



BLA 761228/S-003

**SUPPLEMENT APPROVAL/  
FULFILLMENT OF POSTMARKETING COMMITMENT**

Immunocore Limited  
Attention: Tien M. Huynh, MS  
Director, Global Regulatory Affairs  
Immunocore LLC  
Six Tower Bridge, 181 Washington Street  
Conshohocken, PA 19428-2068

Dear Tien M. Huynh:

Please refer to your supplemental biologics license application (sBLA), dated December 28, 2023, and your amendments, submitted under section 351(a) of the Public Health Service Act for KIMMTRAK (tebentafusp-tebn), Injection, 100 mcg in 0.5 mL.

This Prior Approval supplemental biologics license application updates the Immunogenicity (6.2) and Pharmacokinetics (12.3) sections of the KIMMTRAK (tebentafusp-tebn) Prescribing Information (PI) with information on anti-drug neutralizing antibodies (ADA) based on the Postmarketing Commitment (4180-2) Final Neutralizing Antibody Report.

**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,<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.

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<sup>1</sup> <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*.<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).

### **FULFILLMENT OF POSTMARKETING COMMITMENT**

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

4180-2      Conduct an assessment to determine the presence of neutralizing anti-drug antibodies against Kimmtrak (tebentafusp-tebn) in all patient samples that tested positive for binding anti-drug antibodies in studies IMCgp100-202 and IMCgp100-102 by using the validated neutralizing anti-drug antibody assay. Include an assessment of the clinical impact of the neutralizing anti-drug antibodies on pharmacokinetics, efficacy and safety of Kimmtrak (tebentafusp-tebn) in the study report.

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.

### **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>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>.

If you have any questions, call Nataliya Fesenko, Pharm.D., Senior Regulatory Health Project Manager, at (240) 402-6376.

Sincerely,

*{See appended electronic signature page}*

Chana Weinstock, M.D.  
Deputy Director (acting)  
Division of Oncology 3  
Office of Oncologic Diseases  
Center for Drug Evaluation and Research

ENCLOSURES:

- 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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CHANA WEINSTOCK  
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