LFB S.A. announced today the acceptance by U.S. Food and Drug Administration of the filed Biologic License Application for Coagulation Factor VIIa Recombinant, (eptacog beta activated).

Les Ulis (France) – January 6 2017 – LFB S.A., announced that its Biologic License Application (BLA), requesting marketing approval of Coagulation Factor VIIa (Recombinant) as a treatment for congenital hemophilia A or B in adolescent and adult congenital hemophilia A or B patients with inhibitors, has been accepted for review by the U.S. Food and Drug Administration (FDA). The BLA contains data from Phase 3 pivotal studies in the global PERSEPT (Program for the Evaluation of Recombinant Factor Seven Efficacy by Prospective Clinical Trials) program, designed to evaluate the safety and efficacy of Coagulation Factor VIIa (Recombinant).

About Eptacog Beta, Activated

Eptacog Beta is an innovative recombinant form of human Factor VIIa. This new chemical entity was developed using LFB SA’s proprietary rPRO™ technology. Eptacog beta is currently under clinical development, and has not received commercial approval from any regulatory authority.

“This represents a major step toward LFB’s goal of making an innovative recombinant Factor VIIa treatment available for the treatment of hemophilia A and B patients with inhibitors to Factor VIII or IX,” said Christian Béchon, Chairman and Chief Executive Officer, LFB S.A.

If approved by the FDA, HEMA Biologics, LLC will have full commercialization rights for North America. HEMA Biologics is a joint venture between LFB S.A. and US WorldMeds, LLC. This privately-held biopharmaceutical company is located in Louisville, KY and is exclusively focused on meeting the needs of patients living with rare bleeding disorders, supporting the community that cares for them, and bringing meaningful products and services to the marketplace to help improve their daily lives.

This partnership significantly strengthens LFB presence in North America, with the goal of bringing to patients the first alternative to existing FVIIa treatments in over 20 years.

About LFB S.A.

LFB is a multinational biopharmaceutical group that develops, manufactures, and markets medicinal products for the treatment of serious and often rare diseases in several major therapeutic fields, including Hemostasis, Immunology and Intensive Care. LFB is the leading manufacturer of plasma-derived medicinal products in France and 6th worldwide, and is also among the leading European companies for the development of new-generation medicinal products or treatments based on biotechnologies. LFB is pursuing a growth strategy that seeks to extend its international activities and develop innovative therapies. Today, LFB currently markets its products in more than 40 countries around the world with a global turnover of €502.4 million in 2015. http://www.groupe-lfb.com

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