(System Info - 289396 SMITH MICHAEL 10/17/2014 16:32:55 SMITHM)

RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125549/0 Office: OVRR

Product:
Meningococcal Group B Vaccine

Applicant:
Wyeth Pharmaceuticals Inc.

Telecon Date/Time: 09-Oct-2014 01:30 PM Initiated by FDA? Yes

Telephone Number: 866-453-8391

Communication Categorie(s):
1. Mid-Cycle Communication

Author: MICHAEL SMITH

Telecon Summary:
Mid-cycle communication teleconference summary

FDA Participants:

Drusilla Burns, Ph.D.	Review Committee Chair
Michael Smith, Ph.D.	Lead Regulatory Project Manager
Theodore Garnett, Ph.D.	Regulatory Project Manager
Ramachandra Naik, Ph.D.	Regulatory Project Manager
Carmen Collazo, Ph.D.	Team leader (RRB3/DVRPA/OVRR)
Lucia Lee, M.D.	Clinical reviewer
Laura Polakowski, M.D., M.S.P.H.	Epidemiology/Pharmacovigilance reviewer
Wellington Sun, M.D.	Division director (DVRPA/OVRR)

Non-FDA Participants:

Emilio Emini (R&D), Kathrin Jansen (R&D), Donna Boyce (Reg Strategy), Bill Gruber (Clinical), Joe Eiden (Clinical), John Perez (Clinical), Luis Jodar (Medical), Laura York (Medical), Paul Balmer (Medical), Steve Bailey (Safety), Susan Mather (Safety), Jim Start (Epid), Katherine Arch-Douglas (Reg CMC) and Carmel Devlin (Reg Strategy)

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

See e-mail below:

From: Smith, Michael (CBER)
Sent: Friday, October 17, 2014 4:26 PM
To: Devlin, Carmel (Carmel.Devlin@pfizer.com)
Cc: Burns, Drusilla L.; Garnett, Theodore; Naik, Ramachandra
Subject: STN 125549: Mid-cycle communication teleconference summary

Carmel,

I attached the mid-cycle communication teleconference summary for your records, please confirm receipt of this document.

Regards,

Mike

Mike Smith, Ph.D.
CDR, U.S. Public Health Service
Regulatory Project Manager
U.S. Food and Drug Administration
Center for Biologics Evaluation and Research
Office of Vaccines Research and Review
Division of Vaccines and Related Products Applications

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See summary of mid-cycle communication teleconference below:

Application type and number: BLA 125549/0

Product name: Trumenba, Meningococcal Group B Vaccine

Proposed Indication: Active immunization to prevent invasive meningococcal disease caused by *Neisseria meningitidis* serogroup B in individuals 10 through 25 years of age

Applicant: Wyeth Pharmaceuticals Inc., a subsidiary of Pfizer Inc.

Meeting date & time: October 9, 2014, 1:30 PM

Committee Chair: Drusilla Burns, Ph.D.

RPMs: Michael Smith, Ph.D., Lead Regulatory Project Manager
Theodore Garnett, Ph.D., Regulatory Project Manager
Ramachandra Naik, Ph.D., Regulatory Project Manager

CBER Attendees:

Drusilla Burns, Ph.D.	Review Committee Chair
Michael Smith, Ph.D.	Lead Regulatory Project Manager
Theodore Garnett, Ph.D.	Regulatory Project Manager
Ramachandra Naik, Ph.D.	Regulatory Project Manager
Carmen Collazo, Ph.D.	Team leader (RRB3/DVRPA/OVRR)
Lucia Lee, M.D.	Clinical reviewer
Laura Polakowski, M.D., M.S.P.H.	Epidemiology/Pharmacovigilance reviewer
Wellington Sun, M.D.	Division director (DVRPA/OVRR)

Contractor (PDUFA V)

