disease) Clinical Development Program, which consisted of three multinational clinical trials designed to evaluate the pharmacokinetics, efficacy and safety of Kovaltry. The combined trials evaluated Kovaltry in more than 200 children and adults with severe hemophilia A from 60 sites and 25 countries worldwide.

Bayer is pursuing regulatory approvals of Kovaltry for the treatment of hemophilia A in many markets across the world.

The European 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 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. 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 2014, the Group employed around 119,000 people and had sales of EUR 42.2 billion. Capital expenditures amounted to EUR 2.5 billion, R&D expenses to EUR 3.6 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.

Bayer AG, Investor Relations contacts:

Dr. Alexander Rosar (+49-214-30-81013)
Dr. Jürgen Beunink (+49-214-30-65742)
Peter Dahlhoff (+49-214-30-33022)
Judith Nestmann (+49-214-30-66836)
Constance Spitzer (+49-214-30-33021)
Dr. Olaf Weber (+49-214-30-33567)

Forward-Looking Statements
This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer management. Various known and unknown risks, uncertainties and other factors could lead to material differences between the actual future results, financial situation, development or performance of the company and the estimates given here. These factors include those discussed in Bayer's public reports which are available on the Bayer website at www.bayer.com. The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.