



BLA 761034/S-050

**SUPPLEMENT APPROVAL/
RELEASE FROM
POSTMARKETING REQUIREMENT/COMMITMENT**

Genentech, Inc.
Attention: Michael Stamatis, PharmD
Regulatory Program Management
1 DNA Way
South San Francisco, CA 94080-4990

Dear Dr. Stamatis:

Please refer to your supplemental biologics license application (sBLA), dated November 14, 2022, received November 14, 2022, and your amendment submitted under section 351(a) of the Public Health Service Act for Tecentriq (atezolizumab), liquid single use vial, 1200 mg/20 mL (60 mg/mL).

This Prior Approval supplemental biologics license application provides for the withdrawal of the 1L metastatic urothelial carcinoma (mUC) accelerated approval indication for Tecentriq:

Tecentriq is indicated for the treatment of adult patients with locally advanced or metastatic urothelial carcinoma who:

- *are not eligible for cisplatin-containing chemotherapy and whose tumors express PD-L1 (PD-L1 stained tumor-infiltrating immune cells covering $\geq 5\%$ of the tumor area), as determined by an FDA-approved test, or*
- *are not eligible for any platinum-containing chemotherapy regardless of PD-L1 status*

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, and Medication Guide) 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*.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 Effectuated” (CBE) supplements, for which the 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.

RELEASE FROM POSTMARKETING REQUIREMENTS/COMMITMENT

We have received your submission dated November 14, 2022, related to the following postmarketing requirement and commitment listed in our April 17, 2017, approval letter (3196-1, and 3196-2) and our March 1, 2019, postapproval postmarketing requirement letter (3081-7):

- 3196-1 Conduct clinical trial IMvigor130 entitled, “A Phase III, Randomized Study of Atezolizumab Alone and in Combination with Chemotherapy Versus Chemotherapy Alone in Participants with Untreated Advanced Urothelial Cancer”. Submit the datasets with the final report.

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>.

Final Protocol Submission:	Completed
Trial Completion:	05/31/2020
Final Report Submission:	11/30/2020

- 3196-2 Conduct an updated analysis of duration of response after the median duration is reached for all responders in Cohort 1 of clinical trial IMVIGOR 210 (GO29293) entitled, "A Phase II, Multicenter, Single-Arm Study of MPDL3280A in Patients With Locally Advanced or Metastatic Urothelial Bladder Cancer". The analysis should include information on all responding patients and patients with an IC score of 0/1 or 2/3. Submit the datasets with the final report.

Final Report Submission:	06/30/2018
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- 3081-7 Submit the analysis and datasets with the final report, demonstrating the clinical benefit of atezolizumab from clinical trial WO30070, (ImVigor 130) entitled; "A Phase III, Multicenter, Randomized, Placebo-Controlled Study of Atezolizumab (Anti-PD-L1 Antibody) as Monotherapy and in Combination With Platinum-Based Chemotherapy in Patients With Untreated Locally Advanced or Metastatic Urothelial Carcinoma."

Final Protocol Submission:	02/2016
Final (PFS) Report Submission:	12/2019
Interim (OS) Report Submission:	12/2019
Trial Completion:	04/2021
Final (OS) Report Submission:	10/2021

We have reviewed your submission and have determined that you are released from the above requirements/commitment as they are no longer needed because the indication of metastatic urothelial carcinoma has been withdrawn from the label.

This completes all of your postmarketing requirements and postmarketing commitments acknowledged in our April 17, 2017, letter.

We remind you that there is a postmarketing requirement listed in the May 18, 2016, approval letter that is still open.

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

³ For the most recent version of a guidance, check the FDA guidance web page at <https://www.fda.gov/media/128163/download>.

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

All promotional materials for your drug product that include representations about your drug product must be promptly revised to make it consistent with the labeling changes approved in this supplement, including any new safety-related information [21 CFR 601.12(a)(4)]. The revisions to your promotional materials should include prominent disclosure of the important new safety-related information that appears in the revised labeling. Within 7 days of receipt of this letter, submit your statement of intent to comply with 21 CFR 601.12(a)(4).

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 Kim J. Robertson, Senior Regulatory Health Project Manager, at (301) 796-1441, or kim.robertson@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Daniel Suzman, MD
Supervisory Associate Director
Division of Oncology 1
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
 - Prescribing Information
 - Medication Guide

⁴ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf>

⁵ <http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf>

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/

DANIEL L SUZMAN
12/02/2022 04:03:42 PM