Our STN: BL 125758/50

SUPPLEMENT APPROVAL
July 18, 2025

Orchard Therapeutics (Europe) Limited
Attention: Jason Bablak
Orchard Therapeutics North America
101 Seaport Blvd., 7th Floor
Boston, MA 02210

Dear Jason Bablak:

Please refer to your supplement to your Biologics License Application (BLA) received January 31, 2025, submitted under section 351(a) of the Public Health Service Act (PHS Act) for atidarsagene autotemcel.

We also refer to our supplement approval letter dated May 30, 2025, which contained the following error:

> The letter was missing information regarding the proposed changes to the Package Insert that was submitted under amendment 1, dated March 4, 2025

This replacement approval letter incorporates the correction of the error. The effective approval date will remain May 30, 2025, the date of the original supplement approval letter.

We have approved your request received January 31, 2025, to supplement your Biologics License Application (BLA) submitted under section 351(a) of the Public Health Service Act for atidarsagene autotemcel to remove the type of test procedure used by the Qualified Treatment Centre (QTC) (or their appointed testing center) for patient mycoplasma testing, to allow use of alternative mycoplasma tests. We have also approved the changes to Section 8.6 of the Package Insert, submitted under amendment 1, dated March 4, 2025.

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 submitted under amendment 1, dated March 4, 2025.

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 submitted on March 4, 2025. 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 125758/0 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)).

For each pending supplemental application for this BLA that includes proposed revised labeling, please submit an amendment to update the proposed revised labeling with the change approved today.

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

Sincerely,

Kimberly Schultz, PhD
Director
Division of Gene Therapy 2
Office of Gene Therapy
Office of Therapeutic Products
Center for Biologics Evaluation and Research