Bayer HealthCare

News Release

FDA Approves New 3000 IU Vial Size for Kogenate® FS, antihemophilic factor (recombinant)

Larger Vial Provides Greater Convenience for Patients Requiring Higher Dose

WAYNE, NJ, August 7, 2009 – Today, Bayer HealthCare Pharmaceuticals announced that the U.S. Food and Drug Administration (FDA) has approved a 3000 IU (international unit) vial size of **Kogenate® FS**, antihemophilic factor (recombinant). The new vial size offers greater convenience for patients with hemophilia A who require a higher dose.

The 3000 IU vial may eliminate the need for combining smaller vials and may allow some patients to achieve more precise dosing. It is available in a conventional vial-to-vial reconstitution system and in **Kogenate FS** Grab & Go packaging with BIO-SET®, a compact and complete reconstitution system. Grab & Go includes the Terumo® SURFLO® Infusion Set with filter and other materials necessary for safe reconstitution and fast recombinant Factor VIII treatment in a small, tamper-evident box with anticounterfeiting features.

"The availability of **Kogenate FS** in a 3000 IU vial demonstrates Bayer's commitment to adolescent and adult patients, who are more likely to have a need for higher doses and who will appreciate the greater convenience of the larger vial," said Joni Osip, RN, MS, Hemophilia Nurse Coordinator, Center for Bleeding and Clotting Disorders at the University of Minnesota Medical Center, Fairview, in Minneapolis.

The **Kogenate FS** line of products now includes the following vial sizes: 250, 500, 1000, 2000 and 3000 IU. **Kogenate FS** has one of the smallest diluent volumes available. The 250, 500 and 1000 IU vial sizes are provided with 2.5 mL of diluent; the 2000 and 3000 IU vial sizes are reconstituted with 5 mL of diluent. The 3000 IU vial size is now part of the **Kogenate FS** Free Trial Program, which is open to people with hemophilia A who meet program eligibility criteria.

“The 3000 IU vial size is being offered in response to customer needs and is part of Bayer’s ongoing efforts to introduce enhancements for the benefit of the people who are treated with **Kogenate® FS**,” said Paul Bedard, Vice President and General Manager, Hematology, Bayer HealthCare Pharmaceuticals.

For additional information on **Kogenate® FS**, the 3000 IU vial size and the **Kogenate FS** Free Trial Program, please visit www.kogenatefs.com/3000IU.

INDICATIONS

Kogenate® FS, antihemophilic factor (recombinant), is a recombinant factor VIII treatment indicated for the control and prevention of bleeding episodes and peri-operative management in adults and children (0-16 years) with hemophilia A. **Kogenate FS** is also indicated for routine prophylaxis to reduce the frequency of bleeding episodes and the risk of joint damage in children with hemophilia A with no pre-existing joint damage.

IMPORTANT SAFETY INFORMATION ABOUT KOGENATE® FS

The most serious adverse reactions are systemic hypersensitivity reactions and the development of high titer inhibitors necessitating alternative treatments to AHF. The most common adverse reactions observed in clinical trials were inhibitor formation in previously untreated or minimally treated patients, skin-associated hypersensitivity reactions, infusion site reactions, and central venous access device (CVAD) line-associated infections.

Kogenate® FS is contraindicated in patients who have manifested life-threatening immediate hypersensitivity reactions, including anaphylaxis, to the product or its components, including mouse or hamster proteins.

You are encouraged to report negative side effects of prescription drugs to the FDA.
Visit www.fda.gov/medwatch, or call 1-800-FDA-1088.

Please see the full prescribing information for important risk and use information at www.kogenatefs.com.

About Hemophilia A

Hemophilia A, also known as factor VIII deficiency or classic 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, the most common type of hemophilia, is caused by deficient or defective

blood coagulation proteins, known as factor VIII. Hemophilia A is characterized by prolonged or spontaneous bleeding, especially into the muscles, joints, or internal organs. Approximately one in 5,000 males born in the United States has hemophilia.

About Bayer HealthCare Pharmaceuticals Inc.

Bayer HealthCare Pharmaceuticals Inc. is the U.S.-based pharmaceuticals operation of Bayer HealthCare, an affiliate of Bayer AG. One of the world's leading, innovative companies in the healthcare and medical products industry, Bayer HealthCare combines the global activities of the Animal Health, Consumer Care, Diabetes Care, and Pharmaceuticals divisions. In the United States, Bayer HealthCare Pharmaceuticals comprises the following business units: Women's Healthcare, Diagnostic Imaging, General Medicine, Hematology/Neurology, and Oncology. The company's aim is to discover and manufacture products that will improve human health worldwide by diagnosing, preventing and treating diseases.

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