BLA 761164/S-001

CORRECTED SUPPLEMENT APPROVAL

Bioverativ USA Inc.
Attention: Amanda Meisel
US Lead, North America Rare and Rare Blood Disorders
55 Corporate Drive
Bridgewater, NJ 08807

Dear Ms. Meisel:

Please refer to your Supplemental Biologics License Application (sBLA) dated May 31, 2022, received May 31, 2022, and your amendments, submitted under section 351(a) of the Public Health Service Act for Enjaymo (sutimlimab-jome) injection.

We also refer to our approval letter dated September 23, 2022, which contained the following error: "an extension of intermediate hold time for (b) (4) ". The statement should read "an extension of intermediate hold time for (b) (4) ".

This corrected action letter incorporates the correction of the error. The effective action date will remain September 23, 2022, the date of the original letter.

This Prior Approval sBLA provides for:

1. an upgrade of some drug substance (DS) manufacturing process equipment at (b) (4)
2. an extension of intermediate hold time for (b) (4) ;
3. an extension of the DS shelf life to (b) (4) months from the date of manufacture when stored at long-term storage condition of (b) (4) °C.

APPROVAL

We have completed our review of this sBLA, as amended. This supplement is approved.

This information will be included in your biologics license application file.

If you have any questions, call Melinda Bauerlien, Senior Regulatory Business Process Manager, at (301) 796 - 0906.

Sincerely,

{See appended electronic signature page}

CAPT Cyrus Agarabi, Pharm.D., Ph.D.
United States Public Health Service
Director
Division of Biotechnology Review and Research II
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Cyrus Agarabi

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