

RECORD OF TELEPHONE CONVERSATION

Submission ID: BL 125566/0
Review Office: OBRR
Product: Antihemophilic Factor (Recombinant), PEGylated
Indication: On-demand treatment and control of bleeding episodes; routine prophylaxis to reduce the frequency of bleeding episodes in adolescent (12 to <18 years) and adult (≥ 18 years) patients with hemophilia A (congenital factor VIII deficiency)
Sponsor: Baxalta

Date/Time: August 05, 2015, 1:00 PM
Initiated by FDA? Yes.
Telephone Number: (b) (4)
Author: Yu Do
Purpose: To provide Baxalta with clarification on Item 7 [postmarketing commitment (PMC)/postmarketing requirement (PMR)] and Item 9 (recommendations for the Prescribing Information and vial and carton labels) in the Late-Cycle Meeting Materials and to address questions specified in their meeting package.

FDA Participants:

Stephanie Omokaro, MD, CRB/DHCR/OBRR
Leland Ross Pierce, MD, CRB/DHCR/OBRR
Bindu George, MD, CRB/DHCR/OBRR
Paul D. Mintz, MD, DHCR/OBRR
Ze Peng, PhD, LH/DHRR/OBRR
Edward Thompson, RPMS/IO/OBRR
Yu Do, MS, RPMS/IO/OBRR

Baxalta Participants:

Merhshid Alai,, Sr. Director, Regulatory Affairs
Erik Bjornson, Director, Regulatory Affairs
Nikhil Mehta, Vice President, Regulatory Affairs
Brigitt Abbuehl, Medical Director
Werner Engl, Biostatistician
Bruce Ewenstein, Vice President, Clinical Strategy Hematology
Anne Prener, Vice President, Clinical Research Hematology
Yuli Wu, Medical Safety Director
Frank Horling Sr. Manager, R&D

Amendments: None.

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Summary of Discussion

FDA emphasized to Baxalta that the dates for final protocol submission, study completion, and final report submission must be complete with day, month, and year when submitting timelines for PMC or PMR studies. The most recent protocol amendment date should be used as the final protocol submission date.

Baxalta agreed to comply with the request.

FDA explained that Study #261203 to investigate safety and immunogenicity of ADYNOVATE in previously untreated patients (PUPs) should be submitted as a PMC since there was no such requirement in support of the original BLA.

FDA clarified that Study #261204 for perioperative management of bleeding would require a PMR/PMC because its inclusion of pediatric patients triggers PREA. However, an update regarding how this study should be categorized will be provided to Baxalta after review by the Pediatric Research Committee (PeRC) in September 2015.

FDA elaborated that Study #261303 for safety and efficacy of ADYNOVATE targeting two different trough levels may be considered a PMR if the study was included in the agreed Pediatric Study Plan. FDA will also include this as an action item to be discussed with PeRC.-

Baxalta expressed intent to submit additional data post-approval to support an (b) (4) dose upon completion of their ongoing studies. FDA explained that whether these data will be sufficient for label expansion would be determined upon complete review of the data.

FDA agreed with Baxalta that Study #261203 in PUPs does not have to include monitoring of anti-drug binding antibody formation to CHO proteins.

FDA stated that initial revision of the Package Insert and vial and carton labels will be issued to Baxalta via an Information Request on August 6, 2015 with August 18, 2015 as the deadline for the response.

Signature: _____

Drafted: Yu Do/August 5, 2015

Reviewed: Edward Thompson/August 6, 2015

Reviewed/Revised: Stephanie Omokaro/August 6, 2015

Reviewed/Revised: Ze Peng/August 6, 2015

Reviewed: Bindu George/August 6, 2015

Reviewed: L. Ross Pierce/August 6, 2015

Reviewed: Paul D. Mintz/August 7, 2015