Les Ulis, 6 April 2020

- PRESS RELEASE -

LFB announces FDA approval of SEVENFACT®, a new recombinant coagulation Factor VIIa, for the treatment of adults and adolescents with Hemophilia A or B with inhibitors.

Les Ulis (France) – 6th April 2020 – LFB today announced that the US Food and Drug Administration (FDA) has approved the Biologics License Application (BLA) 2061 for SEVENFACT®, a new recombinant coagulation Factor VIIa [coagulation factor VIIa (recombinant)-jncw], for the treatment and control of bleeding episodes occurring in adults and adolescents 12 years of age and older with Hemophilia A or B with inhibitors (neutralizing antibodies). An exclusive license for the commercialization of the product in the USA and Canada has been granted to HEMA Biologics, a joint venture between LFB and US WorldMeds.

Denis Delval LFB's Chairman and Chief Executive Officer, stated: "*We are very pleased with the FDA approval of SEVENFACT® which provides a new treatment option for hemophilia patients. This approval is a validation of an innovative LFB technology. We will now work towards SEVENFACT® registration in Europe and other core countries, in order to offer this therapeutic option to patients*."

Hemophilia A or B

Hemophilia A or B is a congenital bleeding disorder caused by a dysfunction or deficiency of Coagulation Factor (F) VIII or IX, respectively. People with Hemophilia may bleed for a longer time than others after injury or surgery. They may also have spontaneous bleeding in muscles, joints and organs, which may be life-threatening. Individuals with inhibitors may not respond to factor replacement therapy. According to the *Centers for Disease Control and Prevention (CDC)*, there are an estimated 20,000 people living with Hemophilia in the United States[1]. Bleeding episodes in these individuals are managed by either on-demand treatment or prophylaxis using products containing FVIII or FIX. However, when inhibitors to FVIII or FIX develop in these individuals, treatment of bleeding episodes with FVIII or FIX products may no longer be effective. In these situations, the administration of products such as SEVENFACT®, which bypass the Factor VIII and Factor IX that are blocked by inhibitors, promotes clot formation and controls bleeding.

About SEVENFACT®

SEVENFACT® is an innovative recombinant form of human Factor VIIa (rhFVIIa). This new biological entity is manufactured using LFB's proprietary and state of the art rPRO™ technology.

The safety and efficacy of SEVENFACT® were determined using data from a clinical study that evaluated 27 patients with hemophilia A or B with inhibitors, which included treatment of 465 mild or moderate, and three severe bleeding episodes. The study assessed the efficacy of treatment 12 hours after the initial dose was given. The proportion of mild or moderate bleeding episodes treated successfully both with the lower dose of 75mcg/kg and higher dose of 225 mcg/kg (requiring no further treatment for the bleeding episode, no administration of blood products and no increase in pain beyond 12 hours from initial dose) was approximately 86%. The study also included three severe bleeding episodes that were treated successfully with the higher dose.

[1] Source https://www.cdc.gov/ncbddd/hemophilia/data.html

Another study evaluated the safety and pharmacokinetics of three escalating doses of SEVENFACT® in 15 patients with severe hemophilia A or B with or without inhibitors. Results from this study were used to select the two doses, 75mcg/kg and 225 mcg/kg, that were evaluated in the study described above.

The most common side effects of SEVENFACT® were headache, dizziness, infusion-site discomfort, infusion-related reaction, infusion-site hematoma, and fever.

Serious arterial and venous thrombotic events may occur following administration of SEVENFACT®. There is limited information about the safety of SEVENFACT® in patients with a history of arterial or venous thromboembolic disease, because such patients were excluded from SEVENFACT® trials.

SEVENFACT® is contraindicated in patients with known allergy or hypersensitivity to rabbits or rabbit proteins.

For more information, please see the FDA news release: https://www.fda.gov/news-events/press-announcements/fda-approves-additional-treatment-adults-and-adolescents-hemophilia-or-b-and-inhibitors

About LFB

LFB is a bio-pharmaceutical group that develops, manufactures and markets plasma derived products and recombinant proteins for the treatment of patients with serious and often rare diseases. LFB was founded in 1994 in France and is among the leading European bio-pharmaceutical companies providing mainly hospital-based healthcare professionals, with blood-derived therapeutics with the vision to provide treatment options to patients in three major areas: immunology, haemostasis, and intensive care.
LFB currently markets 15 products in more than 30 countries.
Please visit www.groupe-lfb.com for additional information.

About HEMA Biologics, LLC

HEMA Biologics is a biopharmaceutical company, located in Louisville, KY. HEMA Biologics has commercialization and distribution rights for SEVENFACT® in the U.S. and Canada. HEMA Biologics takes pride in the heritage of LFB, the developer and manufacturer of SEVENFACT®.
The company is dedicated to 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.
Please visit https://hemabio.com/ for additional information.

LFB Contacts (France):
Didier Véron - Executive VP Corporate Affairs
Tel: +33 (0)1.69.82.72.97 or +33 (0)6.08.56.76.54
verondidier@lfb.fr

HEMA Biologics Contacts:

For information contact:
Call: 855.718.HEMA (4362)
Fax: 855.721.HEMA (4362)
medinfo@hemabio.com