

Mid-Cycle Meeting on Kamada Alpha-1-Proteinase Inhibitor (Human) - GLASSIA, October 29, 2009

Meeting Summary

Date: October 29, 2009

Time: 11:00 AM – 12:00 PM

From: Cherie Ward-Peralta

To: STN 125325/0

Re: Mid-Cycle Meeting on Kamada Alpha-1-Proteinase Inhibitor (Human)

FDA Participants:

Cherie Ward-Peralta, Jiahua Qian, Ewa Marszal, Ross Pierce, Iftekhar Mahmood, Stan Lin, and Faith Barash

On the Phone: Dave Doleski, Douglas Frazier, Evi Struble, and Joseph Quander III

Not Present: Jennifer Reed, Jennifer Schmidt, Randa Melhem, Loan Nguyen, Christine Drabick, Dennis Cato, Lilin Zhong, and Pei Zhang

Background:

The sponsor has submitted an Original BLA submission for Alpha-1-Proteinase Inhibitor (Human), intravenous for chronic augmentation and maintenance therapy in individuals with congenital deficiency of alpha-1-proteinase inhibitor (A1-PI) and clinical evidence of emphysema. Reports from clinical studies -(b)(4)-API-001 (PK & safety) and Kamada-API-002 (efficacy & safety) are enclosed within the submission in support of the application. The Integrated Summary of Safety (ISS) and Integrated Summary of Benefits and Risk (ISBR) from Study-API-002 and Study -(b)(4)-API-001 are also enclosed within the submission. The submission also encloses a full pediatric waiver for all pediatric groups according to PREA since this is an adult-related condition.

Discussion:

Scientific Lead provided an update on the need for additional information, finalizing on the organization of the facilities inspection with DH staff for early February, and on organizing the BIMO inspection.

Labeling:

Clinical Reviewer requested the labeling of the product to be modified according to the requested changes made for product Prolastin C. The PLR committee will review the label after the requested labeling change has been done by Kamada.

DBE:

Epidemiologist may request a couple of PMCs such as a registry to have an active surveillance. The side effects are not very severe; however, occasionally anaphylactic reactions occur. Clinical Reviewer recommends two or three PMC clinical studies in order to demonstrate the clinical efficacy and provide additional safety information.

Lot Release:

The Scientific Lead Reviewer will have to perform additional research to determine how to perform a lot release testing on particulates found within the liquid product. FDA has requested three conformance lots that should be submitted in November. Lot Release Testing Reviewer has not received the lot release testing protocol from the sponsor, and will update the committee when the information arrives to begin discussion of possible additional testing in the Lot Release Protocol.

Clinical:

Clinical Reviewer will be requesting additional information on pre-augmentation therapy serum AAT levels of subjects identified to having MZ genotype or phenotype. As stated previously in the meeting, two or three PMC studies will be requested from the sponsor to perform additional safety studies although will need to confirm if the PMCs needs to be reviewed by the FDAAA Safety Work Group. Additional request labeling changes to follow the requests made to other companies for A1-PI products.

PK:

Clinical Pharmacologist Reviewer needs to discuss further with Kamada how PK calculations were performed as FDA calculations do not match the submitted results.

CMC:

Scientific Lead Reviewer will request additional information from the sponsor as indicated in the Mid-cycle review memo.

DMPQ:

Manufacturing/Facilities Reviewer stated that additional information will be requested from the sponsor and it will be verified whether the needle utilized with the product is FDA cleared 510k product.

Action Items:

1. Review Committee to finalize on Mid-Cycle Review Memo to send the sponsor letter ready comments in an information request.
2. Schedule a Meeting with Kamada to discuss PK issues.
3. Clinical Reviewer to provide the labeling request sent to other A1-PI product sponsors.
4. Discuss with APLM the Proprietary Name Review, action item is due December 31, 2009.

Page Last Updated: 08/04/2010

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