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	18-SEP-2017 11:07 AM
Author	NAIK, RAMACHANDRA
FDA Originated?	Yes
Communication Categories	AD - Advice
Telecon Summary	CBER's comments regarding GSK's Pharmacovigilance plan submitted in amendment 40
FDA Participants	Ramachandra Naik, Michael Smith and Carmen Collazo-Custodio
Applicant Participants	Norris Pyle and Jody Gould

Telecon Body: IR e-mail message pasted below.

RECORD OF TELEPHONE CONVERSATION

From: Naik, Ramachandra
Sent: Monday, September 18, 2017 11:07 AM
To: 'Jody Gould'
Cc: Norris Pyle; Smith, Michael (CBER); Collazo, Carmen
Subject: STN 125614/0 SHINGRIX BLA: CBER's comments regarding your Pharmacovigilance Plan
Sensitivity: Confidential

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 regarding your submission received on September 7, 2017 (Amendment 40), which are in response to the FDA Comments/Information Request dated August 29, 2017. These comments listed below are limited to the Pharmacovigilance Plan (PVP), and do not address the active surveillance targeted safety study (TSS), as that study is still being developed by GSK.

1. Please revise the following safety concern in the PVP: "immune-mediated systemic vasculitis (e.g., temporal arteritis) and associated ocular and osseous complications such as arteritic optic ischemic neuropathy and avascular osteonecrosis." The safety concern should describe serious ocular complications that may be due to vasculitis or inflammation, and list examples of conditions that would qualify, such as temporal arteritis, optic ischemic neuropathy, and new or sudden onset of partial or complete blindness. Please describe the MedDRA preferred terms utilized to identify cases in this category (e.g., temporal arteritis, optic ischemic neuropathy, blindness, blindness unilateral, and visual field defect), but this list should not be considered exhaustive, as clinical knowledge and judgement should guide the decision to include or exclude adverse events in this risk category.

2. Please remove the term "osteonecrosis" as an important potential risk, as this can be monitored through routine pharmacovigilance, and does not need to be specifically identified in the PVP.

3. In the second column of Table 11 on page 50 of the risk management plan, "Proposed routine* and additional PhV activities," activities such as routine and enhanced surveillance, and the TSS should be reiterated as appropriate in both the "Risk of potential Immune Mediated Disorders (pIMDs) following HZ/su vaccination" and the "Serious ocular complications that may be due to vasculitis or inflammation" sections. For example, "optic ischemic neuropathy" should be identified in the TSS section of the ocular complications section and not in the pIMD section.

4. We agree with your proposal to include gout as a potential risk in the pIMD section of the PVP, but we request that any reports updating FDA about the

pIMDs observed in post-marketing data should include a subanalysis looking specifically at reports of gout and other pIMDs with primarily arthritic pathology or presentations.

Please provide your responses, in an amendment to STN 125614/0, by Monday, September 25, 2017.

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

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