



BLA 761115/S-005  
BLA 761115/S-013

**SUPPLEMENT APPROVAL/  
FULFILLMENT OF POSTMARKETING REQUIREMENTS**

Immunomedics, Inc  
Attention: Diane Whiteley  
Senior Director, Regulatory Affairs  
300 The American Road  
Morris Plains, NJ 07950

Dear Ms. Whiteley:

Please refer to your supplemental biologics license applications (sBLA), dated November 23, 2020, and your amendments, submitted under section 351(a) of the Public Health Service Act for Trodelvy (sacituzumab govitecan-hziy) Injection.

Prior Approval supplemental biologics application 005 (S-005) provides for updates to the U.S. package insert to include final progression-free survival and overall survival data results from study IMMU-132-05.

Prior Approval supplemental biologics application 013 (S-013) provides for a new indication for the treatment of adult patients with unresectable locally advanced or metastatic triple-negative breast cancer (mTNBC) who have received two or more prior systemic therapies, at least one of them for metastatic disease.

We also refer to your biologics license application (BLA) 761115, approved April 22, 2020, under the regulations at 21 CFR 601 Subpart E for Accelerated Approval of Biological Products for Serious or Life-Threatening Illnesses.

**APPROVAL & LABELING**

We have completed our review of these applications, as amended. They are 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 Food and Drug Administration (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 and Patient Package Insert) 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*.<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 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).

### **SUBPART E FULFILLED**

As noted above, we approved BLA 761115 under the regulations at 21 CFR 601 Subpart E for Accelerated Approval of Biological Products for Serious or Life-Threatening Illnesses (21 CFR 601.41) and required further adequate and well-controlled clinical trials to verify and describe the clinical benefit of sacituzumab govitecan-hziy. Therefore, you were required to conduct postmarketing requirement 3504-1, described below.

### **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 studies requirement for this application because necessary studies are impossible or highly impracticable.

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

<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>.

## **FULFILLMENT OF POST-MARKETING REQUIREMENTS**

We have received your submissions dated October 29, 2020 and March 19, 2021, containing the final reports for the following postmarketing requirements listed in the April 22, 2020, approval letter for BLA 761115.

- 3504-1      Submit the final study report and datasets for progression-free survival and overall survival from trial IMMU-132-05 titled “*Phase III Study of Sacituzumab Govitecan (IMMU-132) in Refractory/Relapsed Triple-Negative Breast Cancer*”, to confirm clinical benefit of sacituzumab that may inform product labeling.
- 3504-2      Submit the clinical study report and related datasets to further characterize the risk of adverse events and UGT1A1 status in the IMMU-132-05 trial to support sacituzumab govitecan dosing recommendation for patients homozygous for UGT1A1\*28 allele that may inform labeling. The study should be conducted for sufficient duration with a sufficient number of patients to evaluate safety following multiple dose administration.
- 3504-4      Submit the final QTc prolongation evaluation report in a sub-study of the ongoing clinical trial IMMU-132-05 titled “*Phase III Study of Sacituzumab Govitecan (IMMU-132) in Refractory/Relapsed Triple-Negative Breast Cancer*” that may further inform labeling about the QT effect of SN-38 at the recommended dose of sacituzumab govitecan.

We have reviewed your submissions and conclude that the above requirements were fulfilled.

We remind you that there is a postmarketing requirement and postmarketing commitments listed in the April 22, 2020, approval letter that are still open.

## **POSTMARKETING COMMITMENT SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B**

We remind you of your postmarketing commitment agreed to under sBLA 761115/S-005:

- 4043-1      Submit the final results from the ongoing study “Testing Sacituzumab Govitecan Therapy in Patients with HER2-Negative Breast Cancer and Brain Metastases” (NCT04647916) or another trial that includes triple negative breast cancer (TNBC) patients with brain metastases that may further inform the efficacy and safety of sacituzumab govitecan in a brain metastases population in TNBC.

The timetable you submitted on March 24, 2021, states that you will conduct this study according to the following schedule:

Final Protocol Submission:	07/2020 (completed)
Trial Completion:	12/2024
Final Report Submission:	02/2025

A final submitted protocol is one that the FDA has reviewed and commented upon, and you have revised as needed to meet the goal of the study or clinical trial.

Submit clinical protocols to your IND 122694 for this product. Submit nonclinical and chemistry, manufacturing, and controls protocols and all postmarketing final reports to this BLA. In addition, under 21 CFR 601.70 you should include a status summary of each commitment in your annual progress report of postmarketing studies to this BLA. The status summary should include expected summary completion and final report submission dates, any changes in plans since the last annual report, and, for clinical studies/trials, number of patients entered into each study/trial. All submissions, including supplements, relating to these postmarketing commitments should be prominently labeled “**Postmarketing Commitment Protocol**,” “**Postmarketing Commitment Final Report**,” or “**Postmarketing Commitment Correspondence**.”

## **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*.<sup>3</sup>

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.<sup>4</sup> Information and Instructions for completing the form can be found at FDA.gov.<sup>5</sup>

## **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).

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

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

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

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If you have any questions, call Jeannette Dinin, Regulatory Project Manager, at 240-402-4978 or email: [Jeannette.Dinin@fda.hhs.gov](mailto:Jeannette.Dinin@fda.hhs.gov).

Sincerely,

*{See appended electronic signature page}*

Laleh Amiri-Kordestani, MD  
Director  
Division of Oncology 1  
Office of Oncologic Diseases  
Center for Drug Evaluation and Research

ENCLOSURE(S):

- Content of Labeling
  - Prescribing Information
  - Patient Package Insert

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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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LALEH AMIRI KORDESTANI  
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