

First Committee Meeting - March 31, 2009 - Hiberix

Hiberix – STN 125347/0
First Committee Meeting
March 31, 2009

Agenda:

1. Review milestones
2. Discuss review assignments
3. Discuss review strategies

Milestones:

Application Received:	March 17, 2009
Committee Assignment	March 24, 2009
1st Committee Meeting	March 31, 2009
Filing Meeting	April 1, 2009 (via e-mail)
Filing Action/Deficiencies Identified	April 16, 2009
Target Action Due Date:	July 31, 2009

Committee Assigned:

Chair Jay Slater, M.D.

Committee Members

Clinical Reviewer/Labeling	Karen Farizo, M.D.
Product CMC/Serology	Mustafa Akkoyunlu, M.D. Ph.D
Product CMC	Scott Norris
Product CMC	Tina Roecklein
Facilities/DMPQ	Joseph George
Advertising/ Promotional Labeling	Maryann Gallagher
Clinical Statistical Reviewer	Ghideon Ghebrejorgis, Ph.D.
Epidemiology	David Menschik, M.D., MPH
DPQ/Lot Testing Plan	Rajesh Gupta, Ph.D.
Lot Release	Joe Quander III
BiMo	Christine Drabick, MS
DVRPA Reviewer	Joe Temenak, Ph.D.

RPMs/RC

DVRPA Regulatory Project Mgr.	Jason Humbert
DBPAP Regulatory Coordinator	Jennifer Bridgewater, MPH

Discussion Items:

Chair

Dr. Jay Slater provided an overview of the unique nature of this BLA and the accelerated approval schedule.

Clinical

Dr. Karen Farizo noted that GSK has submitted a revised concept protocol for Study Hib-097 the day of this meeting, March 31, 2009, but that the concept protocol in the original submission did not incorporate many of CBER's suggestions provided in the pre-BLA meeting. There are concerns about the confirmatory study protocol and those should be addressed in an A/I letter. In the cover letter to the amendment received March 31, 2009, GSK states that the protocol included in this BLA amendment is being filed to the -b(4)- IND (-----b(4)-----)

-----) simultaneously, and requests concurrent review of the protocol in the context of both files. Dr. Farizo stated that the file is acceptable to file, but noted that discussion internally and with GSK will be needed to address concerns with the confirmatory study.

Product

Dr. Mustafa Akkoyunlu noted that the serology included in the BLA appears to be acceptable and the methods are sufficient. There was discussion regarding the assay utilized and whether GMTs are higher with the -b(4)- assays than with the sera assayed by --b(4)--. Dr. Akkoyunlu will attempt to provide Dr. Farizo with information on how these assays compare. This will assist Dr. Farizo in her efforts to assess whether there is consistency across studies.

Facility

Joe George has been in discussion with Linda Kramer of GSK regarding the timing of the PAI. The schedule is filled due to Belgian holidays on May 1, 21 and 22, and a previously scheduled inspection from May 19 -28. The proposed timeframe for the inspection is June 22-July 3, 2009.

Tina Roecklein, Scott Norris and Joe George will be participating in this inspection.

Lot Testing

Dr. Rajesh Gupta indicated that tests to be conducted have been identified. Discussion with Scott Norris, Dr. Akkoyunlu and members of DPQ will continue. Dr. Gupta noted the need to order the samples, as well as any necessary reagents, as soon as possible. Work will continue on the lot release protocol.

Epidemiology

Dr. David Menschik noted that there are no deficiencies in the file from his perspective. A question was raised regarding whether a Pharmacovigilance Plan (PVP) was included in the original submission. Dr. Menschik indicated that the PVP could be found in Section 1.1.6.

Clinical Statistics

Dr. Ghideon Ghebregiorgis stated that he has not found any issues which would preclude the BLA from being filed. Dr. Ghebregiorgis added that he briefly reviewed the data sets included in the amendment received March 31, 2009 and will be in contact with Dr. Farizo.

Advertising/Promotional Labeling

Maryann Gallagher noted the receipt of the information to support the proposed proprietary name, Hiberix, in the amendment received today, March 31, 2009. All of the labeling and package materials have been included in the submission.

The committee acknowledged that a BiMo inspection will not be needed to support this submission.

Next Step:

A filing meeting will be conducted via e-mail on April 1 and 2, 2009 to seek concurrence that the submission may be filed and to identify any deficiencies to be communicated to the sponsor in the Filing Letter.

Goals:

A Filing Letter with or without deficiencies identified will be drafted by the filing action milestone of April 16, 2009.

CBER:OVRD:DVRPA: JHumbert: drafted 4-1-09

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