- PRESS RELEASE -

LFB announces that the European Medicines Agency (EMA) has accepted for filing the Marketing Authorization Application for eptacog beta (activated), a recombinant coagulation Factor VIIa

In addition, LFB announces the online publication of the exploratory *in vitro* study results on eptacog beta in combination with emicizumab in the journal *Haemophilia*.

Les Ulis (France) — March 1st, 2021 — LFB today announced that the European Medicines Agency (EMA), the European regulatory authority, has accepted for filing the Marketing Authorization Application for eptacog beta, a recombinant coagulation Factor VIIa (rFVIIa).

The application includes data from three prospective phase 3 clinical trials (PERSEPT 1, PERSEPT 2, and PERSEPT 3) assessing the efficacy and safety of eptacog beta in the treatment of bleeding episodes in children and adults with congenital haemophilia A or B with inhibitors and for the prevention of bleeding in those patients undergoing surgery or invasive procedures. The final outcome from the EMA review is expected by mid-2022.

This announcement comes less than a year after the approval in April 2020 by the United States Food and Drug Administration (FDA) of LFB's Biologics License Application (BLA) for the coagulation factor VIIa (recombinant)-jncw (eptacog beta), under the name SEVENFACT®, for the treatment and control of bleeding episodes occurring in adults and adolescents (12 years of age and older) with haemophilia A or B with inhibitors. A sBLA efficacy supplement is currently under FDA review, with a regulatory outcome expected by mid-2021. An exclusive license for the commercialization of SEVENFACT® in the USA has been granted to HEMA Biologics, a joint venture between LFB and US WorldMeds.

In parallel, LFB announces the online publication of the exploratory *in vitro* study of eptacog beta in combination with emicizumab in the journal *Haemophilia.*[1] The combination of eptacog beta with emicizumab results in a concentration-dependent increase in thrombin generation in haemophilia plasma that remains below that of normal non-haemophilic plasma.

These exploratory study results provide *in vitro* data supporting the concept of eptacog beta use for the treatment of breakthrough bleeding in haemophilia patients treated with emicizumab. A clinical study is planned in the first quarter 2021 to further evaluate the use of SEVENFACT® in this patient population.[2] The recommendation from the Medical and Scientific Advisory Council (MASAC) of the National Hemophilia Foundation in the USA supports the use of SEVENFACT® for the treatment of breakthrough bleeding in patients using emicizumab prophylaxis.[3]

---

[1] *Grandoni J, Duretz V, Bonzo D, et al. Exploratory in vitro evaluation of thrombin generation of eptacog beta (recombinant human FVIIa) and emicizumab in congenital haemophilia A plasma. Haemophilia 2021 Feb; https://onlinelibrary.wiley.com/doi/full/10.1111/hae.14253 Online ahead of print.*

[2] *ATHN16 study coordinated by the American Thrombosis and Hemostasis Network*: *https://clinicaltrials.gov/ct2/show/NCT04647227*

[3] *MASAC Document 263 - MASAC Recommendations Concerning Products Licensed for the Treatment of Hemophilia and Other Bleeding Disorders (Revised August 2020). National Hemophilia Foundation. Available at: https://www.hemophilia.org/sites/default/files/document/files/263_treatment.pdf last accessed on February 7th, 2020.*

About the exploratory *in vitro* study

The aim of this study was to determine the *in vitro* procoagulant activity of eptacog beta and emicizumab (alone and in combination) utilizing a thrombin generation assay with haemophilia A plasma with and without inhibitors.

A significant increase in peak thrombin, endogenous thrombin potential and velocity was observed for combinations of eptacog beta (0, 1, 2 or 5 µg/mL) with emicizumab (0, 50 or 100 µg/mL) in haemophilia A and haemophilia A plasma with inhibitors; the effect remained below that observed in normal, non-haemophilic plasma.

This study was sponsored by LFB. More details can be found in the study manuscript available at https://onlinelibrary.wiley.com/doi/full/10.1111/hae.14253

About LFB

LFB is a biopharmaceutical group that develops, manufactures, and markets plasma-derived medicinal products and recombinant proteins for the treatment of patients with serious and often rare diseases.
Created in France in 1994, LFB is today one of the leading European companies providing plasma-derived and recombinant medicinal products to healthcare professionals. Its mission is to offer patients new treatment options for unmet needs in three major therapeutic areas: immunology, haemostasis and intensive care.
LFB's current market portfolio includes 15 biomedicinal products sold in over 30 countries.
Please visit www.lfb-group.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 USA 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 *www.hemabio.com* for additional information.

LFB Contacts:
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 (US):
Chris Macie, Senior Director, Medical Affairs
Cell number: (+1) 770-331-5761 - chris.macie@hemabio.com