BLA 761172/S-004

SUPPLEMENT APPROVAL

Ridgeback Biotherapeutics, LP
Attention: Dana Dunn, MS
Regulatory Affairs Agent
2709 Silkwood Court
Oakton, VA 22124

Dear Ms. Dunn:

Please refer to your supplemental biologics license application (sBLA) dated and received November 19, 2021, and your amendments, submitted under section 351(a) of the Public Health Service Act for Ebanga (ansuvimab-zykl).

This Prior Approval sBLA application updates the storage, handling, preparation, and administration conditions in the labeling for Ebanga and provides compatibility data to address PMC 3965-12.

APPROVAL & LABELING

We have completed our review of this sBLA, 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.

Information on submitting SPL files using eLIST may be found in the guidance for industry titled *SPL Standard for Content of Labeling Technical Qs and As* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

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 MS Word format that includes the changes approved in this supplemental application.

CARTON AND CONTAINER LABELS

We acknowledge your May 19, 2022, submission containing final printed carton and container labeling.

FULFILLMENT OF POSTMARKETING REQUIREMENT(S)/COMMITMENT(S)

We have received your submission dated November 19, 2021, containing the final report for the following postmarketing commitment listed in the December 21, 2020 approval letter for BLA 761172.

3965-12 To conduct comprehensive compatibility and in-use stability studies to support the storage, handling, preparation, dilution scheme, and administration conditions and materials described in the ansuvimab labeling and to support the stability of drug product quality attributes during administration. The compatibility studies and in-use stability studies will include evaluation of 5% dextrose as a diluent to support the administration of drug product to neonates. The labeling will be updated based on the results from these studies. The final compatibility study data and updates to the labeling will be reported per 21 CFR 601.12

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

We remind you that there are postmarketing commitments listed in the December 21, 2020 approval letter that are still open.

POSTMARKETING COMMITMENTS NOT SUBJECT TO REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment:

4282-1 To conduct comprehensive compatibility and in-use stability studies to support the use of common administration materials used for infusion by IV bag and syringe, such as polyvinyl chloride (PVC) and ethylene vinyl acetate (EVA). The compatibility studies should evaluate the stability of ansuvimab diluted in 0.9% sodium chloride and 5% dextrose diluents for all the materials of construction assessed and include at minimum an assessment of visible and subvisible particles, aggregates, protein concentration, and recovery. The labeling will be updated based on the results from these studies, as needed. The final compatibility study data and updates to the labeling will be reported per 21 CFR 601.12.

The timetable you submitted on May 13, 2022 states that you will conduct this study according to the following schedule:

Final Protocol Submission:	NA
Study/Trial Completion:	NA
Final Report Submission:	December 2023

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 Kelly Ballard, Senior Regulatory Business Process Manager, at (301) 348 - 3054.

Sincerely,

{See appended electronic signature page}

Susan Kirshner, Ph.D.
Director
Division of Biotechnology Review and Research II
Office of Biotechnology Products
Office of Pharmaceutical Quality
Center for Drug Evaluation and Research

Enclosure:

Content of Labeling

Susan Kirshner

Digitally signed by Susan Kirshner
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