

MID-CYCLE COMMUNICATION

Application type and number: Original BLA STN 125562/0
Product name: Anthrax Immune Globulin (Human) [ANTHRASIL]
Applicant: Cangene Corporation [Emergent Biosolutions]
Action Due Date: March 25, 2015
Meeting date & time: Friday, November 14, 2014, 10:30 AM – 11 AM
Telecon Numbers Toll-free: (b) (4) ; Conference Code: (b) (4)
Committee Chair: Robert Fisher, PhD
RPM: Thomas J. Maruna, MSc, MLS(ASCP)

Purpose: To provide an update on the review status of the BLA

FDA Attendees:

Robert Fisher, PhD, OBRR/DHHR/LPD
Thomas J. Maruna, OBRR/IO/RPMS

Cangene Attendees:

Dr. Laura Saward	VP, Winnipeg Research & Development
Dr. Tim Babinchak	Senior Director, Medical Affairs
Dr. Christine Hall	Director, Clinical
Dr. Shantha Kodihalli	Director, Preclinical
Steve McGregor	Director, Regulatory Affairs
Derek Toth	Director, Bioanalytical & Quality Sciences
Darren Ross	Senior Manager, Project Management
Allison Kennedy	Manager, Regulatory Affairs
Shelley Toth	Specialist, Regulatory Affairs
Vanja Komlenovic	Pharmacovigilance Scientist

Other Attendees: BARDA

Drew Albright
Michael Merchlinsky
Matthew Rose

Discussion Summary:

The following was conveyed to Cangene during the Mid-Cycle Communication teleconference:

1. To date, no significant issues have been identified by the review committee in this BLA that would result in a Complete Response letter.
2. FDA is expecting to receive the un-redacted batch records requested in the October 31, 2014 teleconference with DMPQ.
3. FDA is expecting the TNA validation data requested in the October 6, 2014 Information Request be submitted today, November 14, 2014.
4. The Clinical Reviewer noted that a Black Box Warning for thrombogenesis be required on the label; aside from thrombogenesis, no other safety concerns have been noted.

5. Concerning study AX003 – A Clinical Information Request will be sent requesting that this Postmarketing Requirement be split into two components: (1) a field study to confirm efficacy, safety, and the appropriateness of the recommended dosing regimen in persons exposed in a “broad [anthrax] exposure event scenario,” and (2) a requirement to periodically submit and analyze cumulative data from use of AIGIV in sporadic systemic anthrax cases.
6. The Clinical Pharmacology Reviewer noted concerns about dosing for morbidly obese patients and PK modeling.
 - a. Cangene maintains that a fixed 420 unit dose for emergency use based on ideal weight is sufficient and that weight-based dosing is not necessary; Cangene will submit a literature review to the FDA to address the noted concerns.
7. FDA raised concerns about (b) (4) [REDACTED]
[REDACTED]
(b) (4) [REDACTED]
8. The Late Cycle Meeting is presently scheduled for January 8, 2015.
9. This BLA will not be presented to the Blood Products Advisory Committee.
10. Cangene did not have further comments.

END