



BLA 761034/S-043

**SUPPLEMENT APPROVAL/  
FULFILLMENT OF POSTMARKETING COMMITMENT**

Genentech, Inc.  
Attention: Sili Liu, Ph.D.  
Regulatory Program Management  
1 DNA Way; MS# 451A  
South San Francisco, CA 94080

Dear Dr. Liu:

Please refer to your supplemental biologics license application (sBLA), received July 22, 2021, and your amendments, submitted under section 351(a) of the Public Health Service Act for Tecentriq (atezolizumab) liquid; 1200 mg/20 mL and 840 mg/14 mL (60 mg/mL).

This Prior Approval supplemental biologics application provides for updates to the Dosage and Administration section of the Prescribing Information to incorporate language regarding an approved companion diagnostic indicated for the detection of BRAF V600 mutations based on the summary report to fulfill post-marketing commitment (PMC) 3908-2.

**APPROVAL & LABELING**

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

**WAIVER OF HIGHLIGHTS ½ PAGE LENGTH REQUIREMENT FOR HIGHLIGHTS**

Please note that we have previously granted a waiver of the requirements of 21 CFR 201.57(d)(8) regarding the length of Highlights of Prescribing Information.

**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,<sup>1</sup> that is identical to the enclosed labeling (text for the Prescribing Information)

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<sup>1</sup> <http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm>

and include the labeling changes proposed in any pending “Changes Being Effectuated” (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*.<sup>2</sup>

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 Effectuated” (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.

Because none of these criteria apply to your application, you are exempt from this requirement.

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

We have received your submission dated July 22, 2021, containing the final report for the following postmarketing commitment listed in the July 30, 2020, approval letter for BLA 761034/S-028.

- 3908-2 In consultation with CDRH, commit to providing evidence of the accuracy of detection of the non-V600E/K variants (i.e., D, R, etc.) in the clinical trial, supplemented with additional representation of the accurate detection of these alleles when compared to a validated comparator method, if necessary, to identify unresectable or metastatic melanoma patients who may benefit from the use of atezolizumab administered with cobimetinib and vemurafenib.

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<sup>2</sup> 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>.

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

We remind you that there is a postmarketing commitment listed in the July 30, 2020, approval letter that is still open.

### **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, call Autumn Zack-Taylor, M.S., Regulatory Health Project Manager, at (240) 402-5913.

Sincerely,

*{See appended electronic signature page}*

Lola Fashoyin-Aje, M.D., M.P.H.  
Deputy Director  
Division of Oncology 3  
Office of Oncologic Diseases  
Center for Drug Evaluation and Research

#### ENCLOSURE:

- Content of Labeling
  - Prescribing Information

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**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.**  
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/s/  
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