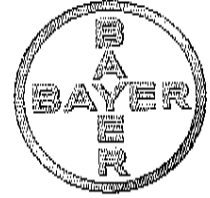


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## Investor News

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### **Bayer HealthCare Receives FDA Approval for Kogenate<sup>®</sup> FS with BIO-SET<sup>®</sup>**

Innovative reconstitution system will offer safety and simplicity for people living with hemophilia A

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**Leverkusen / November 28, 2005** – The Biological Products division of Bayer HealthCare LLC (Bayer BP) announced today that Kogenate<sup>®</sup> FS (Antihemophilic Factor [Recombinant], Formulated with Sucrose) with BIO-SET<sup>®</sup> has been approved by the United States Food and Drug Administration (FDA). Kogenate<sup>®</sup> FS with BIO-SET<sup>®</sup> becomes the first integrated reconstitution system for recombinant factor VIII that eliminates the risk of accidental needle-stick injuries during reconstitution.

“The hemophilia community has been anticipating the approval of this new reconstitution device,” said Regina Butler, R.N., hemophilia nurse coordinator at Children’s Hospital of Philadelphia. “Kogenate<sup>®</sup> FS with BIO-SET<sup>®</sup> is a treatment option that will fit well into the lives of our patients. With fewer components, fewer steps in the reconstitution process, and fewer exposed needles, Kogenate<sup>®</sup> FS with BIO-SET<sup>®</sup> will provide patients with a safe, convenient way to prepare their hemophilia treatment.”

Compared to the conventional vial-to-vial reconstitution method, Kogenate<sup>®</sup> FS with BIO-SET<sup>®</sup> needleless reconstitution system requires fewer than half the components, eliminates the need for double-sided transfer and filter needles, and involves 50 percent fewer steps during the reconstitution process. Results from a recently published study in the *Journal of Outcomes Research*<sup>1</sup>, showed 74 percent of respondents – including patients, caregivers, and healthcare professionals – preferred Kogenate<sup>®</sup> FS with BIO-SET<sup>®</sup> over the evaluated reconstitution methods (the standard reconstitution method and the plastic double-spike stopcock reconstitution device). In

fact, Kogenate® FS with BIO-SET® ranked highest as "favorite device overall" in this study.

"By offering improved safety from needle-stick injuries, proven efficacy, and ease of use, Kogenate® FS with BIO-SET® is a major advance in hemophilia care" said Terry Tenbrunsel, Vice President, Sales and Marketing, Bayer Biological Products. "This is a significant milestone for us at Bayer BP, as it represents the next step in our efforts to advance hemophilia care by providing products and services that improve patient convenience and quality of life."

BIO-SET®, which has received an enthusiastic response in Canada and several EU countries earlier this year, will be available for the U.S. hemophilia community in early 2006.

The FDA also recently approved labeling amendments allowing room temperature storage for Kogenate® FS. Kogenate® FS with BIO-SET® can be stored at 77°F (25°C) for up to three months. These recent approvals further strengthen the excellent record of clinical safety and efficacy of Kogenate® products, represented by more than 17 years of clinical experience.

BIO-SET® is a trademark of Biodome SAS.

#### **About Hemophilia**

Hemophilia is an inherited bleeding disorder characterized by prolonged or spontaneous bleeding, especially into the muscles, joints, or internal organs. About 17,000 Americans have hemophilia. The disease is caused by deficient or defective blood coagulation proteins, known as factor VIII or IX. The most common form of the disease is hemophilia A, or classic hemophilia, in which the clotting factor VIII is either deficient or defective. Hemophilia B is characterized by deficient or defective factor IX.

#### **About Bayer HealthCare AG**

Bayer HealthCare AG, a subgroup of Bayer AG with sales of approximately 8.9 billion Euro in 2004, is one of the worlds leading, innovative companies in the health care and medical products industry.

The company combines the global activities of the divisions Animal Health, Biological Products, Consumer Care, Diagnostics Professional Testing Systems and

Diagnostics Self Testing Systems, and Pharmaceuticals. Bayer HealthCare employs 34,600 people.

Our aim is to discover and manufacture innovative products that will improve human and animal health worldwide. Our products enhance well-being and quality of life by diagnosing, preventing, and treating disease.

Leverkusen, November 28, 2005

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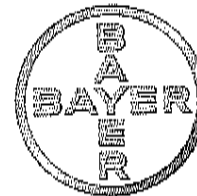
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**Forward-looking statements**

This news release contains forward-looking statements based on current assumptions and forecasts made by Bayer Group 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 our public reports filed with the Frankfurt Stock Exchange and with the U.S. Securities and Exchange Commission (including our Form 20-F). The company assumes no liability whatsoever to update these forward-looking statements or to conform them to future events or developments.

