BLA 761310/S-005

SUPPLEMENT APPROVAL/
FULFILLMENT OF POSTMARKETING
REQUIREMENT

ImmunoGen, Inc.
Attention: Jennifer Eaddy
Executive Director, Regulatory Affairs
830 Winter Street
Waltham, MA 02451

Dear Jennifer Eaddy:

Please refer to your supplemental biologics license application (sBLA), dated and received October 5, 2023, submitted under section 351(a) of the Public Health Service Act for Elahere (mirvetuximab soravtansine-gynx) injection.

This Prior Approval supplemental biologics license application provides for the submission of the study report from the confirmatory phase 3 study IMGN853-0416 (MIRASOL), titled, *"A randomized, open-label, Phase 3 study of Mirvetuximab soravtansine vs. Investigator's choice chemotherapy in platinum-resistant, advanced, high-grade epithelial ovarian, primary peritoneal, or fallopian tube cancers with high folate receptor-alpha expression,"* to satisfy the postmarketing requirement 4347-1 of the previous accelerated approval of mirvetuximab soravtansine-gynx.

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 with minor editorial revisions reflected in the enclosed 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 (Prescribing Information 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).

SUBPART E FULFILLED

We approved this BLA under the regulations at 21 CFR 601 Subpart E for Accelerated Approval of Biological Products for Serious or Life-Threatening Illnesses. Approval of this supplement fulfills your commitments made under 21 CFR 601.41.

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

We have received your submission dated October 5, 2023, containing the final report for the following postmarketing requirement listed in the November 14, 2022, approval letter for BLA 761310.

4347-1 Conduct the clinical trial IMGN853-0416 (MIRASOL) titled "A randomized, open-label, Phase 3 study of Mirvetuximab soravtansine vs. Investigator's choice chemotherapy in platinum-resistant, advanced, high-grade epithelial ovarian, primary peritoneal, or fallopian tube cancers with high folate receptor-alpha expression" and provide the final progression-free

[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.

survival (PFS), overall response rate (ORR), and overall survival (OS) analyses to obtain data on the clinical efficacy of mirvetuximab soravtansine for patients with platinum-resistant ovarian cancer.

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

We remind you that there are postmarketing requirements and postmarketing commitments listed in the November 11, 2022, approval letter that are still open.

POSTMARKETING COMMITMENTS SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitments:

4610-1 Complete the ongoing clinical trial, Study 0416, entitled, "A Study of Mirvetuximab Soravtansine vs. Investigator's Choice of Chemotherapy in Platinum-Resistant, Advanced High-Grade Epithelial Ovarian, Primary Peritoneal, or Fallopian Tube Cancers with High Folate Receptor-Alpha Expression (MIRASOL)," including the pre-specified final overall survival analysis.

The timetable you submitted on March 14, 2024, states that you will conduct this study according to the following schedule:

Trial Completion:	06/2024
Final Report Submission:	12/2024

Submit the final overall survival datasets with the final report submission.

4610-2 Evaluate the effect of anti-mirvetuximab soravtansine antibodies and the effect of neutralizing antibodies against mirvetuximab soravtansine on the efficacy, safety, and pharmacokinetics of mirvetuximab soravtansine. Submit an amended integrated summary of immunogenicity report with data from a sufficient number of patients in ongoing studies and future studies. Key efficacy endpoints should include overall response rate, progression-free survival, and overall survival.

The timetable you submitted on March 14, 2024, states that you will conduct this study according to the following schedule:

Draft Protocol Submission (Analysis Plan):	12/2024
Final Protocol Submission (Analysis Plan):	06/2025
Study Completion:	12/2027
Final Report Submission:	06/2028

Submit the datasets with the final report submission.

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 111915 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/subjects 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.*[3]

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).

[3] For the most recent version of a guidance, check the FDA guidance web page athttps://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

If you have any questions, contact Anna Lananh Nguyen, PharmD, Regulatory Project Manager, via email at Lananh.Nguyen@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
  - Medication Guide

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/

LALEH AMIRI KORDESTANI
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