

Bayer HealthCare Receives FDA Approval for Kogenate® FS with BIO-SET®

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

Berkeley, Calif. (Nov. 28, 2005) - The Biological Products division of Bayer HealthCare LLC (Bayer BP) announced today that Kogenate® FS (Antihemophilic Factor [Recombinant], Formulated with Sucrose) with BIO-SET® has been approved by the United States Food and Drug Administration (FDA). Kogenate® FS with BIO-SET® 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® FS with BIO-SET® 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® FS with BIO-SET® will provide patients with a safe, convenient way to prepare their hemophilia treatment."

Compared to the conventional vial-to-vial reconstitution method, Kogenate® FS with BIO-SET® 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*¹, showed 74 percent of respondents - including patients, caregivers, and healthcare professionals - preferred Kogenate® FS with BIO-SET® 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.

¹ 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.

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.