RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125473/0 Office: OVRR

Product: Timothy Grass Pollen Allergen Extract

Applicant: Merck Sharp & Dohme Corp.

Telecon Date/Time: 09-Apr-2014 02:20 PM Initiated by FDA? Yes

Telephone Number:

Communication Categorie(s): 1. Other -

Author: RANA CHATTOPADHYAY

Telecon Summary: CBER's comments on PMC studies

FDA Participants: Rana Chattopadhyay, Jon Daugherty

Non-FDA Participants: Scott Greenfeder

Trans-BLA Group: No; Related STNs: None; Related PMCs: None

Telecon Body:
From: Chattopadhyay, Rana
Sent: Wednesday, April 09, 2014 2:20 PM
To: Greenfeder, Scott (scott.greenfeder@merck.com)
Cc: Daugherty, Jon
Subject: PMC study proposal-GRASTEK

Dear Scott

Here is the modified PMC study language for GRASTEK about which I mentioned to you over phone.

1. You commit to conduct a post-market claims-based study to further describe the safety profile of GRASTEK in marketed use in the United States. Outcomes of interest in this study will include serious allergic reactions and eosinophilic esophagitis. The study will enroll all new users of GRASTEK identified through claims data from a large US health insurance database for a period of at least three years from launch of GRASTEK. The study observation period will last for at least 3 years and until at least 10,000 patients are accrued between both post-market studies. Outcomes of interest identified through claims data will be verified using medical record review.

Final protocol submission date: January 31, 2015.

Study completion date: June 30, 2017 (projected).

Final Report Submission date: June 30, 2018 (or one year after study completion date, whichever is later).

2. You commit to conduct a post-market electronic medical record study to further describe the safety profile of GRASTEK in marketed use in the United States. Outcomes of interest in this study will include serious allergic reactions and eosinophilic esophagitis. The study will enroll all new users of GRASTEK identified through electronic medical records in a large US integrated health system for a period of at least three years from launch of GRASTEK. The study observation period will last for at least 3 years and until at least 10,000 patients are accrued between both post-market studies. This study will include early exposures to GRASTEK, including administration through starter packs provided in physician offices as well as all subsequent exposures.

Final protocol submission date: November 30, 2015.

Study completion date: June 30, 2017 (projected).

Final Report Submission date: June 30, 2018 (or one year after study completion date, whichever is later).

Regards.

Rana