

From: Thompson, Edward
Sent: Wednesday, March 14, 2018 10:54 AM
To: 'stanley.ammons@octapharma.com'
Subject: Information Request for BLA 125668/0

Dear Mr. Ammons:

We are reviewing your December 28, 2017, biologics license application (BLA), for Immune Globulin Subcutaneous (Human). We determined that the following information is necessary to continue our review for your package insert label:

1. Please include all available interim safety data from all clinical studies in a 120-day safety update. This should include, but not necessarily be limited to data from study protocols SCGAM-01 (IND Phase 3 study), SCGAM-03 (IND Phase 3 extension study), and SCGAM-04 (non-IND Phase 3 study).
2. Please submit the initial protocol, the final protocol, and a summary of all protocol amendments and their dates of implementation for protocol SCGAM-03 and non-IND study SCGAM-03.
3. Please clarify whether your analysis of the rate of total infections was limited to the subset of SCGAM-01 subjects who completed the 12-month post-washout portion of the study and subjects who discontinued the study prematurely. If not, please submit an analysis for this subgroup, as well as separate analyses of adults and pediatric subjects < 17 years of age from this subgroup. This will help to avoid seasonal bias that could result from inclusion of active subjects who have not completed the study.
4. BLA supplement section 2.5.5.5 Serious Adverse Events states in part that all five serious adverse events (SAEs) reported in study SCGAM-01 “were assessed as unrelated to treatment by the responsible investigator.” Please provide your, as sponsor, assessment of the possible relationship between each of these SAEs and prior administration of the investigational product. Please include data on the time interval between the prior infusion and the onset of each SAE as part of your discussion of your causality assessments.
5. Please submit a table of all adverse reactions (AR) for study SCGAM-01 using the following definition of AR: Either the AE was classified at least possibly related to IP administration according to investigator and/or applicant OR the AE began within 72 hours following the end of the IP infusion, OR the investigator’s causality assessment was missing.
6. Please submit subgroup analyses for secondary efficacy variables, [suspected adverse reactions plus adverse reactions using the above definition of AR], SAEs, and withdrawals due to AEs by age groups 2 to < 12, 12 to < 17, 17 to 65, and > 65 years, sex, and race.

Please submit your response to items 2-6 for this information request as an amendment by March 9, 2018, referencing the date of this request. If you anticipate you will not be able to respond by this date, please contact the Agency immediately so a new response date can be identified.

If we determine that your response to this information request constitutes a major amendment, we will notify you in writing.

The action due date for this file is December 29, 2018.

Please send an email message acknowledging receipt of this request.

If you have any questions, please contact me.

Sincerely,

Edward Thompson

Regulatory Project Manager

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