- Press Release -

LFB announces the approval of CEVENFACTA® (eptacog beta) in the European Union

This new recombinant coagulation Factor VIIa is indicated for the treatment of bleeding episodes and for the prevention of bleeding in those undergoing surgery or invasive procedures in adults and adolescents (12 years of age or older) with haemophilia A or B with inhibitors.

- **The first new bypassing agent approved in the European Union for the treatment and control of bleeding episodes in haemophilia A and B patients with inhibitors in over 2 decades.**
- **This marketing authorization in the European Union follows the FDA approval in April 2020 of SEVENFACT® (another brand name of eptacog beta) in the United States for the treatment of bleeding episodes in adults and adolescents with haemophilia A or B with inhibitors.**
- **In addition to this marketing authorization in the United States and in the European Union, LFB has been granted a Marketing Authorization for SEVENFACT® in Mexico on June 2nd, 2022.**
- **The marketing authorization file has also been submitted to the UK authorities (MHRA) and the file is currently under review.**

Les Ulis (France) – July 25, 2022– LFB today announced that the European Medicines Agency (EMA) has granted on July 15th a Marketing Authorisation for CEVENFACTA® (eptacog beta), as the first new bypassing agent in over 20 years. CEVENFACTA® is indicated in adults and adolescents (12 years of age and older) for the treatment of bleeding episodes and for the prevention of bleeding in those undergoing surgery or invasive procedures in the following patient groups:

- in patients with congenital haemophilia with high-responding inhibitors to coagulation factors VIII or IX (i.e. ≥5 Bethesda Units (BU));
- in patients with congenital haemophilia with low titre inhibitors (BU <5), but expected to have a high anamnestic response to factor VIII or factor IX administration or expected to be refractory to increased dosing of FVIII or FIX.

Denis Delval, LFB's Chairman and Chief Executive Officer, stated: "*We are very pleased with the approval of CEVENFACTA® by the EMA, which provides a new treatment option for haemophilia patients with inhibitors in the European Union. This approval is a validation of our innovative LFB technology and the acknowledgement of LFB's deep commitment to patients.*"

Dr. Patrick Delavault, MD, LFB's Executive Vice President Scientific, Medical and Regulatory Affairs, stated: "*We need to keep in mind constantly what a bleeding event, even a single bleeding event, means to a haemophilia patient with inhibitors and to his family. This novel treatment alternative is a significative opportunity to improve patients' lives".*

LFB has been granted a Marketing Authorisation for SEVENFACT® (eptacog beta) in Mexico on June 2nd for the treatment of bleeding episodes in adults and adolescents with haemophilia A or B with inhibitors.

About PERSEPT studies:
The approval of CEVENFACTA® was based on data from the phase III clinical trials, PERSEPT 1 and PERSEPT 3.
The *PERSEPT 1 Phase III*, multicentre, randomised, open-label crossover study of two initial dose regimens (75µg/kg and 225µg/kg), evaluated 468 bleeding episodes across the full type of severity of bleeding episodes (mild, moderate, and severe), in 27 adolescent and adult haemophilia A and B patients with inhibitors (12-54 years of age). Both dosing regimens met the primary endpoint with 81% and 90% of bleeds controlled at 12 hours with the 75µg/kg dose and the 225µg/kg dose respectively. By 24 hours, haemostatic efficacy (secondary endpoint) was retained in 96.7% of bleeding episodes treated with the 75 µg/kg dose regimen and 99.5% of redundancy bleeding episodes treated with the 225 µg/kg dose, without requiring any alternative therapy. The median time to attain haemostatic efficacy was 5.98 hours for the 75 µg/kg dosing regimen and 3 hours for the 225 µg/kg dosing regimen. A median of 2 injections was needed to treat a bleeding episode with the 75 µg/kg and a median of only 1 injection of the 225 µg/kg dosing regimen was needed.

The *PERSEPT 3 Phase III*, multicentre, open-label, single-arm study evaluated the safety and efficacy of CEVENFACTA® in haemophilia A or B patients with inhibitors who were scheduled for an elective surgical or other invasive procedure. 12 patients were enrolled in the study, 6 with minor procedures and 6 with major procedures. For major surgical/invasive procedures, treatment was administered at an initial bolus dose of 200 µg/kg immediately before the start of the invasive procedure. For a minor elective surgical procedure, an initial bolus dose of 75 µg/kg was administered immediately before the start of the procedure. Overall, 81.8% of procedures were reported as successfully treated at 48 hours after the last administration of the product.
No thromboembolic events were reported in these two clinical trials. No Serious Adverse Events (SAEs) were considered as related to the treatment.

Patients should be monitored for any signs of thrombosis, hypersensitivity and neutralising antibodies. The most frequently reported adverse reactions in studies were infusion site discomfort, infusion site haematoma, post-procedural haematoma, infusion related reaction, increased body temperature, dizziness and headache.

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 biomedicinal products in more than 30 countries.
Please visit www.groupe-lfb.com for further information on LFB.

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