



Our STN: BL 125731/0

**MID-CYCLE COMMUNICATION
SUMMARY**

MARCH 4, 2021

Wyeth Pharmaceuticals LLC
Attention: Patrick Thomas
500 Arcola Road
G4450
Collegeville, PA 19426

Dear Mr. Thomas:

Attached is a copy of the summary of your February 4, 2021 Mid-Cycle Communication Teleconference with CBER. This memorandum constitutes the official record of the Teleconference. If your understanding of the Teleconference outcomes differs from those expressed in this summary, it is your responsibility to communicate with CBER as soon as possible.

Please include a reference to STN 125731 in your future submissions related to the subject product.

If you have any questions, please contact Diana Oram, PhD at 301-796-2640 or Diana.Oram@fda.hhs.gov.

Sincerely,

Doran Fink, MD, PhD
Deputy Director - Clinical
Division of Vaccines
and Related Products Applications
Office of Vaccines
Research and Review
Center for Biologics
Evaluation and Research

Mid-Cycle Communication Teleconference Summary

Application type and number: BLA STN 125731
Product name: Prevnar-20 (20-valent Pneumococcal Conjugate Vaccine [Diphtheria CRM197 Protein])
Proposed Indication: Active immunization for the prevention of pneumonia and invasive disease caused by *S. pneumoniae* serotypes 1, 3, 4, 5, 6A, 6B, 7F, 8, 9V, 10A, 11A, 12F, 14, 15B, 18C, 19A, 19F, 22F, 23F and 33F in adults 18 years of age and older
Applicant: Wyeth Pharmaceuticals LLC
Meeting date & time: February 4, 2021 2:00pm- 3:00pm
Committee Chair: Christina Houck
RPM: Juan Lacayo, Kamal Velmurugan, Diana Oram

Attendees:

FDA Discipline	Name	Attended meeting?
Regulatory Project Manager (RPM)	LCDR Juan Lacayo, PhD Kamal Velmurugan, PhD Diana Oram, PhD	Yes Yes Yes
Chair	Christina Houck	Yes
Clinical Reviewer	Tina Mongeau, MD, MPH	Yes
CMC Reviewer	Lisa Parsons, PhD James Erich Keller, PhD Mustafa Akkoyunlu, MD, PhD	Yes Yes Yes
Animal Pharmacology Reviewer	N/A	
Clinical Pharmacology Reviewer	N/A	
Toxicology Reviewer	LCDR Andrew O'Carroll, DVM	Yes
Developmental Toxicology Reviewer	N/A	
OCBQ/DMPQ RPM	Amanda Trayer	No
OCBQ/DMPQ Reviewer	Wei Wang, PhD	Yes
OCBQ/DMPQ/PRB Reviewer	N/A	
Statistical Reviewer of clinical data	Ruoxuan Xiang, PhD	Yes
Statistical Reviewer of non-clinical data	Ruoxuan Xiang, PhD	Yes
Postmarketing Safety Epidemiological Reviewer	Phillip Blanc, MD, MPH	Yes
OCBQ/APLB Reviewer	Sonny Saini, PharmD, MBA	Yes
OCBQ/BIMO Reviewer	Colonious King	Yes
OCBQ/DBSQC or OVRRL/LIB Reviewer	Darya Melnyk, MSc Hyesuk Kong, PhD Kouassi Ayikoe, PhD Ritu Agarwal, PhD	Yes Yes Yes Yes

