July 23, 2025

Dear Advocacy Partner,

We are pleased to share that the U.S. Food and Drug Administration (FDA) granted delpacibart zotadirsen (abbreviated as del-zota) Breakthrough Therapy designation for the treatment of people living with Duchenne muscular dystrophy amenable to exon 44 skipping (DMD44).

We understand that there has been significant news in the DMD community over the past week, and we share your sense of urgency and desire to bring therapies to the DMD community as quickly as possible.

Our expected timelines for development and potential approval of del-zota remain unchanged, and we remain on track for a planned Biologics License Application (BLA) submission at year end 2025.

Breakthrough Therapy designation is granted by FDA to expedite the development and review of drugs for serious or life-threatening conditions. To achieve Breakthrough Therapy designation, there must be preliminary clinical evidence that demonstrates the drug may have a substantial improvement on at least one clinically significant endpoint over currently available therapies.

We want to thank the entire DMD community for your time, commitment and continued contributions to the development of del-zota. In particular, we are so grateful to the participants in the EXPLORE44® and EXPLORE44-OLE™ studies, their families, the investigators and their teams. Your participation in the EXPLORE44 program generated the data that support this designation as well as the data needed to advance del-zota to the next stage of development.

This designation from the FDA further reinforces the significant potential of del-zota to address the underlying cause of DMD44 and underscores the unmet need in the DMD community. Del-zota is currently an investigational product. It has not been approved by the FDA or any other regulatory authority for commercial use, and the safety and efficacy of del-zota have not been established.

You can view our full press release announcing today's DMD44 news here: *Avidity Biosciences Receives FDA Breakthrough Therapy Designation for Delpacibart Zotadirsen (del-zota) for the Treatment of DMD in People with Mutations Amenable to Exon 44 Skipping*

We encourage you to contact your doctor if you have any questions about del-zota or the EXPLORE44 and EXPLORE44-OLE trials.

Sincerely,

The Avidity Team