



Telecon

Date: July 19, 2019

Sponsor: Merck Sharp & Dohme Corp.

File: STN 125690/0

Merck Participants: Thomas Armstrong, Luca Benetti, Joe Califano, Lou Coless, Beth-Ann Collier, Kristine Ellis, Jennifer Friz, Prashast Gandiga, Kimberly Hassis, Dirk Holtkamp, Risat Jannat, Bill Lapps, Tim McHugh, Yvonne Narjes, Christine Neudert, Darrell Sehlin, Jayanthi Wolf

BARDA Participants: David Aglow, Amanda Zarrabian

CBER Participants: Qiao Bobo, Carmen Collazo, Richard Daemer, Timothy Fritz, Sara Gagneten, Marion Gruber, Robin Levis, Richard Lewis, Christian Lynch, Loris McVittie, Randa Melhem, Laura Montague, Stephanie Polo, Iryna Zubkova

SUMMARY OF DISCUSSION:

Merck requested this telecon to obtain CBER's feedback on the interim report of the investigation into Process Performance Qualification (PPQ) results that fell outside of comparability criteria ranges and the out of specification potency result for (b) (4) PPQ Lot (b) (4). Merck presented the attached slide deck, which included an update on the manufacturing schedule at the (b) (4), site and projected dates for the submission of CMC data to the BLA. Merck indicated that the final investigation report will be available at the end of August 2019.

CBER noted that the investigation report referred to an equipment malfunction (cold room (b) (4)) that was not included in the list of deviations provided to the CBER inspection team during the pre-license inspection of the (b) (4) facility conducted in (b) (4). Merck agreed to submit the deviation report to the BLA.

CBER stated that data from (b) (4) PPQ Lots (b) (4) will support the licensure of V920, and that the (b) (4) engineering lot will provide additional supportive data. CBER noted that data from (b) (4) PPQ Lot (b) (4) may be required to be submitted as a postmarketing commitment, which will depend on CBER's review of the data from (b) (4) PPQ Lots (b) (4), as well as the timeline for the expedited review of the BLA. Merck indicated that the data from (b) (4) PPQ Lot (b) (4) is expected to be available for submission in February 2020. CBER asked if Merck could submit interim data for (b) (4) PPQ Lot (b) (4) in October 2019, and Merck noted that the interim report with data for (b) (4) PPA Lot (b) (4) will be available on October 3, 2019. However, Merck clarified that the full report ((b) (4) PPQ Lots (b) (4), including comparability and validation data) will not be available for submission until November 25, 2019. CBER acknowledged that the data from DP PPQ Lot (b) (4) will be submitted in September 2019, as originally planned.