BLA 761228/S-002

**SUPPLEMENT APPROVAL/**
**FULFILLMENT OF POSTMARKETING**
**COMMITMENT**

Immunocore, Ltd.
Attention: Mark Moyer
Senior Vice President
Regulatory Sciences, Immunocore LLC
Six Tower Bridge
181 Washington Street, Suite 540
Conshohocken, PA 19428-2068

Dear Mr. Moyer:

Please refer to your supplemental biologics license application (sBLA), received November 1, 2022, and your amendments, submitted under section 351(a) of the Public Health Service Act for KIMMTRAK (tebentafusp-tebn), intravenous infusion.

This Prior Approval supplemental biologics application provides for updates to the KIMMTRAK (tebentafusp-tebn) Package Insert (USPI), Section 2.1 Patient Selection including a reference to FDA-approved CDx tests and adding a clarification to select patients for treatment of unresectable or metastatic uveal melanoma with KIMMTRAK based on a positive HLA-A*02:01 genotyping test of a whole blood sample.

## 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 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).

## FULFILLMENT OF POSTMARKETING COMMITMENT

We have received your submission dated April 29, 2022, containing the final report for the following postmarketing commitment listed in the January 25, 2022, approval letter for BLA 761228.

4180-1 Conduct an assay validation study to demonstrate that the assay can accurately differentiate HLA-A*02:01 from other HLA A alleles for identification of patients with uveal melanoma who may benefit from treatment with Kimmtrak (tebentafusp-tebn) and use the data to support an FDA approved companion diagnostic HLA typing assay patient selection test.

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

We remind you that there are postmarketing commitments listed in the January 25, 2022, approval letter that are 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]

[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.

[3] For the most recent version of a guidance, check the FDA guidance web page athttps://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 Nataliya Fesenko, Pharm.D., Regulatory Health Project Manager, at (240) 402-6376.

Sincerely,

*{See appended electronic signature page}*

Steven Lemery, M.D., M.H.S.
Director
Division of Oncology 3
Office of Oncologic Diseases
Center for Drug Evaluation and Research

ENCLOSURE:

- Content of Labeling
  - Prescribing Information

[4] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM083570.pdf
[5] http://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM375154.pdf

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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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STEVEN J LEMERY
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