From: Chattopadhyay, Rana
To: "Greenfeder, Scott"
Cc: Lacayo, Juan; Daugherty, Jon; Rivers, Katie; Valenti, Elizabeth
Subject: RE: Revised PMC synopses...Merck concurrence
Date: Wednesday, April 09, 2014 11:29:00 AM

Hi Scott
We concur with your proposal for the PMC studies for GRASTEK as stated below in your e-mail. Please submit it to your BLA, STN 125473.

Regards.

Rana
Rana Chattopadhyay, Ph.D.
Biologist [Regulatory]
Division of Vaccines & Related Product Applications
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From: Greenfeder, Scott [mailto:scott.greenfeder@merck.com]
Sent: Tuesday, April 08, 2014 2:12 PM
To: Chattopadhyay, Rana
Cc: Lacayo, Juan; Daugherty, Jon; Rivers, Katie; Valenti, Elizabeth
Subject: Revised PMC synopses...Merck concurrence
Importance: High

Dear Rana,
As requested by Ron Rabin during our phone call of April 8, 2014 Merck proposes to revise the PMC synopses as follows for BLA 125473:

Proposed revisions are in red text.
Merck concurs with this version including these revisions.

Please acknowledge CBER's concurrence and I will submit this email to BLA 125473.
1. You commit to conduct a post-market claims-based study of serious allergic reactions and eosinophilic esophagitis in marketed use of GRASTEK in the United States. 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 of serious allergic reactions and eosinophilic esophagitis in marketed use of GRASTEK in the United States. 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,

Scott

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