

Record of Telephone Conversation - GLASSIA, June 8, 2009

RECORD OF TELEPHONE CONVERSATION

Submission Type: Original Application

Submission ID: 125325/0

Office: OBRR

Product: Alpha-1-Proteinase Inhibitor (Human)

Applicant: Kamada Ltd.

Telecon Date/Time: 08-JUN-2009 08:00 AM

Initiated by FDA? No

Telephone Number: 918007723126

Communication Category(ies): Other

Author: JENNIFER REED

Telecon Summary:

Kamada described ongoing work toward immunogenicity assay development for A1PI.

FDA Participants: Jennifer L. Reed, OBRR/DH/LPD

Ewa Marszal, OBRR/DH/LPD

Non-FDA Participants:

Rulf Wolfson, Vice President of Regulatory Affairs, Kamada Ltd.

Pnina Strauss, Manager of Clinical Development and IP, Kamada

Mark Kessler, Program Manager, Kamada

David Nakar, Project Manager, Kamada

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Tcon was at the request of Kamada's Pnina Strauss. Ms. Strauss had been informed by Dr. Mark Brantly (University of Florida) of ongoing collaborative research between OBRR and UF, toward development of an immunogenicity assay for alpha-1 proteinase inhibitor (A1PI). Ms. Strauss approached Jennifer Reed on May 19, 2009 at the American Thoracic Society International Conference in San Diego, and asked if CBER could immunogenicity assay research with Kamada. Jennifer Reed agreed and Ms. Strauss followed up with a email and call-in phone number.

On June 8th, Jennifer Reed and Ewa Marszal briefly discussed ongoing immunogenicity assay research with Kamada representatives, who are also working toward immunogenicity assay development. Kamada indicated that they were planning to use a contract lab to perform the immunogenicity assay work. Ewa Marszal asked which lab would likely perform the studies, and Mark Kessler indicated it would probably be -----(b)(4)-----. Kamada is considering in particular a ---(b)(4)-- - assay format, and mentioned that they intended -----(b)(4)----- ----- to facilitate the assay. Kamada asked if CBER had any experience with this format. Jennifer Reed indicated that the -(b)(4)-- assay format is

one of several under investigation in the lab. Jennifer Reed asked if Kamada had in-house positive control sera, that they perhaps would share with CBER to facilitate assay development. Kamada indicated that they intended to use commercial antibodies for assay development and validation, so no materials transfer was deemed useful at this time.

The meeting ended cordially.

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

Page Last Updated: 06/02/2016

Note: If you need help accessing information in different file formats, see [Instructions for Downloading Viewers and Players](#).

Language Assistance Available: [Español](#) | [繁體中文](#) | [Tiếng Việt](#) | [한국어](#) | [Tagalog](#) | [Русский](#) | [اڤيبرعلا](#) | [Kreyòl Ayisyen](#) | [Français](#) | [Polski](#) | [Português](#) | [Italiano](#) | [Deutsch](#) | [日本語](#) | [ايسراف](#) | [English](#)