Our STN: BL 125444/225

SUPPLEMENT APPROVAL
PMC FULFILLED
November 3, 2017

Bioverativ Therapeutics, Inc.
Attention: Mr. Michael Poirier
225 Second Avenue
Waltham, MA 02451

Dear Mr. Poirier:

We have approved your request dated October 27, 2015, to supplement your Biologics License Application submitted under section 351(a) of the Public Health Service Act (42 U.S.C. 262) for Coagulation Factor IX (Recombinant), Fc Fusion Protein to to include the completed pediatric study (9HB02PED) final report for reportable PMC #1 in the Approval letter issued on March 28, 2014, for STN 125444/0 with revised package insert labeling.

The review of this supplement was associated with the following National Clinical Trial (NCT) numbers: 00716716; 01027364; 01425723; 01440946; 02234310

LABELING

We hereby approve the draft package insert labeling submitted under amendment 22, dated November 2, 2017.

In addition, please submit the final content of labeling (21 CFR 601.14) in 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.

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.

This submission fulfills your postmarketing commitment in the approval letter identified in the October 28, 2015, approval letter for STN BLA 125444/0, for Coagulation Factor IX (Recombinant), Fc Fusion Protein. The commitment addressed in this submission is as follows:

PMC #1 Biogen Idec commits to evaluate the safety and efficacy of ALPROLIX in previously treated patients < 12 years of age with hemophilia B in Study 9HB02PED entitled, “An Open-label, Multicenter Evaluation of Safety, Pharmacokinetics, and Efficacy of Recombinant Coagulation Factor IX Fc Fusion Protein, BIIB029, in the Prevention and Treatment of Bleeding Episodes in Pediatric Subjects With Hemophilia B.”

To evaluate the safety and efficacy of ALPROLIX™ in Study 9HB02PED in the ongoing, open-label, multi-center, evaluation of safety, pharmacokinetics, and efficacy in the prevention and treatment of bleeding episodes in pediatric subjects (PTPs) with Hemophilia B.

Final protocol submission date: Submitted in STN BL 125444/0
Study/trial completion date: July 31, 2015
Final Report Submission date: July 31, 2016

We will include information contained in the above-referenced supplement in your Biologics License Application 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