

STN 125690 – Internal Meeting Summary

Application number: BLA 125690
Product name: V920 Ebola Zaire Vaccine (rVSVΔG-ZEBOV-GP, Live, Attenuated)
Proposed Indication: For active immunization of at-risk individuals 18 years of age and older to protect against Ebola Virus Disease (EVD) caused by Zaire Ebola virus
Applicant: Merck Sharp & Dohme Corp.
Meeting date & time: June 27, 2019

Attendees: Richard Daemer, Sara Gagneten, Marion Gruber, Robin Levis, Laura Montague, Stephanie Polo, Dmitriy Volokhov

Background:

On June 5, Merck provided CBER with an update on the V920 Process Performance Qualification (PPQ) at the MSD manufacturing site in (b) (4). Merck indicated that (b) (4) PPQ Lots (b) (4) have passed release testing. (b) (4) PPQ Lot (b) (4) potency was on the low side but met specification). Preliminary potency information for (b) (4) PPQ Lot (b) (4) indicates the yield of the batch is low and out of specification. An investigation is ongoing to evaluate process, equipment, and operations to determine the root cause in order to complete the (b) (4) PPQ. Studies have been initiated as part of the investigation, and results from these studies are expected to be available at the end of this month.

Merck indicated that they will invalidate (b) (4) PPQ Lot (b) (4) and make a (b) (4) PPQ lot. This will delay the submission of the (b) (4) PPQ Final Report (b) (4) Lots) that we will need to complete our review. It is now targeted for submission to the BLA in November rather than September.

This Review Committee meeting was held with OVRM Management in attendance to decide what CMC data will be needed to support licensure of V920.

Meeting Discussion:

The Review Committee discussed whether to accept the data from (b) (4) PPQ Lot (b) (4) to support licensure, considering the low yield, the results that fell outside of comparability criteria ranges, as well as the (b) (4) process. It was noted that (b) (4) PPQ Lot (b) (4) met all release specifications, even the specification for potency. The Review Committee discussed whether Merck would need to submit data for (b) (4) more (b) (4) PPQ lots to show manufacturing consistency. The Review Committee also discussed considering the data from the (b) (4) engineering lot as part of the total CMC package to demonstrate a consistent process. It was mentioned that data from (b) (4) PPQ Lot (b) (4) could be submitted as a PMC. The Review Committee indicated that they will also need to see the interim report of the root cause investigation to see if the root cause was correctly identified and corrective actions implemented prior to beginning the (b) (4) manufacturing process for (b) (4) PPQ Lot (b) (4).

The Review Committee and OVRM Management agreed that data from (b) (4) PPQ Lot (b) (4) would be acceptable to support licensure of V920, with supportive data from the engineering lots, provided the data are adequate. CBER would accept data from a further (b) (4) PPQ Lot post-licensure. CBER will send an information request to Merck to see if they can provide the data from (b) (4) PPQ Lot (b) (4) in October 2019, rather than November 2019.