

Information Request Email, Immunogenicity, October 28, 2014 - BEXSERO

- RECORD OF TELEPHONE CONVERSATION

Submission Type: BLA Submission ID: 125546/0 Office: OVRR

Product:

Meningococcal Group B Vaccine

Applicant:

Novartis Vaccines and Diagnostics, Inc.

Telecon Date/Time: 28-Oct-2014 04:48 PM Initiated by FDA? Yes

Telephone Number:

Communication Category(ies):

1. Information Request

Author: KIRK PRUTZMAN

Telecon Summary:

IR regarding immunogenicity

FDA Participants: None

Non-FDA Participants: None

Trans-BLA Group: No

Related STNs: None

Related PMCs: None

Telecon Body:

From: Prutzman, Kirk C

Sent: Tuesday, October 28, 2014 4:48 PM

To: Stoehr, Patricia (patricia.stoehr@novartis.com)

Cc: Wolfgang, Edward; Naik, Ramachandra

Subject: STN 125546 - Information Request

Dr. Stoehr,

Please find attached a request for additional information regarding STN 125546 (Meningococcal Group B Vaccine). Please provide your responses to this information request in an Amendment to STN 125546 by November 11, 2014. If you have any questions about this communication, please contact Kirk Prutzman, Ramachandra Naik, or Ed Wolfgang at (301) 796-2640.

Regards,

Kirk Prutzman, PhD

Primary Reviewer/Regulatory Project Manager

CBER/OVRR/DVRPA/CMC3

Food and Drug Administration

10903 New Hampshire Avenue

Building 71 and Room 3041
Silver Spring, MD 20993-0002
Phone: (301) 796-2640
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CENTER FOR BIOLOGICS EVALUATION AND RESEARCH
OFFICE OF VACCINES RESEARCH AND REVIEW
DIVISION OF VACCINES AND RELATED PRODUCTS APPLICATIONS

DATE: OCTOBER 28, 2014 PAGES: 3

TO: NOVARTIS VACCINES AND DIAGNOSTICS, INC

ATTENTION: PATRICIA STOEHR, PH.D.

Senior Group Manager Regulatory Affairs

Novartis Vaccines & Diagnostics

350 Massachusetts Avenue

Cambridge, MA 02139

USA

FAX: (617) 871-8060 TEL: (617) 871-4711

FROM: KIRK PRUTZMAN, PH.D.

Regulatory Project Manager

FAX: (301) 595-1244 TEL: (301) 796-2640

SUBJECT: STN: BL 125546/0 – Request For Information

MESSAGE:

Dear Dr. Stoehr:

We have the following request for additional information regarding your submission of
Biologics License Application STN 125546 (Meningococcal Group B Vaccine):

The following comments pertain to some IR responses submitted to STN

125546.0, Amendment 17, on October 3, 2014:

**Regarding study V72_29 and Group rMenB+OMV only, please address the
following issues:**

1. Please provide results of analyses related to the endpoint hSBA titers \geq LLOQ for all 3 indicator strains (the composite response) at baseline (prior to vaccination), one, and eleven months after the second vaccination. Analyses are to be performed on the immunogenicity MenB MITT and PP populations. Please provide the results in the form of an appropriate table, which should supply numbers and percentages of subjects with the corresponding 95% CIs.
2. Per Clinical Study Report (page 97), you defined immunogenicity sub-populations, called immunogenicity MenB MITT and PP populations, for one month post first and second vaccinations. Please specify/define PP population for statistical analyses of the immune responses to rMenB+OMV NZ vaccine against H44/76, 55/99, and NZ98/254 strains for eleven months after the second vaccination.
3. Please justify that immunogenicity MenB population, which are to be used for eleven months post the second vaccination analyses, are representative of the overall enrollment population. Please also supply a disposition of subjects included in the 11 month post 2nd vaccination analyses.

4. Please provide information on 45 subjects who were enrolled into the study but were not included in the immunogenicity MenB PP population for the purpose of the analysis of immune responses to rMenB+OMV NZ vaccine one month post the 2nd dose.
5. In Table Q1-3b, you presented the statistical results for immunogenicity MITT data related to hSBA \geq LLOQ at baseline and after the second dose. For the rMenB+OMV group, please supply results of similar analyses related to hSBA \geq LLOQ but based on immunogenicity PP populations.

Regarding study V72_41, please provide:

6. Results of analyses related to the endpoint hSBA titers \geq LLOQ for all 3 indicator strains (the composite response) at baseline (prior to vaccination) and one month after the second vaccination. Analyses are to be performed on the immunogenicity PP populations for each lot, and for all lots together. Please provide the results in the form of an appropriate table, which should supply numbers and percentages of subjects with the corresponding 95% CIs.

Regarding study V72P10, please provide:

7. Results of analyses related to the endpoint hSBA titers \geq LLOQ for all 3 indicator strains (the composite response) at baseline (prior to vaccination) and one month after the last vaccination (in the Primary Vaccination Course). Analyses are to be performed on the immunogenicity PP populations for rMenB01_C, rMenB02_C, and rMenB012 groups. Additionally, for the combined rMen01_C + rB012 group, please provide results of similar analyses after the second dose of the rMenB+OMV NZ vaccine. Please provide the results in the form of an appropriate table, which should supply numbers and percentages of subjects with the corresponding 95% CIs.

Regarding study V102_03 and rMenB+OMV group, please provide:

8. Results of analyses related to the endpoint hSBA titers \geq LLOQ for all 3 indicator strains (the composite response) at baseline (prior to vaccination) and one month after the second vaccination. Analyses are to be performed on the FASi (Full Analysis Set for immunogenicity) and PPSi (Per-Protocol Set for immunogenicity) for the rMenB+OMV group. Please provide the results in the form of an appropriate table, which should supply numbers and percentages of subjects with the corresponding 95% CIs.

Please provide your responses to this information request in an Amendment to STN 125546 by November 11, 2014. We recommend that you restate each item and follow it with your explanation or clarification. Use of this format helps organize the relevant information and provides a self-contained document that facilitates future reference. If you have any questions about this communication, please contact Kirk Prutzman, Ramachandra Naik, or Ed Wolfgang at (301) 796-2640.