BLA 761169/S-002

APPROVAL LETTER

Regeneron Pharmaceuticals, Inc.
Attention: Daniel Vasilchuk, PhD
Associate Manager CMC Regulatory Affairs
1 Global View
3rd Floor
Troy, NY 12180

Dear Dr. Vasilchuk:

Please refer to your supplemental biologics license application (sBLA) dated and received March 29, 2021, and your amendments, submitted under section 351(a) of the Public Health Service Act for Inmazeb (atoltivimab, maftivimab, and odesivimab-ebgn) injection.

We acknowledge receipt of your major amendment dated July 12, 2021 and July 14, 2021, which extended the goal date by two months.

This Prior Approval sBLA provides for the following:

- Updates to the Prescribing Information for REGN-EB3

APPROVAL & LABELING

We have completed our review of this supplemental application, as amended. It is approved, effective on the date of this letter, for use as recommended in the enclosed agreed-upon labeling.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, submit, via the FDA automated drug registration and listing system (eLIST), the content of labeling [21 CFR 601.14(b)] in structured product labeling (SPL) format, as described at FDA.gov, [1] that is identical to the enclosed labeling text for the Prescribing Information, and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements.

Information on submitting SPL files using eLIST may be found in the guidance for industry *SPL Standard for Content of Labeling Technical Qs and As*.[2]

The SPL will be accessible via publicly available labeling repositories.

Also within 14 days, amend all pending supplemental applications that include labeling changes for this BLA, including pending "Changes Being Effected" (CBE) supplements, for which FDA has not yet issued an action letter, with the content of labeling [21 CFR 601.12(f)] in Microsoft Word format that includes the changes approved in this supplemental application, as well as annual reportable changes. To facilitate review of your submission, provide a highlighted or marked-up copy that shows all changes, as well as a clean Microsoft Word version. The marked-up copy should provide appropriate annotations, including supplement number(s) and annual report date(s).

CARTON AND CONTAINER LABELING

Submit final printed carton and container labeling that are identical to enclosed carton and container labeling and carton and container labeling submitted on March 29, 2021, as soon as they are available, but no more than 30 days after they are printed. Please submit these labels electronically according to the guidance for industry *Providing Regulatory Submissions in Electronic Format – Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications*. For administrative purposes, designate this submission "**Product Correspondence – Final Printed Carton and Container Labeling for approved BLA 761169/S-002.**" Approval of this submission by FDA is not required before the labeling is used.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)

We have received your submission dated March 29, 2021, containing the final report for the following postmarketing commitment listed in the October 14, 2020 approval letter for BLA 761169.

3936-7 Re-evaluate and update REGN-EB3 drug substance (DS) and drug product lot release and stability specifications based on lots manufactured by the (b) (4) DS processes. The corresponding data, the analysis, and updated specifications will be submitted with the PAS for the registration of the (b) (4) commercial manufacturing process.

We have reviewed your submission and conclude that the above commitment was fulfilled.

We remind you that there are postmarketing commitments listed in the October 14, 2020 approval letter that are still open.

This information will be included in your biologics license application file.

If you have any questions, call Anh-Thy Ly, Regulatory Business Process Manager, at (240) 402 - 1001.

Sincerely,

{See appended electronic signature page}

Kathleen A Clouse, Ph.D.
Director
Division of Biotechnology Review and Research I
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure(s):
Content of Labeling
Carton and Container Labeling

Kathleen
Clouse Strebel

Digitally signed by Kathleen Clouse Strebel
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