August 4, 2025

To the Duchenne Muscular Dystrophy Community:

We recognize and share the sense of urgency in the community and are inspired every day by the strength of individuals, families and caregivers. This is what drives our work to advance potential therapies designed to deliver functional improvement for people living with Duchenne muscular dystrophy (DMD).

Today, we are pleased to share that the U.S. Food and Drug Administration (FDA) has granted **Breakthrough Therapy Designation to DYNE-251**, our investigational therapy for the treatment of patients with DMD, amenable to exon 51 skipping.

The FDA grants Breakthrough Therapy Designation to therapies that show early promise of being significantly better than current treatments, especially in improving meaningful outcomes for patients. This special FDA designation means we'll receive added support from senior FDA experts and have early, frequent communication with them to help guide our development and regulatory strategy more efficiently and effectively.

**While DYNE-251 remains investigational and has not yet been approved by the FDA or other regulatory agencies, this designation affirms our belief in its potential and further energizes our team to continue to work with focus, care and urgency.**

We remain grateful to the entire patient community for your trust and engagement. Participation in the DELIVER clinical trial generated the data that supports this designation and helps progress this program forward.

Looking ahead, we plan to deliver data from the ongoing Registrational Expansion Cohort of the DELIVER clinical trial in late 2025, and expect these data, as well as results from previous parts of the trial, to support a potential submission for Accelerated Approval in the United States in early 2026.

We invite you to read our full press release here and encourage you to reach out to your healthcare provider if you have questions about the DELIVER trial or DYNE-251.

With gratitude and hope,

The Dyne Therapeutics Team

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