31 March 2025

Dear members of the World Duchenne Organization,

We are sharing a community letter in response to your request for updates about our Duchenne clinical development programme.

On March 18 Sarepta announced the sad news regarding a young man with Duchenne muscular dystrophy who passed away following treatment with delandistrogene moxeparvovec, having suffered acute liver failure. You can find the community letter about this on the Sarepta website (link). There is still an ongoing assessment and analysis of information following this sad event.

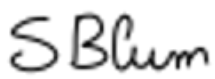
As part of our commitment to keeping the community informed we want to share that the European Medicines Agency (EMA) has requested a temporary clinical hold on Study 104 (NCT06241950), Study 302 (ENVOL, NCT06128564), and Study 303 (ENVISION, NCT05881408) until the analysis into the cause of death is complete. You can find additional information about each of these studies below.

We are pausing enrollment and dosing of participants in these studies at EU country study sites, as well as the UK for the Roche-sponsored ENVOL study. Patient safety monitoring for already enrolled participants and ongoing collection of data will continue.

Patient safety and well-being are Roche's top priority. We will be collaborating closely with EMA and sharing updates as we have them.

Thank you as always for the role you play in advancing outcomes in Duchenne. We truly appreciate your leadership and the opportunity to work together with you in these efforts.

Sincerely,



Sandra Blum, on behalf of the Roche Global DMD team
Global Patient Partnership Leader

- Study 104 (NCT06241950), a Sarepta-sponsored Phase I open-label, systemic gene delivery study to evaluate the safety, tolerability and expression of Elevidys in association with imlifidase in individuals aged 4 to 9 years with pre-existing antibodies to recombinant adeno-associated virus serotype, rAAVrh74.
- ENVOL (Study 302, NCT06128564), a Roche-sponsored Phase II study evaluating the safety of Elevidys and expression of Elevidys micro-dystrophin protein in young children, including babies and newborns.
- ENVISION (Study 303, NCT05881408), a Sarepta-sponsored global Phase III study investigating the safety and efficacy of Elevidys in participants who are ambulatory (aged 8 to <18 years old) and non-ambulatory (no age limitation).