



To members of the Duchenne community,

As you know from our announcement this week, the U.S. Food and Drug Administration (FDA) placed a clinical hold on our application to initiate a clinical trial for DYNE-251 in patients with Duchenne muscular dystrophy amenable to skipping exon 51.

We understand that the term ‘clinical hold’ can be very concerning to the Duchenne community, given the history of clinical holds for other potential therapies in development for DMD.

It is important to note that DYNE-251 is not yet in the clinic; hence *this clinical hold is not related to an incident in the clinic or in a Duchenne patient; this clinical hold asks for additional clinical and nonclinical information about our program.* We expect to respond to the FDA’s request with data from existing and ongoing studies in the second quarter of 2022, and if satisfactory to the FDA, we plan to begin dosing patients by mid-2022 as we previously communicated.

We are committed to resolving the clinical hold as quickly as possible, and we remain urgent in our commitment to our mission of developing life-transforming therapies for people with serious muscle diseases.

The Duchenne community has helped guide the development of our program from its earliest days via patient advisory workshops, community advisory boards and other feedback mechanisms. Your insights have been invaluable, and we will continue our commitment to this partnership.

Thank you for your interest and support.

Molly White
Vice President, Global Head of Patient Advocacy and Engagement
Dyne Therapeutics

