

## Meeting Summary

**Date:** June 16, 2010

**Time:** 2:00 PM – 4:00 PM

**From:** Cherie Ward-Peralta

**To:** STN 125325/0

**Re:** Finalization Update Meeting for Kamada Alpha-1-Proteinase Inhibitor (Human)

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### **FDA Participants:**

Cherie Ward-Peralta, Ewa Marszal (phone), Dorothy Scott (phone), Jennifer Reed (phone), Basil Golding, Nisha Jain, L. Ross Pierce, Dave Doleski (phone), Iftekhar Mahmood, Nannette Cagungun, Mark Shields

### **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 request for all pediatric groups according to PREA since this is an adult-related condition. A Major Amendment was submitted on March 11, 2010 extending the action due date to July 01, 2010.

### **Discussion:**

Division Director requested updates from the review committee and made some additional questions to gain clarity on a couple of issues discovered during the review of discipline reviewer memos.

Division Director questioned whether Kamada measured the potency of Prolastin used in the study, whether the potency of both products was compared and whether the specific activity of Prolastin was known.

Lead Reviewer reminded that the lower trough levels were observed for both products.

Division Director requested to confirm with the sponsor whether Prolastin was dosed based on the potency marked on the vial.

Clinical Reviewer stated that during Prolastin C head to head clinical studies lower levels of A1-PI were also observed comparing to the original clinical studies for Prolastin.

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Lead Reviewer stated a discussion was being held on additional viral safety PMC, but this request will not be added to the approval letter because discussed testing is not required and the problem will be solved by the language change in the PI. - (b)(4) -  
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DMPQ Reviewer stated this method will be further discussed with Mary Malarky as CDER guidance does allow for retesting, and it has been viewed at other facilities.

DMPQ Reviewer informed the committee of a recent amendment received by the sponsor to include a ----- (b)(4) ----- in the manufacturing, but does not seem to have sufficient data to support this change in the BLA; therefore, he may request for the sponsor to withdraw this change and to submit this as a supplement after the BLA is approved.

DMPQ Reviewer informed the committee that the sponsor has initiated media fills to complete validation of a change requested by FDA (----- (b)(4) -----  
----- by Kamada), and will provide the information two days before the action due date.

Lead Reviewer informed the committee that additional information request may still be needed to determine if Kamada can use the second filter needle. Also, hold times need to be double checked, but none of these issues should affect the approval of the BLA.

Branch Chief informed that the PERC Committee have agreed to the full waiver.

Lead Reviewer informed the package insert has a couple of minor corrections to be made regarding the viral safety information and table formatting, and -----(b)(4)-----  
----- . The highlight section seems to fit within the half page.

Branch Chief recommended the sponsor to submit the mock up of the highlight section of the package insert to ensure the information follows the regulations.

Lead Reviewer will confirm the requested information by the Division Director.

End of Meeting