



Our STN: BL 125758/50

SUPPLEMENT APPROVAL

May 30, 2025

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

Dear Jason Bablak:

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 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