Merck Sharp & Dohme Corp.
Attention: Charisse Mandimika, M.D.
351 N. Sumneytown Pike
P.O. Box 1000
UG2D-68
North Wales, PA 19454

Dear Dr. Mandimika:

Attached is a copy of the memorandum summarizing your May 12, 2021 Late-Cycle Meeting 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 in writing as soon as possible.

Please include a reference to STN 125741/0 in future submissions related to Pneumococcal 15-Valent Conjugate Vaccine [CRM197 Protein], (b) (4) (VAXNEUVANCE).

If you have any questions, please contact the Regulatory Project Manager, Taruna Khurana, PhD at Taruna.Khurana@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

Late-Cycle Meeting Summary

Meeting Date and Time:	May 12, 2021 at 2:00 p.m. (EDT)
Meeting Location:	Teleconference
Application Number:	BLA STN 125741/0
Product Name:	Pneumococcal 15-Valent Conjugate Vaccine [CRM197 Protein], (b) (4) (VAXNEUVANCE)
Proposed Indications:	For active immunization for the prevention of invasive pneumococcal disease caused by *Streptococcus pneumoniae* serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F) in adults 18 years of age and older
Applicant Name:	Merck Sharp and Dohme Corp.
Meeting Chair:	Qun Wang, PhD
Meeting Recorders:	Taruna Khurana, PhD and Tatiana Claro da Silva, PhD

FDA ATTENDEES:

Mustafa Akkoyunlu, MD, PhD	OVRR/DBPAP
Maria Allende, MD	OVRR/DVRPA
Marie Anderson, PhD	OCBQ/DBSQC
Dennis Cato	OCBQ/DIS
John Cipollo, PhD	OVRR/DBPAP
Tatiana Claro DaSilva, PhD	OVRR/DVRPA
Jon Daugherty, PhD	OVRR/DVRPA
Brendan Day, MD, MPH	OBE/DE
Martin Dave Green, PhD	OVRR/DVRPA
Theresa Finn, PhD	OVRR
Marion Gruber, PhD	OVRR
Nick Geagan, DO	OVRR/DVRPA
Kelsy Hoffman, PhD	OVRR/DVRPA
Taruna Khurana, PhD	OVRR/DVRPA
Philip Kraus, MD	OVRR
Sarah Lee, MPH	OCBQ/DMPQ
Tsai-Lien Lin, PhD	OBE/DB
Narayan Nair, MD	OBE/DE
CAPT Tim Nelle, PhD	OVRR/DVRPA
Scott Norris, BS	OVRR/DBPAP
Tao Pan, PhD	OCBQ/DBSQC
Douglas Pratt, MD	OVRR/DVRPA
Anuja Rastogi, MD, MHS	OVRR/DVRPA
Jay Slater, MD	OVRR/DBPAP
Daphne Stewart	OVRR/DVRPA
Lisa Stockbridge, PhD	OCBQ/APLB

Xinyu Tang, PhD	OBE/DB
Willie Vann, PhD	OVRR/DBPAP
Qun Wang, PhD	OVRR/DVRPA
Claire Wernly, PhD	OCBQ/DBSQC
Lihan Yan, PhD	OBE/DB
Emnet Yitbarek, PhD	OCBQ/DBSQC

APPLICANT ATTENDEES:

Charisse Mandimika, MD	Associate Director, Global Regulatory Affairs, Vaccines & Infectious Diseases
James Kollmar, MD	Executive Director, Global Regulatory Affairs, Vaccines & Infectious Diseases
Dave Gutsch, MD	Vice President, Global Regulatory Affairs, Vaccines & Infectious Diseases
Ulrike Buchwald, MD, MS	Distinguished Scientist, Clinical Research, Vaccines
Luwy Musey, MD	Distinguished Scientist, Clinical Research, Vaccines
Alain Bouckenooghe, MD, MPH	Scientific Associate Vice President, Clinical Research, Vaccines
Paula Annunziato, MD	Vice President, Clinical Research, Vaccines
Alison Pedley, PhD	Senior Principal Scientist, Biostatistics
Jonathan Hartzel, PhD	Executive Director, Biostatistics
Michael Jordan, PhD	Director, Global Regulatory Affairs, Vaccines CMC
Heather Eurenius, BS	Executive Director, Global Regulatory Affairs, Vaccines CMC
Scott Woollens, MS	Associate Vice President, Global Regulatory Affairs, Vaccines CMC
Shrita Patel, MD	Distinguished Scientist, Clinical Safety and Risk Management
Katrina Nolan, PhD	Principal Scientist, Pharmacokinetics
Roy Helmy, PhD	Executive Director, Pharmacokinetics
Christine Fandozzi, PhD	Associate Vice President, Pharmacokinetics
Lisa Plitnick, PhD	Distinguished Scientist, Preclinical Development
Tracie Spangler, M. Eng	Director, Project Management
Neika Vendetti, MPH	Principal Scientist, Epidemiology
Patricia Saddier, MD, PhD	Executive Director, Epidemiology

BACKGROUND:

BLA 125741/0 was submitted on November 17, 2020 for Pneumococcal 15-Valent Conjugate Vaccine [CRM$_{197}$ Protein], (b) (4) (VAXNEUVANCE)

Proposed indications: For active immunization for the prevention of invasive pneumococcal disease caused by *Streptococcus pneumoniae* serotypes (1, 3, 4, 5, 6A, 6B, 7F, 9V, 14, 18C, 19A, 19F, 22F, 23F and 33F) in adults 18 years of age and older
PDUFA goal date: July 18, 2021

In preparation for this meeting, FDA issued the Late-Cycle Meeting Materials on April 30, 2021.

DISCUSSION

1. Discussion of Substantive Review Issues

   At this time, CBER does not have any substantive review issues.

2. Information Requests

   The Applicant has responded to all the information requests and there are no outstanding requests for additional information at this time. CBER will be communicating an information request on Friday May 14, 2021 regarding the lot release protocol template and (b) (4) testing of the drug substance.

3. Risk Management Actions (e.g., REMS)

   CBER has not identified any issues related to risk management; therefore, REMS is not needed.

4. Major Labeling Issues

   The prescribing information, carton and container labels and patient information sheet are being reviewed. CBER is working towards providing labeling comments before June 16, 2021.

5. Review Plans

   CBER intends to take action on this application no later than July 18, 2021.

6. Applicant Questions

   Applicant had no questions for CBER.

7. Wrap-up and Action Items

   CBER intends to provide labeling comments before June 16, 2021.
   CBER intends to take action on this application no later than July 18, 2021.

This application has not yet been fully reviewed by the signatory authorities, Division Directors and Review Committee Chair and therefore, this meeting did not address the final regulatory decision for the application.