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## Investor News

**Not intended for U.S. and UK Media**

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The World Federation of Hemophilia 2012 World Congress:

### **Kogenate® Bayer was Effective in Reducing Bleeding Frequency when used as Secondary Prophylaxis in Adults with Severe Hemophilia A**

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**Leverkusen, Germany, July 12, 2012** – Bayer HealthCare announced today that Kogenate® Bayer (octocog alfa) was effective and well tolerated at reducing bleeding frequency in adults with severe hemophilia A when administered as a secondary prophylactic regimen versus on-demand treatment. These data were presented as a late-breaker at the 50<sup>th</sup> annual World Federation of Hemophilia (WFH) World Congress, July 8-12, in Paris, France.

“Patients on the prophylactic regimen experienced significantly fewer bleeds than those using on-demand treatment,” said Marilyn Manco-Johnson, M.D., Principal Investigator of the study, and Director, Mountain States Regional Hemophilia and Thrombosis Center, University of Colorado at Denver and Health Sciences Center. “Those bleeds that did occur on the prophylactic regimen were predominantly mild to moderate. Such information can help healthcare professionals provide appropriate treatment to their patients.”

The SPINART study, which is ongoing, was designed to evaluate the effect of secondary prophylaxis with Kogenate Bayer on bleeding frequency and joint damage compared to episodic treatment in adults with severe hemophilia A.

84 subjects were randomized to either receive prophylaxis (25 IU/kg three times per week) or on-demand treatment, with a total follow up period of 3 years. After a median follow-up period of 1.7 years, results show significantly fewer total bleeding events occurred per year with prophylaxis vs. on-demand (median, 0.0 vs. 27.9 respectively,  $p < 0.0001$ . No bleeds seen in 52% of prophylaxis patients). The results also showed

significantly fewer joint bleeds on prophylaxis as compared to on-demand (median, 0.0 vs. 21.2. No bleeds seen in 62% of prophylaxis patients). The majority of bleeds in prophylaxis patients were mild (44%) or moderate (36%), while most bleeds in on-demand patients were moderate (58%) or severe (19%). Observed adverse events were consistent with the product insert and no inhibitor formation was observed.

Routine prophylaxis, the regular use of clotting factor concentrates, can prevent bleeds before they start and help reduce or prevent joint damage<sup>i</sup>. *Primary prophylaxis* is defined as treatment started before or immediately after the first joint bleed, and before the age of two years, while *secondary prophylaxis* is defined as treatment started after multiple bleeding episodes have occurred<sup>ii</sup>.

### **About SPINART**

Bayer's SPINART study follows the Joint Outcome Study (JOS) which demonstrated that the use of Kogenate Bayer as routine prophylaxis compared with an enhanced on-demand regimen reduced the frequency of bleeding episodes and risk of joint damage in children with severe hemophilia A and no pre-existing joint damage. The effects of secondary prophylaxis upon bleeding episodes have not yet been fully determined. SPINART is an ongoing, phase III study evaluating the effect of secondary prophylaxis with rFVIII on bleeding frequency (number of bleeds per year) and on joint damage compared to episodic treatment in adults and adolescents.

### **About Hemophilia A**

Hemophilia A, also known as factor VIII deficiency or classical hemophilia is largely an 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. Approximately 400,000 people around the world have hemophilia.

To learn more about hemophilia, please visit:

[www.bayerpharma.de/hemophilia](http://www.bayerpharma.de/hemophilia)

### **About Bayer HealthCare**

The Bayer Group is a global enterprise with core competencies in the fields of health care, nutrition and high-tech materials. Bayer HealthCare, a subgroup of Bayer AG with annual sales of EUR 17.2 billion (2011), is one of the world's leading, innovative companies in the healthcare and medical products industry and is based in Leverkusen,

Germany. The company combines the global activities of the Animal Health, Consumer Care, Medical Care and Pharmaceuticals divisions. Bayer HealthCare's aim is to discover, develop, manufacture and market products that will improve human and animal health worldwide. Bayer HealthCare has a global workforce of 55,700 employees (Dec 31, 2011) and is represented in more than 100 countries. Find more information at [www.bayerhealthcare.com](http://www.bayerhealthcare.com).

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**Forward-Looking Statements**

This release may contain forward-looking statements based on current assumptions and forecasts made by Bayer Group or subgroup 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](http://www.bayer.com). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

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<sup>i</sup> Manco-Johnson, MJ, Abshire, TC, *et al.* Prophylaxis versus episodic treatment to prevent joint disease in boys with severe hemophilia, *NEJM* 2007;357(6):535–544.

<sup>i</sup> Berntorp E, Astermark J, *et al.* Consensus perspectives on prophylactic therapy for haemophilia: summary statement. *Haemophilia* 2003, 9 (suppl), 1-4.