June 25, 2026

Dear DMD Community:

We are pleased to share that we have submitted an application to the U.S. Food and Drug Administration (FDA) seeking approval of delpacibart zotadirsen (also known as "del-zota" or AOC 1044) as a treatment option for people living with Duchenne muscular dystrophy (DMD) who have a genetic variant that may be treated through exon 44 skipping (DMD44).

This application, known as a Biologics License Application (BLA), includes data from the Phase 1/2 EXPLORE44® and EXPLORE44-OLE™ clinical trials. The application was submitted through the FDA's Accelerated Approval pathway, which is designed to help bring therapies for serious diseases to patients sooner while additional confirmatory data continue to be collected.

A global phase 3 trial (SAFARI44™) is initiated as a confirmatory trial and is intended to further evaluate the long-term safety of del-zota and help confirm its clinical benefit. The study will be conducted outside the United States. You can learn more about the phase 3 trial by visiting the study's page on clinicaltrials.gov.

This important milestone would not have been possible without the participation and dedication of the individuals and families who took part in the EXPLORE44® clinical development program. We extend our sincere gratitude to all trial participants, their caregivers and families, advocacy organizations, investigators, and study teams. Your commitment has helped advance the development of a potential new treatment option for the DMD44 community.

If you have questions about del-zota or the EXPLORE44® or EXPLORE44-OLE™ clinical trials, please speak with your healthcare provider.

Sincerely,

The AOC1044 Clinical Development team
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