<sup>1</sup> Butler, et al. Evaluation of user preference for a needleless factor VIII delivery device for haemophilia patients, *Journal of Outcomes Research* 2004; 8:63-78.

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## Investor News

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### **Avelox<sup>®</sup> Approved in US to Treat Complicated Intra-abdominal Infections**

Once-a-day Dosage Offers Effective and Convenient Treatment Option

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**Leverkusen / November 30, 2005** – Bayer HealthCare announced today that the FDA has approved its quinolone antibiotic Avelox<sup>®</sup> (moxifloxacin) for the treatment of complicated intra-abdominal infections (cIAI) in the US. This news follows just six months after the US regulator approved Avelox in complicated skin and skin structure infections (cSSSI) and represents a further broadening of Avelox's key indications beyond respiratory tract infections. Avelox is now the only promoted fluoroquinolone monotherapy approved by the FDA for the treatment of cIAI. In the US, Avelox is marketed by Bayer's partner Schering-Plough Corporation.

Intra-abdominal infections can be caused by conditions such as trauma, intra-abdominal surgery or other diseases that result in spillage or spread of bacteria from the gastrointestinal tract into the abdomen. There are approximately 3.5 million cases each year in the US<sup>1</sup>.

"Avelox offers considerable benefits over standard therapy for intra-abdominal infections" said Dr Martin Springsklee, Head of Anti-Infective Global Clinical Development from Bayer HealthCare's Pharmaceuticals Division, "Not only does it offer the convenience of a single daily-dose monotherapy but also allows an easy step-down from IV to oral treatment. This makes Avelox an attractive proposition for healthcare professionals treating this indication".

Clinical trials demonstrated that sequential IV to oral Avelox therapy given once daily was as effective as IV piperacillin/tazobactam given four times daily followed by oral amoxicillin/clavulanic acid twice daily. A second study compared Avelox with IV

ceftriaxone plus metronidazole followed by oral amoxicillin/clavulanic acid. Avelox was effective at eradicating the key pathogens in cIAls including *E.coli* and *B.fragilis*.

“The additional indications this year of first cSSSI and now LAI will make Avelox an even more attractive option for hospital formulary committees and offer substantial opportunities for growth in the hospital market.” said Alan Westwood, Vice-President, Anti-infective Global Strategic Marketing from Bayer HealthCare’s Pharmaceuticals Division.

Bayer plans to make a submission to the European Regulatory authorities for this indication in due course.

#### **About Avelox®**

In Europe<sup>2</sup>, Avelox® IV (+ oral sequential therapy) is approved to treat Community Acquired Pneumonia (CAP), and Complicated Skin and Skin Structure Infections (cSSSI).

Avelox® Oral is approved to treat Community Acquired Pneumonia (CAP) – except severe cases, Acute Bacterial Sinusitis (ABS) where adequately diagnosed, and Acute Exacerbations of Chronic Bronchitis (AECB).

In the US, Avelox is approved to Acute Exacerbations of Chronic Bronchitis (AECB), Acute Bacterial Sinusitis (ABS), Community Acquired Pneumonia (CAP), Uncomplicated Skin and Skin Structure Infections (uSSSI), Complicated Skin and Skin Structure Infections (cSSSI) and Complicated Intra-Abdominal Infections (cIAI).

In Germany Avelox is known as Avalox.

For Avelox prescribing information and indicated organisms, log on to [www.avelox.com](http://www.avelox.com) or email [global.avelox@bayer.com](mailto:global.avelox@bayer.com).

#### **About Bayer HealthCare AG**

Bayer HealthCare AG, a subsidiary of Bayer AG, is one of the world’s leading, innovative companies in the health care and medical products industry. In 2004, the Bayer HealthCare subgroup generated sales amounting to some 8.5 billion Euro.

The company combines the global activities of the divisions Animal Health, Biological Products, Consumer Care, Diabetes Care, Diagnostics and Pharmaceuticals. Bayer HealthCare employed 35,300 people worldwide in 2004.

Bayer HealthCare's aim is to discover and manufacture innovative products that will improve human and animal health worldwide. The products enhance well-being and quality of life by diagnosing, preventing and treating disease.

Leverkusen, November 30, 2005

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**References:**

1. Data Source: The Hospital Antibiotic Market Guide by AMR/Arlington Medical Resources, Inc.; MAT June 2004. (Intra-abdominal Infection cases based on Bayer HealthCare customized definition)
2. Avelox IV is licensed in the following 17 European Member States: Austria, Belgium, Denmark, Finland, Germany, Greece, Republic of Ireland, Luxembourg, Malta, The Netherlands, Sweden, Hungary, Estonia, Latvia, Lithuania, Slovakia and Slovenia.