Our STN: BL 125817/0

MID-CYCLE COMMUNICATION SUMMARY

October 30, 2024

Novavax Inc.
Attention: Kathleen Callahan
700 Quince Orchard Road
Gaithersburg, MD 20878

Dear Ms. Callahan:

Attached is a copy of the summary of your September 30, 2024, 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 125817 in your future submissions related to COVID-19 Vaccine, Adjuvanted (Nuvaxovid).

If you have any questions, please contact (b) (6) (b) (6) @FDA.hhs.gov), (b) (6) @fda.hhs.gov), and (b) (6) @fda.hhs.gov) via email or by phone at (b) (6)

Sincerely,

(b) (6)
Office of Vaccines Research and Review
Center for Biologics Evaluation and Research

U.S. Food & Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993
www.fda.gov

Mid-Cycle Communication Teleconference Summary

Application Type and Number: BLA STN 125817/0

Product Name: COVID-19 Vaccine, Adjuvanted (Nuvaxovid)

Proposed Indication for Use: For the prevention of COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older.

Applicant: Novavax Inc.

Meeting Date & Time: September 30, 2024, 1:30 pm ET

Committee Chair: (b) (6)

RPMs: (b) (6)

Attendees:

FDA:

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Novavax:

John Trizzino; President, Chief Operating Officer
Rick Crowley; Executive Vice President, Chief Operations Officer
Henrietta Ukwu, MD; Executive Vice President and Chief Regulatory Officer
Robert Walker, MD; Senior Vice President, Chief Medical Officer
Denny Kim, MD; Senior Vice President, Chief Safety Officer
Raburn Mallory, MD; Senior Vice President, Deputy Chief Medical Officer
Kathleen Callahan; Senior Vice President, Regulatory Affairs
Michael Kasai; Senior Vice President, Quality Assurance and Quality Control
Marco Cacciuttolo; Senior Vice President, CMC Development
Iksung Cho; Vice President, Biostatistics
Stephanie Garcia; Vice President, Quality Assurance Operations
Derek Gilpin; Vice President, Production Engineering
Katharine Smith, MD; Vice President, Head of Medical Safety
Jannine Cobb; Executive Director, Regulatory Affairs, CMC
Rachael Gerlach, PhD; Executive Director, Regulatory Affairs, Clinical/Nonclinical, Labeling
Alexandra Parnell; Director, Regulatory Affairs, Clinical/Nonclinical
Alice McGarry; Manager, Biostatistics

Sanofi:

(b) (4)

Agenda:

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

   CMC:
   We are concerned that insufficient CMC and related information has been included in your BLA to support approval of a vaccine formula relevant for current strains, as your BLA includes only information regarding product based on the no-longer-circulating Wuhan strain. Although it may be possible to update your BLA with CMC and related information pertinent to the JN.1 variant, for which you have received authorization under EUA 28237 as your 2024-2025 formula, we are concerned that the amendments you have recently submitted to that EUA (SNs 0208, 0221, 0224) include data that describe a rapid decrease in product potency. We further note that in the September 17, 2024, amendment to your EUA (SN 0221), you state that you are currently evaluating the manufacturing process and potency testing to support product potency for at least (b) (4) months. Reference is made to our communication sent on August 29, 2024, on the stability of your 2024-2025 formula. Please be advised that if you choose to expeditiously update your BLA with CMC, nonclinical, and labeling information for product based on your 2024-2025 formula made by the same process as used for the originally described Wuhan-based product, the available stability data for your 2024-2025 formula may limit the shelf-life to that authorized under EUA 28237.

   We acknowledge your request for a teleconference to discuss potential remediations and the information needed to demonstrate the stability profile of current variant-based product and recommend that you formally submit the request for a teleconference to IND 22430 as a Type C meeting request.

   Meeting Discussion:
   The FDA CMC reviewer discussed the above information. Novavax asked CBER to clarify the mechanism by which they should submit the requested JN.1 information (i.e., as a response to an information request, or as a response to this meeting teleconference). Furthermore, Novavax asked CBER to confirm whether any additional data regarding the XBB.1.5 variant strain would need to be submitted to the BLA, or if all efforts moving forward should be focused on the JN.1 variant. CBER advised Novavax to submit an amendment to the BLA containing their proposal (and any additional questions) for review and feedback. Additionally, Novavax indicated they plan to connect JN.1 data to Wuhan data and their intent to submit (b) (4) pre-filled syringe) to the BLA, (b) (4) with a 3-month shelf life. CBER reiterated the request for Novavax to submit their proposal as an amendment to the BLA for review and feedback.

Datasets:
We have concerns regarding the efficacy and solicited reactogenicity tabulations you submitted in response to our July 29, 2024, comments regarding the datasets provided for study 301 in adults. Our review of this information is ongoing. Additional Information Requests (IRs) may be forthcoming.

Meeting Discussion:
Novavax asked when they can expect to receive the dataset IR. CBER responded that their review of datasets is ongoing and they will provide an update on the proposed date of IR communication to Novavax following internal discussion.

2. Information regarding major safety concerns.

   There are no major safety concerns identified at this time.

   Meeting Discussion:
   There was no further discussion of this item during the telecon.

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

   The review of the Pharmacovigilance Plan, including assessment of any potential PMR/PMC safety study(ies), is ongoing.

   Meeting Discussion:
   There was no further discussion of this item during the telecon.

4. Any information requests sent, and responses not received.

   (b) (6) issued an IR on September 20, 2024, regarding CCIT validation for the drug product in vial presentations. Your response is expected by October 2, 2024.

   Meeting Discussion:
   There was no further discussion of this item during the telecon.

5. Any new information requests to be communicated.

   a. See above regarding an IR for the JN.1 package and potential future IRs regarding the datasets.

b. Please submit the final CSR and datasets for Study 313 to the BLA as an amendment to potentially support administration of a single vaccine dose regardless of vaccine history. Updated labeling, particularly to Section 2.3 Dosing and Schedule, should also be submitted in this amendment.

Meeting Discussion:
There was no further discussion of this item during the telecon.

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

a. The LCM between you and the Agency will be scheduled no later than December 15, 2024.

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.

Meeting Discussion:
There was no further discussion of this item during the telecon.

7. Update regarding plans for the Vaccines and Related Biological Products Advisory Committee (VRBPAC) Meeting.

A discussion of this application at a VRBPAC is not anticipated at this time.

Meeting Discussion:
There was no further discussion of this item during the telecon.

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

a. Initial labeling comments will be communicated no later than March 2, 2025.

b. Any PMR requests and PMC requests will be communicated no later than February 4, 2025, and March 2, 2025, respectively.

c. First Action Due Date: April 1, 2025.

Meeting Discussion:
There was no further discussion of this item during the telecon.

9. Discuss status of inspections (GMP, (b) (6), GLP) including issues identified that could prevent approval.

We have no issues to report on the status of inspections.

Meeting Discussion:
There was no further discussion of this item during the telecon.