FDA Discipline	Name	Attended meeting?
	Marie Anderson, PhD Anil Choudhary, PhD, MBA	Yes
Consult Reviewer(s)	Hector Izurieta, MD	Yes
OCBQ/DMPQ/Lead Inspector	N/A	
CMC Inspector	N/A	
Labeling Reviewer	Daphne Stewart	Yes
Other FDA Attendees	Maria Allende, MD	Yes
	Drusilla Burns, PhD	Yes
	Tatiana Claro de Silva, PhD	Yes
	Carmen Collazo, PhD	Yes
	Jon Daugherty, PhD	Yes
	Sheila Dreher-Lesnick, PhD	Yes
	Maryna Eichelberger, PhD	Yes
	John Eltermann, RPh, MS	Yes
	Karen Farizo, MD	Yes
	Doran Fink, MD, PhD	Yes
	Nicholas Geagan, MD	Yes
	Ravi Goud, MD, MPH	Yes
	M. Dave Green, PhD	Yes
	Marion Gruber, PhD	Yes
	Kelsy Hoffman, PhD	Yes
	Lei Huang, PhD	Yes
	Philip Krause, MD	Yes
	Loris McVittie, PhD	Yes
	Timothy Nelle, PhD	Yes
	Douglas Pratt, MD	Yes
	Muhammad Shahabuddin, PhD	Yes
	Jay Slater, MD	Yes
	Matthew Steele, PhD	Yes
	Lisa Stockbridge, PhD	Yes
	Wille Vann, PhD	Yes
	Leslie Wagner	Yes
	Qun Wang, PhD	Yes
	Lihan Yan, PhD	Yes
Wyeth Pharmaceuticals LLC Attendees	Annaliesa Anderson, PhD	Yes
	Katherine Arch-Douglas	Yes
	Barry Ballan, PMP	Yes
	Donna Boyce	Yes
	Alejandro Cane, MD	Yes
	Erica Chilson, PharmD	Yes
	Stephanie Ferrari, MS	Yes
	Bradford Gessner, MD	Yes

FDA Discipline	Name	Attended meeting?
	John Ginis	Yes
	William Gruber, MD	Yes
	Heather Holloway, MD	Yes
	Kathrin Jansen, PhD	Yes
	Luis Jodar, PhD	Yes
	Rob Maroko, MD	Yes
	Michael Pastorino, PhD	Yes
	Yahong Peng, PhD	Yes
	Ann Pennington, MS	Yes
	Michael Pride, PhD	Yes
	Cynthia Rohde, PhD	Yes
	Paul Rohlfing	Yes
	Dan Scott, MD	Yes
	Ingrid Scully, PhD	Yes
	Heather Sings, PhD	Yes
	Nancy Summerton	Yes
	Patrick Thomas, MS	Yes
	Wendy Watson, MD	Yes

Discussion Summary:

1. Any significant issues/major deficiencies, categorized by discipline, identified by the Review Committee to date.

At this time the review committee has not identified any significant issues or major deficiencies.

2. Information regarding major safety concerns.

No major safety concerns have been identified to date.

3. Preliminary Review Committee thinking regarding risk management.

We have not identified any issues related to risk management, therefore, REMS is not needed.

4. Any information requests sent and responses not received.

We have not received responses to the following information requests:

IR sent on January 19, 2021- Regarding post marketing safety- Response is expected on February 9, 2021. Received February 5, 2021

IR sent on January 21, 2021- Regarding identity testing SOP for the 20-valent (b) (4) drug product- Response is expected on February 4, 2021. Received February 2, 2021

IR sent on January 21, 2021- Regarding manufacturing facility and equipment- Response is expected on February 4, 2021. Received February 2, 2021

IR sent on January 26, 2021- Regarding comparability and exclusivity- Response is expected on February 9, 2021. Received February 9, 2021

IR sent on February 1, 2021- Regarding datasets- Response is expected on February 23, 2021.

5. Any new information requests to be communicated.

None at this time.

6. Proposed date for the Late-Cycle meeting (LCM).

The LCM between you and the Review Committee is currently scheduled for April 7, 2021 at 1 p.m. We intend to send the LCM meeting materials to you approximately 10 days in advance of the LCM.

7. Updates regarding plans for the Advisory Committee (AC) meeting.

We do not anticipate the need for an AC meeting.

8. Other projected milestone dates for the remainder of the review cycle, including changes to previously communicated dates.

Late Cycle Meeting: To be held on April 7, 2021

Labeling Comments: We intend to send labeling comments to you no later than May 7, 2021.

Meeting discussion included questions from the sponsor as to if they can expect to receive labeling comments before May 7, 2021. CBER replied that we are working toward providing labeling comments before May 7, 2021.

Action Due Date: We intend to take action on this application no later than June 8, 2021.