



Our STN: BL 125835/0

**LATE-CYCLE  
MEETING MEMORANDUM**

ModernaTX, Inc.  
Attention: Trung Ly  
325 Binney Street  
Cambridge, MA 02142

Dear Mr. Ly:

Attached is a copy of the memorandum summarizing your March 31, 2025, 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 the appropriate Submission Tracking Number (STN) in future submissions related to the subject product.

If you have any questions, please contact Joseph Kulinski by email (Joseph.Kulinski@fda.hhs.gov).

Sincerely,

**Loris D.  
McVittie -S**

Digitally signed by Loris D.  
McVittie -S  
Date: 2025.04.30 12:27:21  
-04'00'

Loris D. McVittie, PhD.  
Director  
Division of Review Management and Regulatory Review  
Office of Vaccines Research and Review  
Center for Biologics Evaluation and Research

### Late-Cycle Meeting Summary

**Meeting Date and Time:** March 31, 2025; 1:00 PM – 2:00 PM EDT  
**Teleconference #:** [+1 412-912-1530](#), (b) (4)  
**Phone conference ID:** (b) (4)  
**Application Number:** STN 125835/0  
**Product Name:** Moderna COVID-19 Vaccine, mRNA (MNEXSPIKE)  
**Proposed Indication:** Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older who have been previously vaccinated with any COVID-19 Vaccine.  
**Applicant Name:** Moderna TX, Inc.  
**Meeting Chair:** Joseph Kulinski, Ph.D.  
**Meeting Recorders:** Sylvia Park, PharmD.; Donna Elhindi, PharmD.

#### FDA ATTENDEES:

Sudhakar Agnihothram, PhD	CBER/OVRR
Karin Bok, PhD	CBER/OVRR
Timothy Brennan, MD, PhD	CBER/OVRR/DCTR
Anissa Cheung, MS	CBER/OVRR/DVP
Alena Dabrazhynetskaya, PhD	CBER/OVRR/DVP
Nicolette Devore	CBER/OD
Donna Elhindi, PharmD	CBER/OVRR/DRMRR
David C. Kaslow, MD	CBER/OVRR
Joseph Kulinski, PhD	CBER/OVRR/DRMRR
Loris McVittie, PhD	CBER/OVRR/DRMRR
Rakesh Pandey, PhD	CBER/OVRR/DRMRR
Keith Peden, PhD	CBER/OVRR/DVP
Sylvia Park, PharmD	CBER/OVRR/DRMRR
Douglas Pratt, MD	CBER/OVRR/DCTR
Kirk Prutzman, PhD	CBER/OVRR/DRMRR
Anuja Rastogi, MD	CBER/OVRR/DCTR
Josephine Resnick, PhD	CBER/OVRR/DRMRR
Christian Sauder, PhD	CBER/OVRR/DVP
Swati Verma, PhD	CBER/OVRR/DVP
Xiao Wang, PhD	CBER/OVRR/DCTR
Peter Weina, MD, PhD	CBER/OVRR
Jerry Weir, PhD	CBER/OVRR/DVP

**APPLICANT ATTENDEES:**

Darin Edwards  
Rahnuma Wahid  
Taro Fujimori  
Brian Doyle  
Erin Tulip  
Spyros Chalkias  
Carla Vinals  
Trung Ly

Executive Director, Program Leader  
Senior Director, Program Leader  
Senior Director, Global Reg. Science  
Senior Director, Process Development  
Director, Analytical Development  
Senior Director, Clinical Development  
VP, Regulatory Affairs Strategy  
Senior Manager, US Regulatory Liaison

**BACKGROUND**

BL 125835/0 was submitted on September 30, 2024, for COVID-19 Vaccine, mRNA.

Proposed indication: Active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older previously vaccinated with any COVID-19 vaccine.

PDUFA goal date: May 30, 2025

In preparation for this meeting, FDA issued the Late-Cycle Meeting Materials on March 21, 2025.

## DISCUSSION

The applicant was instructed that the review of STN 125835/0 is still ongoing, and CBER will not engage in any discussions regarding the anticipated final regulatory action for the application. CBER noted that discussion of a mRNA-1283 New Variant Update for 2025-2026 Formula was beyond the scope of the late cycle meeting telecon.

