July 28, 2025

Dear Duchenne Community,

Sarepta To Reinstate Shipment of ELEVIDYS to Ambulatory Patients

We are writing to share news of today's FDA announcement that Sarepta may resume ELEVIDYS shipments for ambulatory patients. This enables us to lift the voluntary pause of ELEVIDYS shipments for the ambulatory patient population. Sarepta will begin shipping to sites of care imminently.

FDA's review of the safety data in the ambulatory population included the case of an 8-year-old in Brazil whose death was deemed unlikely to be related to treatment with ELEVIDYS by the Brazilian health authorities. FDA's investigation has concluded the death was unrelated to treatment with ELEVIDYS and confirmed that Sarepta can resume shipments.

Sarepta's team will be reaching out to sites of care that had infusions scheduled for July and August to inform them of the availability of ELEVIDYS for ambulatory patients, encourage them to have conversations with patients and families about the risks and benefits of treatment, and allow them to make informed decisions about their care.

We will continue to engage with FDA and respond to requests for information through the regulatory Safety Labeling Change Notification process and expect to update the ELEVIDYS prescribing information based on the outcome of our ongoing engagement with the agency.

We will continue to maintain our voluntary hold on shipping to non-ambulant patients and will work collaboratively with the FDA to discuss recommendations for supplemental immunosuppression to enhance the safety in the non-ambulant patient population.

Sarepta commends FDA for its swift action to review the data. We share FDA's recognition for the importance of the patient community's voice and we, too, are committed to continuing to listen and take input from the community as we move forward.

Wendy

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