Our STN: BL 125444/651

SUPPLEMENT APPROVAL
PMC FULFILLED
July 12, 2019

Bioverativ Therapeutics, Inc.
Attention: Dr. Martin Solberg
Bioverativ, A Sanofi Company
225 Second Avenue
Waltham, MA 02451

Dear Dr. Solberg:

We have approved your request submitted and received on September 14, 2018, to supplement your Biologics License Application (BLA) under section 351(a) of the Public Health Service Act for Coagulation Factor IX (Recombinant), Fc Fusion Protein, to include your final study report on postmarketing commitment (PMC) #2 in the approval letter dated March 28, 2014, for your BLA, STN BL 125444/0 and revisions to your prescribing information label in Section 6.1 Clinical Trials Experience and in Section 14 CLINICAL STUDIES.

LABELING

We hereby approve the draft package insert labeling submitted under amendment 14, dated July 5, 2019.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm. Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125444/0 at the time of use (prior to marketing) and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

Please submit an amendment to all pending supplemental applications for this BLA that include revised labeling incorporating a revised content of labeling that includes these changes.

FULFILLED POSTMARKETING REQUIREMENT/COMMITMENTS

This submission fulfills your postmarketing commitment #2 identified in the March 28, 2014, approval letter for BLA STN BL 125444/0 for Coagulation Factor IX (Recombinant), Fc Fusion Protein. The commitment addressed in this submission is as follows:

2. To evaluate the safety and efficacy of ALPROLIX™ in study 9HB01EXT, an open-label, multi-center evaluation of the long-term safety and efficacy in the prevention and treatment of bleeding episodes in previously treated patients with Hemophilia B.

   Final protocol submission date: Submitted in STN BL 125444/0
   Study/trial completion date: December 31, 2018
   Final Report Submission date: December 31, 2019

PEDIATRIC REQUIREMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients, new indications, new dosage forms, new dosing regimens, or

new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication in pediatric patients unless this requirement is waived, deferred, or inapplicable.

Because the biological product for this indication has an orphan drug designation, you are exempt from this requirement.

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Tejashri Purohit-Sheth, MD
Director
Division of Clinical Evaluation and
Pharmacology/Toxicology
Office of Tissues and Advanced Therapies
Center for Biologics Evaluation and Research