



Our STN: BL 125770/0

**MID-CYCLE COMMUNICATION
SUMMARY**
May 10, 2023

Pfizer Ireland Pharmaceuticals
Attention: Gosia Mineo
Pfizer Inc.
1 Pfizer Way
190/004/4405
Pearl River, NY 10965

Dear Ms. Mineo:

Attached is a copy of the summary of your April 21, 2023 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 125770/0 in your future submissions related to PENBRAYA.

If you have any questions, please contact the Regulatory Project Managers, Brynn Hollingsworth, PhD (Brynn.Hollingsworth@fda.hhs.gov), Moonsuk Choi, PhD (Moonsuk.Choi@fda.hhs.gov) and Maria Bagh, PhD (Maria.Bagh@fda.hhs.gov) via email or at (301) 796-2640.

Sincerely,

Loris McVittie, PhD
Deputy Director-Regulatory
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 125770/0
Product Name: Meningococcal Groups A, B, C, W, and Y Vaccine (PENBRAYA)

Proposed Indication for Use: Active immunization of individuals 10 through 25 years of age to prevent invasive disease caused by *Neisseria meningitidis* groups A, B, C, W, and Y.

Applicant: Pfizer Ireland Pharmaceuticals

Meeting Date & Time: April 21, 2023 at 3:30 PM

Committee Chair: CAPT Mike Smith, PhD

RPMS: Brynn Hollingsworth, PhD, Moonsuk Choi, PhD and Maria Bagh, PhD

FDA Attendees:

Mike Smith, PhD	OVRP/DVRPA
Brynn Hollingsworth, PhD	OVRP/DVRPA
Maria Bagh, PhD	OVRP/DVRPA
Lucia Lee, MD	OVRP/DVRPA
Moonsuk Choi, PhD	OVRP/DVRPA
Elizabeth Sutkowski, PhD	OVRP/DVRPA
Douglas Pratt, MD, MPH	OVRP/DVRPA
Joseph Toerner, MD	OVRP/DVRPA
Loris McVittie, PhD	OVRP/DVRPA

Applicant Attendees:

Eduardo Forleo, MD	Vice President, Vaccines Clinical Research & Development
Johannes Beeslaar, MD	Senior Director, Vaccines Clinical Research & Development
Jason D. Maguire, MD, MPH	Senior Director, Vaccines Clinical Research & Development
(b) (6)	Safety Risk Lead, Safety Surveillance & Risk Management
Paul Balmer, PhD	Vice President, Global Medical Affairs
Paula Peyrani	Senior Director, Global Medical Affairs
(b) (6)	Drug Safety Team Lead, Drug Safety R&D
Ashlesh Murthy, MBBS, PhD	Director, Bacterial Vaccines and Technology
Paul Rohlfing	Executive Director, Global Regulatory Sciences, Vaccines CMC

Nathalie Dubois	Senior Director, Global Regulatory Sciences, Vaccines CMC
Claire Roche	Director, Global Regulatory Sciences, Vaccines CMC
Joan Kwong	Director, Global Regulatory Sciences, Vaccines CMC
Matthew Marsden, PhD	Senior Director, Global Regulatory Sciences
Gosia Mineo	Director, Global Regulatory Sciences

Agenda and Discussion Summary: The agenda was sent to Pfizer on April 19, 2023, and it is listed below, followed by the summary of the discussion for each item in italics.

1. Any significant issues/major deficiencies, categorized by discipline, identified by the Review Committee to date.
 - a. Clinical: Depending on your response to the CBER IR sent on April 19, 2023 under IND 13812 regarding the 2-dose PREA waiver in children 1 < 10 years of age, you may need to amend your request for deferral of MenABCWY studies to include plans to conduct MenABCWY Phase 2 and Phase 3 studies and to update the milestone dates for study C3511005 and the Phase 3 study, respectively.
 - Estimated protocol submission date:
 - Estimated study initiation date:
 - Estimated study completion date:
 - Estimated final report submission date:
 - b. CMC: None identified to date.
 - c. Toxicology: None identified to date.
 - d. Statistical: None identified to date.
 - e. Epidemiological/Pharmacovigilance: None identified to date.
 - f. Real World Evidence: None identified to date.
 - g. BIMO: None identified to date.
 - h. Facilities: None identified to date.

Discussion Summary: *Pfizer will submit their revised PREA documents that are required for PeRC to STN 125770/0 by May 2023. Pfizer will also submit their request for a waiver for their Trumenba 2-dose PMR and include the data that justifies their request to STN 125549. The review team is striving to take STN 125770/0 and the related STN 125549/0 PREA issue before PeRC in July 2023.*

2. Information regarding major safety concerns.

There are no major safety concerns identified at this time.

Discussion Summary: *There was no additional discussion on this item.*

3. Preliminary Review Committee thinking regarding a.) risk management, b) the potential need for any post-marketing requirement(s) (PMRs), and c.) the ability of adverse event reporting and CBER's Sentinel Program to provide sufficient information about product risk.

The review of the a) Risk Management Plan, b) PMR's and c) the ability of adverse event reporting and CBER's Sentinel Program is ongoing.

Discussion Summary: *There was no additional discussion on this item.*

4. Any information requests sent, and responses not received.
 - a. Information request regarding Pfizer's plans to evaluate content uniformity during the release testing on your commercial lots [dated April 6, 2023]
 - b. Information request regarding the meningococcal serogroup ACWY (MenACWY)-specific human complement serum bactericidal assays (hSBAs) [dated April 10, 2023]

Discussion Summary: *There was no additional discussion on this item.*

5. Any new information requests to be communicated.

No new information requests at this time.

Discussion Summary: *There was no additional discussion on this item.*

6. Proposed date for the Late-Cycle meeting (LCM).
 - a. The LCM between you and the Agency will be scheduled for no later than Thursday, July 6, 2023.
 - b. We intend to send the LCM materials to you approximately 10 days in advance of the LCM date.
 - c. If these timelines change, we will communicate updates to you during the course of the review.

Discussion Summary: *There was no additional discussion on this item.*

7. Updates regarding plans for the AC meeting.

This BLA submission will not be brought presented to the VRBPAC.

Discussion Summary: *There was no additional discussion on this item.*

8. Other projected milestone dates for the remainder of the review cycle, including changes to previously communicated dates, and notification of intent to inspect manufacturing facilities.
 - a. Initial labeling comments will be communicated to you no later than September 21, 2023.
 - b. Any postmarketing requirement and postmarketing commitment requests will be communicated to you no later than August 26, 2023, and September 21, 2023, respectively.
 - c. First Action Due Date: October 20, 2023

Discussion Summary: *There was no additional discussion on this item.*