Drug Databases (http://www.fda.gov/Drugs/InformationOnDrugs/default.htm)

# Postmarket Requirements and Commitments

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| | |
|---|---|
| **Applicant:** | SAREPTA THERAPEUTICS INC |
| **Product:** | Exondys 51 (Eteplirsen) |
| **NDA/BLA Number:** | 206488 |
| **NDA/BLA Approval Date:** | 09/19/2016 |
| **Annual Report Due Date:** (must be submitted within 60 days of this date) | 09/19/2026 |
| **Annual Report Received:** | 11/14/2025 |

### Requirement/Commitment Number: 1

| | |
|---|---|
| **Required Under:** | Accelerated Approval |
| **Original Projected Completion Date:** | 05/31/2021 |
| **Description:** | PMR 3095-1: In order to verify the clinical benefit of eteplirsen, conduct a 2-year randomized, double-blind, controlled trial of eteplirsen in patients who have a confirmed mutation of the DMD gene that is amenable to exon 51 skipping. Patients should be randomized to the approved dosage of eteplirsen (30 mg/kg weekly) or to a dosage that provides significantly higher exposure, e.g., 30 mg/kg daily. The primary endpoint will be the North Star Ambulatory Assessment. |
| **Current Status:** | Delayed |
| **Explanation of Status:** | The final report milestone was missed, because the sponsor requested milestone extensions due to study delays. Agency Acknowledged revised milestone in letter dated 12/20/24. |

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