

# First Committee Meeting on Kamada Alpha-1-Proteinase Inhibitor (Human) - GLASSIA, June 22, 2009

## Meeting Summary

**Date:** June 22, 2009

**Time:** 10:30 AM

**From:** Cherie Ward-Peralta

**To:** STN 125325/0

**Re:** First Committee Meeting on Kamada Alpha-1-Proteinase Inhibitor (Human)

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## FDA Participants:

Cherie Ward-Peralta, Ewa Marszal, Jennifer Reed, Stan Lin, Faith Barash, Dave Doleski, Christine Drabick, Iftekhar Mahmood, Douglas Frazier, Loan Nguyen, Lilin Zhong, and Evi Struble

## Background:

The sponsor has submitted an Original BLA submission for Alpha-1 Proteinase Inhibitor (Human), intravenous in the treatment of chronic augmentation and maintenance therapy in individuals with congenital deficiency of alpha-1-proteinase inhibitor (A1-PI) and clinical evidence of emphysema. One clinical study Kamada-API-002 is 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. A Pharmacokinetic narrative performed within Study -(b)(4)-API can be found 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:

The review committee members briefly discussed the completeness on the submission. APLB raised concern that the Proprietary Name Application was not submitted within the package, we will need to request this information. As noted in CBER meeting minutes dated February 26, 2009 and CBER letter dated January 12, the sponsor can submit additional information during the review process. The committee will have to confirm that Kamada is following previous agreements proposing submission during the review cycle of items listed in the cover letter. The stability data and viral clearance data have been provided within the submission, and seem to be complete. The facility and equipment information needed for DMPQ may have not been provided, but will check with previous meeting minutes to determine what information should be provided. BIMO submission seems to be in order and will coordinate with the review team to determine which sites and subjects will be needed for the inspection, and can begin to prepare the assignments. Biostatistician reviewer will have to consult with the clinical reviewer on

the size of the study to establish non-inferiority to the product. A placebo was not used as well in the study to determine the established response for Prolastin. Pharmacokinetic study does not seem to have any issues, but will need to be further reviewed. Validation information does not seem to contain enough information; therefore we may need to request additional information. In conclusion, the committee will need to create a list of the items that were agreed upon in previous correspondence/meetings with the sponsor that will be submitted during the review cycle, and a list of possible refuse to file issues should be prepared by July 7 before the Filing Meeting.

**Action Items:**

1. All reviewers will prepare a list of refuse to file items issued by July 7 for discussion in the Filing Meeting.
2. A list will be created of the data that were agreed upon in previous meetings/correspondence that could be provided during the review cycle
3. Will confirm with the sponsor if a Proprietary Name Application will be submitted and request the submission in the timely manner.

<https://www.fda.gov/BiologicsBloodVaccines/BloodBloodProducts/ApprovedProducts/LicensedProductsBLAs/FractionatedPlasmaProducts/default.htm>

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