

From: Maruna, Thomas
Sent: Wednesday, March 02, 2016 2:33 PM
To: 'Denloye, Aderonke O'
Cc: Reed, Jennifer
Subject: BLA 125596.0 - Mid-Cycle Communication Agenda - Scheduled for 04-Mar-2016

Importance: High

Ms. Denloye

Please find the agenda for Friday's Mid-Cycle (MC) Communication teleconference for BLA 125596/0. Please let me know if you have any questions.

AGENDA

1. Significant issues/major deficiencies identified by the review committee to date.

- There are no significant / major deficiencies have been identified at this time.

2. Major safety concerns.

- There are no major safety concerns that have been identified at this time.

3. Preliminary review committee thinking regarding risk management.

- Overall the review team considers the product to represent relatively low risk due to 1) the high similarity of the manufacturing process to manufacturing of the licensed IGI, 10%; 2) specific antibodies content, (b) (4), and impurities are consistent across clinical and conformance lots; 3) acceptable stability profile.
- Most important risk to the product is determined to be variability in (b) (4) characteristics. This critical intermediate is prepared at different facilities, (b) (4). Proposed risk management strategies are the same as currently in place for IGI, 10%.
- Please note that (b) (4) and (b) (4) data in this submission are not interpretable as presented.

4. Information requests sent with responses not received

- February 25, 2016 IR requesting SAS program for studies 170903 and 170904 (response due March 3, 2016) – may be received by MC Communication

5. New information requests to be communicated

- Regarding (b) (4) and (b) (4) assays: Please report (b) (4), along with the values for controls and a ratio of (b) (4) relating IGIV samples to plasma control. Please provide several dilutions of IGIV (b) (4)

(b) (4)). Please calibrate the (b) (4) assay using the (b) (4) standard and report the lower limit of detection I mIU (b) (4).

6. Proposed date(s) for the late-cycle meeting

- Presently scheduled for May 19, 2016, 3 pm – 4:30 pm, EST
 - May be rescheduled depending on availability
 - Baxalta may elect to cancel the late-cycle meeting or convert to an alternative format (i.e. teleconference)

7. Updates regarding plans for the Advisory Committee (AC) meeting

- This application will not be referred to the Blood Products Advisory Committee

8. Other projected milestone dates for the remainder of the review cycle

- Labeling negotiation will take place after the late-cycle meeting (May 19, 2016)
- The action due date is September 13, 2016

END

Baxalta may elect to cancel the scheduled teleconference; if so, please notify me by responding to this email.

Very Respectfully,

Thomas J. Maruna, MSc, MLS(ASCP), CPH

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