

Record of Telephone Conversation - September 29, 2009 - Prevnar 13

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RECORD OF TELEPHONE CONVERSATION

Submission Type: Original Application Submission ID: 125324/0 Office: OVR

Product:

Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein)

Applicant:

Wyeth Pharmaceuticals Inc.

Telecon Date/Time: 29-SEP-2009 03:55 PM Initiated by FDA? Yes

Telephone Number: 845-602-1283

Communication Category(ies):

Information Request

Author: JULIENNE VAILLANCOURT

Telecon Summary:

CBER asked the sponsor questions concerning post marketing studies in high risk groups

FDA Participants: Julienne Vaillancourt and Mike Smith

Non-FDA Participants: Jack Love and Carmel Devlin

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

Discussion:

The sponsor's plans to study Prevnar 13 in high risk groups and experience from Prevnar post marketing studies in high risk groups were discussed as follows:

1. The sponsor was asked to confirm that the pending, revised, proposed post marketing plan for Prevnar 13 would not include studies in high risk groups such as individuals, who are either HIV-infected, have Sickle Cell Disease or are stem cell transplant recipients. The sponsor agreed that the pending, revised, proposed post marketing plan for Prevnar 13 would not include these studies. The sponsor explained that the originally proposed pharmacovigilance plan (PVP), which had been submitted to IND -(b)(4)-, prior to submission of the BLA, did include plans for conducting studies in these high risk groups (see IND(b)(4)-, amendment 199, submitted 12/12/2008). However, the sponsor and CBER since agreed that these studies did not belong in the PVP, because the studies were designed to include children > 5 years of age and adults, which is beyond the age range for the proposed initial indication for Prevnar 13. The sponsor noted that a letter had been submitted to IND-(b)(4), on March 16, 2009 (see amendment 217), in which the sponsor noted that these studies would be removed from the post marketing plan. [Note: in follow-up to this teleconference CBER located the noted letter. However, the letter noted that the high risk studies would be removed from the PREA request and not the sponsor's proposed post marketing plan.]

2. The sponsor was asked whether the firm has any plans to conduct similar studies in younger children (≤ 5 years of age) in these high risk groups. The sponsor noted that the firm has no plans to do so now. The sponsor noted however, that they are planning to conduct a study in bone marrow transplant recipients as young as two years of age across several countries and that this study was recently revised to include children as young as two years of age. The sponsor noted that submission of the protocol for this study to IND(b)(4), was pending. The sponsor explained that bone marrow transplant recipients are unique from other high risk groups in that they are naïve and would be treated the same with regard to immunization, regardless of age, whether they are 2 years of age or 22 years of age and that is why the age has been lowered. CBER suggested that perhaps the issue of including this study as a post marketing commitment should be discussed, given that it will now include children < 6 years of age.
3. CBER noted that similar studies in high risk groups were conducted as post marketing commitments after initial approval of Prevnar and requested a list of published references for these studies to review the age ranges and details. The sponsor agreed to provide either the references or reprints of publications for these studies.
4. CBER noted that one of the post marketing studies for Prevnar was conducted in HIV-infected infants and questioned why the firm did not plan to do studies, such as this one in younger children in high risk groups, but for Prevnar 13. The sponsor explained that at the time the studies were done primarily to support dosing recommendations for children in these high risk groups. The sponsor added that at the time these were investigator-initiated studies. The sponsor agreed to question the clinical group at Wyeth about the rationale for limiting the age range to ≥ 6 years of age for the studies in the other high risk groups (i.e., HIV-infected individuals and children with Sickle Cell Disease). CBER noted that it would be helpful to receive such a rationale in writing.

End of telecon.