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Pfizer Launches Prefilled Dual-Chamber Syringe for Use with Hemophilia A Treatment

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Innovative Device for the Delivery of XYNTHA® Now Available to the Hemophilia Community

NEW YORK, January 4 – Pfizer Inc. (NYSE: PFE) today announced the launch of the Prefilled Dual-Chamber Syringe for the administration of XYNTHA® Antihemophilic Factor (Recombinant) Plasma/Albumin-Free. For the first time, both the XYNTHA powder and the diluent are supplied within the Prefilled Dual-Chamber Syringe, eliminating the transfer step during reconstitution.

"The Prefilled Dual-Chamber Syringe offers patients with hemophilia A an all-inclusive system for conveniently reconstituting XYNTHA, providing an exciting option in the care and treatment of hemophilia," said Angela Lambing, MSN, ANP, GNP, Henry Ford Hospital Hemophilia and Thrombosis Center, Detroit, MI.

“I have a few patients in mind who can benefit from eliminating the transfer step in the reconstitution process.”

The new Prefilled Dual-Chamber Syringe provides 3000 IU of XYNTHA, the highest dose, in a low 4 mL volume. Other dosages of XYNTHA will be available in the Prefilled Dual-Chamber Syringe this year. The device is used to deliver XYNTHA by intravenous (IV) infusion after reconstitution of a freeze-dried powder with the diluent (0.9% Sodium Chloride).

The Prefilled Dual-Chamber Syringe was approved by the U.S. Food and Drug Administration (FDA) on August 6, 2010, and is now available to hemophilia A patients who use XYNTHA, a recombinant factor VIII product indicated for both the control and prevention of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency or classic hemophilia) and for surgical prophylaxis in patients with hemophilia A. XYNTHA does not contain von Willebrand factor and, therefore, is not indicated in von Willebrand’s disease.

“With the availability of the Prefilled Dual-Chamber Syringe, we now have an all-inclusive system that eliminates the transfer step and simplifies the reconstitution of XYNTHA,” said Emil Andrusko, vice president, marketing, Specialty Care Biologics at Pfizer Inc. “Convenience and ease-of-use are critical factors in the effective management of hemophilia, and the launch of the device reinforces our commitment to helping people with hemophilia live active lives.”

The Pfizer Hemophilia Franchise evolved as part of a commitment to biotechnology that began three decades ago. The Prefilled Dual-Chamber Syringe is the latest demonstration of Pfizer’s continuing commitment to the goal of advancing science and technology for the hemophilia community.

For more information on XYNTHA and the Prefilled Dual-Chamber Syringe, visit www.xyntha.com.

About XYNTHA

XYNTHA is a recombinant factor VIII product approved by the FDA in February 2008 for both the control and prevention of bleeding episodes in patients with hemophilia A (congenital factor VIII deficiency or classic hemophilia) and for surgical prophylaxis in patients with hemophilia A. XYNTHA does not contain von Willebrand factor and, therefore, is not indicated in von Willebrand's disease. XYNTHA uses a state-of-the-art manufacturing and purification process that is completely albumin-free, from cell culture to final formulation.

XYNTHA is the only recombinant factor VIII product using a synthetic peptide ligand in lieu of a mouse monoclonal antibody (Mab) in the purification process. It is designed to eliminate the potential risk of murine viral contamination. The purification process also includes a solvent detergent viral inactivation step and a nanofiltration step. These manufacturing and purification processes are designed to reduce the risk of potential viral contamination.

About Hemophilia A

Hemophilia A is an inherited disease that prevents the blood from clotting properly. People with hemophilia A have a deficiency of a blood protein, also called a clotting factor, which is necessary to clot the blood and stop bleeding. Hemophilia A is caused by the absence or deficiency of the protein factor VIII. Most patients with hemophilia A are dependent on factor VIII replacement therapy. According to the National Heart Lung and Blood Institute, about 18,000 people – predominantly males – are affected with hemophilia A in the United States.

Indication for XYNTHA

XYNTHA is indicated for the control and prevention of bleeding episodes in patients with hemophilia A and surgical prophylaxis in patients with hemophilia A. XYNTHA does not contain von Willebrand factor, and, therefore, is not indicated in von Willebrand's disease.

Important Safety Information for XYNTHA

- Allergic reactions are possible with XYNTHA. Signs of an allergic reaction may include hives, rash with itching, chest tightness, difficulty breathing, faintness, or fast heartbeat. XYNTHA contains trace amounts of hamster protein. You may develop an allergic reaction to these proteins. Tell your doctor if you have had an allergic reaction to hamster protein.
- Call your doctor right away if bleeding is not controlled after using your factor VIII replacement therapy; this may be a sign of an inhibitor. Inhibitors have been observed in patients receiving factor VIII products, including XYNTHA.
- The most common adverse reaction in study 1 (safety, efficacy, and pharmacokinetics) is headache (24% of subjects) and in study 2 (surgery) is fever (41% of subjects). Other common side effects of XYNTHA include nausea, vomiting, diarrhea, or weakness.
- XYNTHA is an injectable medicine administered by intravenous (IV) infusion.

Please see full Prescribing Information for XYNTHA, available at www.xyntha.com.

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.

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wellness, prevention, treatments and cures that challenge the most feared diseases of our time. Consistent with our responsibility as the world's leading biopharmaceutical company, we also collaborate with health care providers, governments and local communities to support and expand access to reliable, affordable health care around the world. For more than 150 years, Pfizer has worked to make a difference for all who rely on us. To learn more about our commitments, please visit us at www.pfizer.com.

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