Christopher Sese	Consultant, Eastern Research Group

Pfizer Attendees:
Emilio Emini (R&D), Kathrin Jansen (R&D), Donna Boyce (Reg Strategy), Bill Gruber (Clinical), Joe Eiden (Clinical), John Perez (Clinical), Luis Jodar (Medical), Laura York (Medical), Paul Balmer (Medical), Steve Bailey (Safety), Susan Mather (Safety), Jim Start (Epid), Katherine Arch-Douglas (Reg CMC) and Carmel Devlin (Reg Strategy)

Discussion Summary:

The review committee chair informed Pfizer of the following items (discussions that occurred during the meeting are in italics):

1. Status of issues identified and their resolution
    - Information Requests
        - CBER indicated that they have sent a number of information requests to which Pfizer has responded and that CBER has reviewed those responses. CBER indicated that they believe that most issues have been resolved.
        - CBER noted that they are awaiting official responses to some of the IR comments that were sent on 8/29/14 and 9/30/14 along with associated updates to the BLA based on those responses.
        - CBER stated that while they reserve the right to send additional information requests, they do not have, nor do they foresee, any additional substantive requests.

    - Labeling
        - CBER noted that they have provided comments on the carton/container labeling
        - CBER acknowledged ongoing efforts to resolve issues with the package insert labeling

    - Launch lots
        - CBER noted that Pfizer had indicated that release test data for launch lots will be available on October 24, 2014, at the earliest.

        Pfizer confirmed that date and also indicated that they are submitting the agreed upon lot release protocol on October 10, 2014.

2. Status of safety concerns
    - CBER stated that they have not identified any safety concerns that would preclude approval.

3. Risk management
    - CBER indicated that Pfizer's proposed plans for monitoring safety of the vaccine are adequate. These plans include routine surveillance, review of safety data from ongoing studies B1971009, B1971014, B1971015, and B1971016, as well as evaluating safety in pregnancy (proposed study B1971052).

Pfizer clarified that they have proposed study B1971052, in lieu of a pregnancy registry.

CBER agreed.

4. Miscellaneous items
   - Meetings update
     - CBER stated that, if needed, a late cycle meeting for this submission is tentatively scheduled for December 11, 2014. CBER reiterated that they have determined that an Advisory Committee meeting will not be necessary for this application.

   - Projected milestones
     - CBER stated that the official milestones for a priority review remain the same; however, because of the urgent public health need for a vaccine against invasive meningococcal group B disease, CBER is making efforts to expedite their review as much as possible.

   - Post-marketing issues

     CBER summarized their thinking on post-marketing requirements, post-marketing commitments and other post-marketing issues as described below:

     - Post-Marketing Requirements

       - In accordance with the accelerated approval regulations, confirmatory studies in the post-marketing period should be conducted to evaluate the ability of the vaccine to elicit hSBA responses against a panel of strains to provide clinical data to confirm and describe the breadth of coverage for meningococcal B strains that are epidemiologically relevant in US adolescents and young adults.
         - The ongoing studies that would fulfill this commitment are B1971009 and B1971016

       - In order to fulfill PREA requirements, the following pediatric studies should be conducted as proposed in Pfizer's Pediatric Study Plan:
         - B1971017
         - B1971035
         - A phase 3 study in children 1 to 10 years of age

     - Post-marketing Commitments

       - In order to further describe the safety of Trumenba, Pfizer should commit to providing the data from the ongoing large scale safety study, B1971014.

       - In order to assess the safety and immune response when Trumenba is given concomitantly with Tdap/Meningococcal ACYW-135

vaccine, Pfizer should commit to provide the data from ongoing study B1971015.

- Pfizer should commit to conduct proposed study B1971052 to examine the risk of pregnancy-associated adverse events and birth outcomes following vaccination with Trumenba.

- CMC issues
  - CBER noted that Pfizer has submitted written agreements to provide additional information and data concerning specific CMC issues that CBER has requested but which CBER has deemed to be non-critical for approval. CBER also noted that Pfizer has included timelines for these submissions in their written agreements. CBER indicated that Pfizer should provide this information/data as product correspondence to the BLA file per their indicated timelines. CBER also indicated that these issues will be followed up on inspection as required.