BLA 125486/S-037
BLA 125486/S-038

SUPPLEMENT APPROVAL

Genentech, Inc.
Attention: Mandy Dorsey
Regulatory Program Management
1 DNA Way, MS 407B
South San Francisco, CA 94080

Dear Mandy Dorsey:

Please refer to your supplemental biologics license application (sBLA) received December 18, 2024 (S-037), and January 31, 2025 (S-038), and your amendments, submitted under section 351(a) of the Public Health Service Act for Gazyva (obinutuzumab) injection.

These Prior Approval supplemental biologics license applications provide for:

S-037	Treatment of adult patients with active lupus nephritis (LN) who are receiving standard therapy
S-038	A short duration infusion of approximately 90 minutes from the second infusion onwards in patients with active lupus nephritis (LN) who have completed the first obinutuzumab administration at the standard infusion rate without experiencing any Grade ≥ 3 infusion-related reactions (IRRs)

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)

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

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(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).

REQUIRED PEDIATRIC ASSESSMENTS

Under the Pediatric Research Equity Act (PREA) (21 U.S.C. 355c), all applications for new active ingredients (which includes new salts and new fixed combinations), new indications, new dosage forms, new dosing regimens, or new routes of administration are required to contain an assessment of the safety and effectiveness of the product for the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

We are waiving the pediatric study requirement for ages 0 to less than 5 years because necessary studies are impossible or highly impracticable, due to low incidence of the disease in this age group.

We are deferring submission of your pediatric studies for ages 5 to less than 18 years for this application because this product is ready for approval for use in adults and the pediatric studies have not been completed.

Your deferred pediatric studies required by section 505B(a) of the Federal Food, Drug, and Cosmetic Act are required postmarketing studies. The status of this postmarketing studies must be reported annually according to 21 CFR 601.28 and section 505B(a)(4)(B) of the Federal Food, Drug, and Cosmetic Act. These required studies are listed below.

[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.

4887-1 Conduct a multicenter, randomized, double-blind, placebo-controlled study to evaluate the efficacy, safety, pharmacokinetics, and pharmacodynamics of obinutuzumab in pediatric patients ages 12 to <18 years with proliferative lupus nephritis (Class III and IV) receiving standard of care therapy.

Study Completion: 03/2027
Final Report Submission: 12/2027

4887-2 Provide pharmacokinetic and safety information to support the pediatric assessment of obinutuzumab for the treatment of pediatric patients ages 5 to <12 years with proliferative lupus nephritis (Class III and IV) receiving standard of care therapy.

Study Completion: 12/2028
Final Report Submission: 06/2029

Reports of these required pediatric postmarketing studies must be submitted as a BLA or as a supplement to your approved BLA with the proposed labeling changes you believe are warranted based on the data derived from these studies. When submitting the reports, please clearly mark your submission "**SUBMISSION OF REQUIRED PEDIATRIC ASSESSMENTS**" in large font, bolded type at the beginning of the cover letter of the submission.

PROMOTIONAL MATERIALS

You may request advisory comments on proposed introductory advertising and promotional labeling. For information about submitting promotional materials, see the final guidance for industry *Providing Regulatory Submissions in Electronic and Non-Electronic Format-Promotional Labeling and Advertising Materials for Human Prescription Drugs.*[3]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 601.12(f)(4)]. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

[3] For the most recent version of a guidance, check the FDA guidance web page at https://www.fda.gov/media/128163/download.
[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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 Suprat Saely, Regulatory Project Manager at suprat.saely@fda.hhs.gov or 240-402-1604.

Sincerely,

{See appended electronic signature page}

Raj Nair, MD
Director
Division of Rheumatology and Transplant Medicine
Office of Immunology and Inflammation
Office of New Drugs
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
  - Prescribing Information

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/

RAJ NAIR
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