



March 19, 2026

Dear Duchenne Community,

We are writing to share an important update that reflects continued progress in the journey we are all on together.

Today, Sarepta provided an update on its interactions with FDA regarding AMONDYS 45 and VYONDYS 53 following completion of ESSENCE, our post-marketing requirement study that was completed last year.

### **What guidance did we get from FDA on next steps for AMONDYS and VYONDYS?**

Following the completion of ESSENCE, Sarepta sought guidance from FDA on submitting supplemental new drug applications (sNDAs) to convert the accelerated FDA approvals of AMONDYS 45 and VYONDYS 53 to traditional approvals.

Today we shared that FDA provided feedback and we plan to submit data from ESSENCE and additional published real-world evidence as part of the sNDAs packages to support the review.

### **What happens next?**

Sarepta plans to submit supplemental regulatory applications by the end of April seeking traditional approval for AMONDYS 45 and VYONDYS 53. The regulatory applications will include the data from ESSENCE along with an extensive body of real-world evidence supporting the impact of these therapies on Duchenne.

Dystrophin restoration therapies aim to preserve and protect remaining muscle and the body of data over the last decade continues to grow.

For families, patients, caregivers, clinicians, and advocates living with Duchenne muscular dystrophy, progress is rarely measured in headlines. It is measured in everyday moments—steps taken, strength preserved, time gained, hope sustained over years, not months.

What stands out is the continued commitment to listen, to learn, and to bring forward all available evidence—clinical data alongside real-world outcomes—to ensure that decisions reflect the full picture of life with Duchenne.



To the families who have contributed to research, trials, and care—your strength continues to shape the path forward. Your participation, your advocacy, and your perseverance are the foundation of every advancement we see today. Thank you.

Please reach out to [advocacy@sarepta.com](mailto:advocacy@sarepta.com) if you have any questions.

Wendy

A handwritten signature in black ink, appearing to read "Wendy Erler", with a stylized, cursive script.

**Wendy Erler**

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