

Mid-Cycle Communication

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Public Health Service

Food and Drug Administration

Center for Biologics Evaluation and Research

Application:BL STN 125444/0, Original BLA

Product:Coagulation Factor IX (Recombinant), Fc Fusion Protein

Proposed Indication:For the control and prevention of bleeding episodes, routine prophylaxis and perioperative management (surgical prophylaxis) in individuals with hemophilia B

Applicant:Biogen Idec, Inc.

Chair:Nancy Kirschbaum, PhD, Chemist, DH/LH

RPM:Edward Thompson, DBA/RPMB

Meeting:Wednesday, June 19, 2013, 1:00 – 1:30 p.m

FDA Attendees:

Nancy Kirschbaum, PhD, CBER/OBRR/DH/LH

Edward Thompson, CBER/OBRR/DBA/RPMB

Kimberly Taylor, CDER/OPI/OPA/PES

Christopher Sese, Independent Assessor, ERG

Biogen Idec Attendees:

Name, Title

Amin Abujoub VP, Global Quality Control

Aoife Brennan Senior Director, Medical Research

Doug Cecchini Director, Technical Development

Paula Cobb VP, Program Management

Nadine Cohen Senior VP, Regulatory Affairs

Lynda Cristiano Director, Drug Safety and Risk Management

Ann Dodds-Frerichs VP, CMC Regulatory Affairs

Kim Hocknell Director, CMC

Alison Innes Associate Director, Biostatistics

Clive Patience VP, Global Quality Assurance

Glenn Pierce Senior VP, Global Medical Affairs

Heidi Reichert Director, CMC

Paula Sandler VP, Regulatory Affairs

Denise Schultz Associate Director, CMC Regulatory Affairs

Debra Segal Director, Regulatory Affairs

Daniel Soroko Associate Director, Regulatory Affairs

Suzanne Stella Director, CMC Regulatory Affairs

Discussion Summary

1. Any significant issues identified by the review committee members to date
There are no review issues identified, to date, which would prevent approval; however, the review is ongoing.
2. Information regarding major safety concerns

To date, clinical review has not identified any major safety issues. If complete review finds that clinical efficacy and safety data met pre-determined endpoints and outcomes, Biogen may obtain its proposed clinical indications for patients 12 years and older.

3. Preliminary review committee thinking regarding risk management

Best approaches to post-marketing risk management for orphan drugs are still under discussion. For rFIXFc, it has been proposed that Biogen include in the package insert, a patient information sheet highlighting the new dosing schedule.

4. Any information requests sent and not received

There are no outstanding information requests.

5. Any new information requests to be communicated

A multi-discipline information request will be conveyed to Biogen by 01 July 2013. FDA is requesting that Biogen respond by 12 August 2013.

6. Proposed date for the Late-cycle meeting

The late cycle meeting is scheduled for 12 September 2013, 10:00 – 11:00 a.m.

7. Updates regarding plans for an Advisory Committee meeting

BL STN 125444/0 will not be presented to an advisory committee.

8. Other projected milestones:

Milestone	Date
Pre-license inspection of Biogen Idec Large Scale Manufacturing Facility in ----- ---(b)(4)-----	22 – 26 July 2013
Second PNR review and action letter	27 September 2013
Complete Label Review	28 November 2013
Post-marketing commitments (PMC) and post-marketing requirements (PMR) finalized	28 November 2013
Action due date and press release	28 December 2013

END

Author: Dr. Nancy Kirschbaum

Revisions: Edward Thompson

Reviewed; Mark Shields/June 28, 2013

- [Mid-Cycle Communication Document, July 17, 2013 - ALPROLIX \[ARCHIVED\]](#)