BLA 761340/Original 2

BLA APPROVAL

Samsung Bioepis Co., Ltd.
c/o Samsung Bioepis United States Inc
Attention: Yelena Vaydman
Senior Manager
400 Frank W Burr Blvd
Glenpointe The Atrium, Suite #125
Teaneck, NJ 07666

Dear Yelena Vaydman:

Please refer to your biologics license application (BLA) dated April 21, 2023, received April 21, 2023, and your amendments, under section 351(k) of the Public Health Service Act for Epysqli (eculizumab-aagh) injection.

We acknowledge receipt of your amendment dated August 8, 2025, which constituted a request for approval following our July 19, 2024, provisional determination.

BLA 761340 initially provided for:

- Epysqli (eculizumab-aagh) 300 mg/30 mL (10 mg/mL) injection for intravenous (IV) use in a single-dose vial (vial) as biosimilar to and interchangeable with US-Soliris (eculizumab) 300 mg/30 mL (10 mg/mL) injection for IV use in a vial.

For administrative purposes, BLA 761340 was split as follows:

- BLA 761340/Original 1 – biosimilarity
- BLA 761340/Original 2 – interchangeability

The subject of this correspondence is BLA 761340/Original 2. A separate correspondence was issued for BLA 761340/Original 1 on July 19, 2024.

LICENSING

We have approved BLA 761340/Original 2 for Epysqli (eculizumab-aagh) as an interchangeable biosimilar product effective this date. You are hereby authorized to introduce or deliver for introduction into interstate commerce, Epysqli under your existing Department of Health and Human Services U.S. License No. 2046.

Epysqli is indicated for the following indications:

- The treatment of patients with paroxysmal nocturnal hemoglobinuria (PNH) to reduce hemolysis, and

- The treatment of patients with atypical hemolytic uremic syndrome (aHUS) to inhibit complement-mediated thrombotic microangiopathy.
- The treatment of generalized myasthenia gravis (gMG) in adult patients who are anti-acetylcholine receptor (AchR) antibody positive.

MANUFACTURING LOCATIONS

For information regarding approved manufacturing locations, see the Manufacturing Locations section of the correspondence for BLA 761340/Original 1 dated July 19, 2024, and all approval letters for supplements to BLA 761340/Original 1 that were issued prior to this letter, if applicable.

FDA LOT RELEASE

For information regarding FDA lot release, see the FDA Lot Release section of the correspondence for BLA 761340/Original 1 dated July 19, 2024.

APPROVAL AND 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] Content of labeling must be identical to the enclosed labeling (text for the Prescribing Information and Medication Guide). 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.

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

[1] http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm
[2] We update guidances periodically. For the most recent version of a guidance, check the FDA Guidance Documents Database at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

the claimed indication(s) in pediatric patients unless this requirement is waived, deferred, or inapplicable.

At this time, we have determined that, with respect to the treatment of gMG in pediatric patients aged 0 to 6 years of age, no pediatric assessment will be required under PREA for your BLA. You have provided a pediatric assessment for the treatment of gMG in pediatric patients aged 6 years to less than 17 years of age, and nothing further is required at this time.

POSTMARKETING COMMITMENTS NOT SUBJECT TO THE REPORTING REQUIREMENTS UNDER SECTION 506B

We remind you of your postmarketing commitment:

4619-1 Perform real-time drug product commercial container closure system leachate studies using appropriate test methods to identify and quantify volatile organic compounds (VOC), semi-VOC, non-VOC, and trace metals at regular intervals through the end of shelf life. The study results will be updated annually in the BLA Annual Report. The final results of this study and the toxicology risk evaluation for the levels of leachates detected in the drug product will be provided in the final study report to the BLA.

Final Report Submission: 07/2026

RISK EVALUATION AND MITIGATION STRATEGY (REMS) REQUIREMENTS

The REMS for Epysqli was originally approved on July 19, 2024, and the most recent REMS modification was approved on November 10, 2025. The REMS consists of a elements to assure safe use, an implementation system, and a timetable for submission of assessments of the REMS.

Your approved REMS is appended to this letter.

The timetable for submission of assessments of the REMS remains the same as that approved on July 19, 2024.

There are no changes to the REMS assessment plan described in our July 19, 2024, letter.

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]

You must submit final promotional materials and Prescribing Information, accompanied by a Form FDA 2253, at the time of initial dissemination or publication [21 CFR 601.12(f)(4)]. Form FDA 2253 is available at FDA.gov.[4] Information and Instructions for completing the form can be found at FDA.gov.[5]

REPORTING REQUIREMENTS

You must submit adverse experience reports under the adverse experience reporting requirements for licensed biological products (21 CFR 600.80).

Prominently identify all adverse experience reports as described in 21 CFR 600.80.

You must submit distribution reports under the distribution reporting requirements for licensed biological products (21 CFR 600.81).

You must submit reports of biological product deviations under 21 CFR 600.14. You should promptly identify and investigate all manufacturing deviations, including those associated with processing, testing, packing, labeling, storage, holding and distribution. If the deviation involves a distributed product, may affect the safety, purity, or potency of the product, and meets the other criteria in the regulation, you must submit a report on Form FDA 3486 to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
5901-B Ammendale Road
Beltsville, MD 20705-1266

Biological product deviations, sent by courier or overnight mail, should be addressed to:

Food and Drug Administration
Center for Drug Evaluation and Research
Division of Compliance Risk Management and Surveillance
10903 New Hampshire Avenue, Bldg. 51, Room 4207
Silver Spring, MD 20903

[3] For the most recent version of a guidance, check the FDA guidance web page at https://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 questions, contact Anh-Thy Ly, Project Manager, at 240-402-1001 or Anh-Thy.Ly@fda.hhs.gov.

Sincerely,

{See appended electronic signature page}

Tanya Wroblewski, MD
Deputy Director
Division of Nonmalignant Hematology
Office of Cardiology, Hematology,
Endocrinology, and Nephrology
Center for Drug Evaluation and Research

ENCLOSURES:

- Content of Labeling
  - Branded Product Labeling
    - Prescribing Information
    - Medication Guide
  - Unbranded Biological Product Labeling
    - Prescribing Information
    - Medication Guide
- REMS

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/

TANYA M WROBLEWSKI
11/28/2025 09:22:04 AM