U.S. FOOD & DRUG ADMINISTRATION

Information Request

Our Reference: STN: 125752/2

Information Request #36

Date: December 16, 2021

To: **Michelle Olsen, Ph.D.**
ModernaTX, Inc.
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From: **Joseph Kulinski, Ph.D.**
DVRPA/OVRR/CBER
Email: Joseph.Kulinski@fda.hhs.gov

Product: COVID-19 Vaccine, mRNA (SPIKEVAX)

Subject: Safety Data

Our review of your August 24, 2021 submission (STN 125752/2) is ongoing and we have the following request for information:

Reference is made to the clinical data for Study mRNA-1273-P301 submitted in Module 5 of STN 125752/2.

1. In the 28 day follow-up period after any vaccination,
    a. For lymphadenopathy, please provide:
        i. Median day of onset and range (in days) following dose 1 and dose 2 in mRNA-1273 vs placebo arms
        ii. Median duration and range (in days) of lymphadenopathy in mRNA-1273 arm and placebo arm.
    b. For vertigo or positional vertigo, please provide:
        i. Details of participants reporting vertigo/ positional vertigo in mRNA-1273 arm vs placebo arm, such as onset from dose 1 and dose 2, concomitant medications, concomitant AEs, other underlying conditions.
        ii. Median day of onset and range (in days) following mRNA-1273 dose 1 and dose 2 vs placebo dose 1 or dose 2.

iii. Median duration and range (in days) of vertigo

2. For Part A of study P301, please provide separate tables for broad with narrow combined and narrow Standardised MedDRA Queries (SMQs) for autoimmune disorders (MedDRA version 24). For each table provide the following information:
    a. # of events reported for each term for each group
    b. 'n' participants and percentage (%) who reported each term for each group

3. For each of the SMQs listed below (submitted to CBER under STN 125752) and for the autoimmune disorders SMQ, please provide sensitivity analyses excluding events that occurred after unblinding in Part A of Study P301. Please provide separate tables for broad with narrow combined, and narrow scope.
    a. Embolic and Thrombotic events
    b. Hearing and vestibular disorders
    c. Angioedema events
    d. Arthritis events
    e. Convulsion
    f. CNS vascular disorder
    g. Hypersensitivity events
    h. Peripheral neuropathy events
    i. Demyelination events
    j. Thrombophlebitis events
    k. Vasculitis events
    l. Hematopoietic cytopenia events
    m. Cardiomyopathy events
    n. Ischemic heart disease, cardiac arrhythmia, cardiac failure

Please confirm your receipt of this request and submit your response as an amendment to STN 125752 as soon as possible but no later than December 17, 2021.

Please contact me if you have questions and include Sudhakar Agnihothram (sudhakar.agnihothram@fda.hhs.gov) and Josephine Resnick (josephine.resnick@fda.hhs.gov) on all communications.