RECORD OF TELEPHONE CONVERSATION

Submission Information

Application Type	BLA
STN	125614/0.0
Review Office	OVRR
Applicant	GlaxoSmithKline Biologicals / Lic. # 1617
Product	Zoster Vaccine Recombinant, Adjuvanted

Telecon Details

Telecon Date/Time	30-JUN-2017 03:55 PM
Author	NAIK, RAMACHANDRA
FDA Originated?	Yes
Communication Categories	IR - Information Request
Telecon Summary	IR regarding pharmacovigilance plan, and case narrative of subject PID 29688 in study Zoster-022 regarding amyotrophic lateral sclerosis
FDA Participants	Ramachandra Naik, Michael Smith and Carmen Collazo-Custodio
Applicant Participants	Jody Gould and Norris Pyle

Telecon Body: E-mail message and IR attachment pasted below.

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From: Naik, Ramachandra
Sent: Friday, June 30, 2017 3:55 PM
To: 'Jody Gould'
Cc: Collazo, Carmen; Smith, Michael (CBER); Norris Pyle
Subject: STN 125614/0: IR regarding pharmacovigilance plan, and subject PID 29688 case narrative

Dear Dr. Gould,

Attached is a request for additional information regarding STN 125614/0 (Zoster Vaccine Recombinant, Adjuvanted). Please provide your responses, in an amendment to STN 125614/0, by Friday, July 21, 2017.

Please confirm receipt of this message, and let us know if you have any questions or need additional information.
Regards,
Ram

Ramachandra S Naik, Ph.D.
Primary Reviewer/Regulatory Project Manager
Food and Drug Administration
CBER/OVRR/DVRPA/RRB3
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CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
OFFICE OF VACCINES RESEARCH AND REVIEW
DIVISION OF VACCINES AND RELATED PRODUCT APPLICATIONS

Date: **June 30, 2017**

Pages: **2**

To: **Jody Gould, Ph.D.**
Senior Director
North American Regulatory Affairs, Vaccines
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Rockville, MD 20850
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From: **Division of Vaccines and Related Products Applications**
Office of Vaccines Research and Review
Point of Contact: Ramachandra Naik, Ph.D.
Regulatory Project Manager
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Silver Spring, MD 2993-0002
Telephone: (301)-796-2640 Fax: (301)-595-1124

STN: **125614/0**

Product: **Shingrix (Zoster Vaccine Recombinant, Adjuvanted)**

Subject: **Request for additional information**

Dear Dr. Gould,

Our review of the information provided in your BLA dated October 21, 2016, for Zoster Vaccine Recombinant, Adjuvanted, is ongoing. We have the following comments and request for additional information:

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Pharmacovigilance plan:

1. The study data that was submitted as part of the BLA demonstrated imbalances in adverse events (AE) for some ocular and osseous pathology, which could be due to a biologically plausible relationship with the immune response caused by vaccination with Shingrix. Please submit a revised pharmacovigilance plan (PVP) so that it reflects your assessment of risks from inflammation after exposure to Shingrix vaccine that could result in:

    - Ocular neurovascular and vascular pathology that could cause serious disturbances of visual acuity (e.g. optic ischemic neuropathy, temporal arteritis, polymyalgia rheumatica). The incidence of ocular pathology is low, but due to concern for potential serious disability, the PVP should adequately plan for monitoring these AEs.

    - Osseous pathology that may be due to inflammation (e.g. arthralgia, gout, osteonecrosis)

Clinical:

2. Subject PID 29688 in Zoster-022 experienced the SAE of amyotrophic lateral sclerosis post-vaccination. According to the dataset and narrative, polyneuropathy was a baseline medical condition. Please provide a brief but detailed case narrative for this subject which includes the date of onset and nature [e.g., whether a sensory or motor polyneuropathy (if not specified, then signs and symptoms), any specific diagnosis or differential diagnosis, and clinical course] of this subject's polyneuropathy. If the date of onset is unknown, please include any available information about the duration of polyneuropathy as a concurrent medical condition at the time of enrollment.

Please provide your responses, in an Amendment to STN 125614/0. We recommend that you restate the item and follow it with your explanation or clarification. Use of this format helps organize the relevant information and provides a self-contained document that facilitates future reference. If you have any questions about this communication, please contact Ramachandra Naik, Ph.D. or Michael Smith, Ph.D. at (301) 796-2640.