Meeting participants were reminded to mute themselves unless they needed to speak and each participant was asked to identify themselves before they began speaking.

A brief regulatory history relevant to the discussion was provided:

- A pre-BLA telecon was held between Moderna and FDA on July 10, 2024
- FDA issued responses to additional pre-BLA questions from Moderna on August 9, 2024
- On September 30, 2024, FDA received BLA STN 125835/0 for product mRNA-1283 with a proposed indication of active immunization to prevent COVID-19 caused by SARS-CoV-2 in individuals 12 years of age and older previously vaccinated with any COVID-19 vaccine.

### 1. Discussion of Substantive Review Issues

- **Issue 1 - CMC and nonclinical information for mRNA-1283 [2024-2025 Formula]:**

CMC and nonclinical information submitted to date in STN 125835/0 pertains to mRNA-1283 encoding the N-terminal domain (NTD) and receptor-binding domain (RBD) of the Spike protein from SARS-CoV-2 Omicron variant lineage **XBB.1.5**, component of COVID-19 Vaccines (2023-2024 Formula) and not the updated COVID-19 vaccines (2024-2025 Formula) for use in the United States (U.S.) beginning in fall 2024 (see [FDA's Advice to Manufacturers of COVID-19 Vaccines \(2024-2025 Formula\)](#)).

Reference was made to the communication from Margaret Kautz to Dr. Joseph Kulinski (19 March 2025, 6:44 PM ET), containing a proposed data package (CMC and nonclinical) for mRNA-1283 (2024-2025 Formula) to be submitted to STN 125835/0 for FDA review to support an indication for use of mRNA -1283 (2024-2025 Formula). In the same communication, (b) (4)

It was also noted that until the CMC and nonclinical data for mRNA-1283 (2024-2025 Formula) has undergone a substantive review, we cannot comment at this time on the adequacy of the proposed submitted information to support an indication for use of mRNA-1283 (2024-2025 Formula). We

request that the applicant provide timely responses to any upcoming information requests related to the review of this information.

## 2. Additional Applicant Data

On March 28, 2025, Moderna submitted a data package (CMC and nonclinical) for mRNA-1283.167 (JN.1) in amendment 37 to STN 125835/0 for FDA review to support an indication for use of mRNA -1283 (2024-2025 Formula).

Moderna detailed the contents of their March 28, 2025, submission, including non-clinical study MOD-7153-1283.167, Drug Substance (DS) and Drug Product (DP) CMC data for mRNA-1283.167 (JN.1) and batch analysis data for mRNA-1283.167 DP. FDA reiterated that it would not be possible to comment at this time on the adequacy of the proposed submitted information to support an indication for use of mRNA-1283 (2024-2025 Formula).

## 3. Information Requests

- a. There was one clinical Information Request pending as of March 21, 2025. (Response was received on March 28, 2025)
  - Request to revise the estimated final study report completion dates for pediatric studies.
- b. It was acknowledged that as of March 30, 2025, an additional request for revisions to Study P904 protocol synopsis for the assessment of long-term outcomes of myocarditis following administration of the mRNA-1283 issued on March 28, 2025 was currently pending.
  - Moderna acknowledged that a response is expected by April 4, 2025.

## 1. Review Plans

There are no plans for an advisory committee meeting specifically to discuss mRNA-1283 (2024-2025 Formula). The need for PMRs and PMCs are currently under review and will be communicated at a later date. Labeling is currently under review and comments will be provided in the near future. The review team continues to work toward the May 31, 2025, Action Due Date.

## 2. Applicant Questions

The applicant inquired as to when they should expect the Agency to provide responses to Moderna's Request for Information (RFI) for the mRNA-1283 New Variant Update (NVU) 2025-2026 submitted to IND 27196/SN0069 on 31 Jan 2025. The Agency noted that discussions regarding this RFI are beyond the scope of the late cycle communication.

## 3. Wrap-up and Action Items

The applicant was requested to send the list of Moderna participants by email, and the CBER regulatory team will provide Moderna with a list of FDA participants

following the telecon. CBER noted that the final meeting summary will be sent to the applicant by no later than April 30, 2025.

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.