BLA 125326/S-75

SUPPLEMENT APPROVAL

Novartis Pharmaceuticals Corporation
Attention: Lisa Perkins, MBA
Senior Global Program Regulatory Manager
One Health Plaza
Building 337/03/A13L2-40
East Hanover, NJ 07936

Dear Ms. Perkins:

Please refer to your supplemental biologics license application (sBLA), dated and received March 8, 2022, and your amendments, submitted under section 351(a) of the Public Health Service Act for Kesimpta (ofatumumab), injection.

This Prior Approval sBLA provides for the following revisions to the Prescribing Information:

1. Revises Section 12 (Clinical Pharmacology) to provide updated information regarding B-cell repletion following treatment discontinuation based on pharmacokinetic/pharmacodynamic modeling, as well as information regarding elimination and excretion of ofatumumab.

2. Revises Section 14 (Clinical Studies) to align the efficacy data with that presented in the final Clinical Study Report.

APPROVAL & LABELING

We have completed our review of this 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, Instructions for Use, and Medication Guide) and include the labeling changes proposed in any pending "Changes Being Effected" (CBE) supplements.

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm

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(s), 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).

REPORTING REQUIREMENTS

We remind you that you must comply with reporting requirements for an approved BLA (in 21 CFR 600.80 and in 21 CFR 600.81).

If you have any questions, contact CDR Candido Alicea, Regulatory Project Manager, at candido.alicea@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Paul R. Lee, MD, PhD
Deputy Director
Division of Neurology 2
Office of Neuroscience
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Medication Guide
  - Instructions for Use

[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.

This is a representation of an electronic record that was signed electronically. Following this are manifestations of any and all electronic signatures for this electronic record.

/s/

PAUL R LEE
09/02/2022 02:03:05 PM