Our STN: BL 125795/90

SUPPLEMENT APPROVAL
September 23, 2026

Takeda Pharmaceuticals U.S.A., Inc.
Attention: Arjun Singh Channi
125 Binney Street
Cambridge, MA 01242

Dear Mr. Channi:

We have approved your request received August 27, 2026, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for ADAMTS13, recombinant-krhn [ADZYNMA] to add a Boxed Warning and update the Warnings and Precautions, Immunogenicity, and Patient Information sections of the US Prescribing Information for ADZYNMA to include the risk of serious outcomes including death due to developing neutralizing antibodies to ADAMTS13.

The review of this supplement was associated with our February 5, 2026, Safety Labeling Change Notification letter and our May 20, 2026, Safety Labeling Change Order letter invoking authority under section 505(o)(4) of the Federal Food, Drug, and Cosmetic Act to require safety related label changes to the labeling of ADZYNMA. This was to address the safety information related to the development of neutralizing antibodies to ADAMTS13, resulting in decreased or lack of response to recombinant or plasma-derived ADAMTS13, associated with serious outcomes including death.

LABELING

Under 21 CFR 201.57(c)(18), patient labeling must be referenced in section 17 PATIENT COUNSELING INFORMATION. Patient labeling must be available and may either be reprinted immediately following the full prescribing information of the package insert or accompany the prescription product labeling.

We hereby approve the draft content of labeling Package Insert and the Patient Package Insert submitted under amendment 2, dated September 17, 2026.

CONTENT OF LABELING

As soon as possible, but no later than 14 days from the date of this letter, please submit the final content of labeling (21 CFR 601.14) in Structured Product Labeling (SPL) format via the FDA automated drug registration and listing system, (eLIST) as described at http://www.fda.gov/ForIndustry/DataStandards/StructuredProductLabeling/default.htm.

Content of labeling must be identical to the Package Insert and Patient Package Insert submitted on September 17, 2026. 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* at http://www.fda.gov/downloads/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/UCM072392.pdf.

The SPL will be accessible via publicly available labeling repositories.

All final labeling should be submitted as Product Correspondence to this BLA, STN BL 125795 at the time of use and include implementation information on Form FDA 356h.

ADVERTISING AND PROMOTIONAL LABELING

You may submit two draft copies of the proposed introductory advertising and promotional labeling with Form FDA 2253 to the Advertising and Promotional Labeling Branch at the following address:

Food and Drug Administration
Center for Biologics Evaluation and Research
Document Control Center
10903 New Hampshire Ave.
WO71–G112
Silver Spring, MD 20993-0002

You must submit copies of your final advertising and promotional labeling at the time of initial dissemination or publication, accompanied by Form FDA 2253 (21 CFR 601.12(f)(4)).

All promotional claims must be consistent with and not contrary to approved labeling. You should not make a comparative promotional claim or claim of superiority over other products unless you have substantial evidence or substantial clinical experience to support such claims (21 CFR 202.1(e)(6)).

We will include information contained in the above-referenced supplement in your BLA file.

Sincerely,

Bindu George, MD
Acting Director
Division of Clinical Evaluation Hematology
Office of Clinical Evaluation
Office of Therapeutic Products
Center for Biologics Evaluation and Research