

European Commission Approves ReFacto AF(TM) as a Variation to the Refacto(R) Marketing Authorisation

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- Improvements in Purification Process Represent Important Advance in the Treatment of Haemophilia A

MAIDENHEAD, England, March 11 /PRNewswire/ -- Wyeth announced today it has received a positive decision from the European Commission for a variation of the marketing authorisation for ReFacto moroctocog alfa (Recombinant Coagulation Factor VIII), a treatment for haemophilia A. The manufacturing process for ReFacto has been modified, and the name has been changed to ReFacto AF moroctocog alfa (Recombinant Coagulation Factor VIII). The decision by the European Commission follows a positive recommendation from the Committee for Medicinal Products for Human Use on 18 December 2008.

ReFacto AF - indicated for the treatment and prophylaxis of bleeding in adults and children of all ages with haemophilia A - is a recombinant factor VIII product free of added exogenous human- or animal-derived protein in its cell culture, manufacturing, purification processes and final formulation.

"This milestone is an important step in the evolution of haemophilia A treatment and establishes a new standard in recombinant factor VIII product purification," says Andreas Krebs, President, Wyeth Europe. "We believe the state-of-the-art manufacturing and purification process used for ReFacto AF make it an exciting new therapeutic option for many patients with Haemophilia A."

Wyeth is planning to make ReFacto AF available in the European Union (EU), where the predecessor product ReFacto is currently commercially available, in June 2009. The product will be launched in most EU member countries at the same time to ensure that haemophilia A patients have access to the therapy as soon as possible. Once ReFacto AF is introduced, Wyeth will no longer supply ReFacto. The company will work with health care professionals, haemophilia treatment centres and home health care companies to help them manage their supply while transitioning from ReFacto to ReFacto AF.

Improvements in Purification Technology

Until now, the purification process for all recombinant factor VIII products used monoclonal antibodies derived from mouse cell lines. ReFacto AF is completely albumin-free, uses a synthetic peptide ligand that is totally free of animal materials and includes a viral-retaining nanofiltration purification step to further reduce the risk of potential viral contamination.

"Reducing the risk of transmitted infection is a major consideration. ReFacto AF was developed in response to the community's desire to completely remove albumin as a theoretical source of pathogen transmission. We believe that by having access to a product which in its production process is both free of exogenous animal or human-derived proteins and relies on a sophisticated purification process will give both health care providers and patients a greater sense of security," says Mikael Dolsten, MD, PhD, President, Wyeth Research.

About Haemophilia A

Haemophilia A is a rare, inherited blood clotting disorder, which affected approximately 30,000 people in the European Union in 2005. People with haemophilia A are deficient in a key protein - factor VIII - which is vital in the clotting mechanism to prevent bleeding. This condition can be characterized by

spontaneous haemorrhages or prolonged bleeding, typically into joints and soft tissue. Most patients with haemophilia A are dependent on factor VIII replacement therapy.

Wyeth and Haemophilia

Wyeth is a leader in hemophilia science, having developed the first and only albumin-free recombinant factor IX therapy for the treatment of haemophilia B, and continues to research new recombinant products for the treatment of bleeding disorders. With the introduction of ReFacto AF, Wyeth is the only company to offer state-of-the-art recombinant factor VIII and IX therapies for the treatment of haemophilia A and B, respectively. Wyeth also works to help improve the health of haemophilia patients through education, patient assistance programs, and by supporting associations such as the World Federation of Haemophilia, the European Association for Haemophilia and Allied Disorders, and the European Haemophilia Consortium.

ABOUT WYETH:

Wyeth is one of the world's largest research-based pharmaceutical and health care products companies. It is a leader in the discovery, development, manufacturing, and marketing of prescription drugs and over-the-counter medications. It is also a global leader in vaccines, biotechnology and animal health care.

To access further media information relating to this press release, additional information on ReFacto AF and future media announcements, please register on the media centre at <http://www.wyeth.eu>. If you subscribe to receive our emails you will get updates as soon as new content is added to the site. Please note you will be able to unsubscribe at any time and we will not pass your details to any third party.

Source: Wyeth Pharmaceuticals Limited