Dear DMD Community,

As you may be aware, there have been recent online discussions about patient deaths involving individuals living with Duchenne muscular dystrophy (DMD) who were being treated with DUVYZAT® (givinostat). We remain deeply saddened to learn that these individuals have passed away.

Based on all available information, and applying internationally recognised standards, Italfarmaco has assessed these deaths are not related to treatment with DUVYZAT, and the product's benefit-to-risk profile remains unchanged. All relevant data and assessments have been submitted to regulatory authorities. Should this assessment change, we will promptly communicate updates to regulatory authorities, healthcare professionals, and the DMD community, as part of the standard process for ensuring patient safety and transparency.

At Italfarmaco, our commitment to patient safety is a top priority. We understand how concerning any patient adverse event may be for families and healthcare providers. To date, nearly 2,000 patients living with DMD have been treated with givinostat (DUVYZAT), with some receiving therapy for over 10 years. All serious adverse events reported to Italfarmaco are reported to health authorities in accordance with regulatory requirements, and we work in collaboration with regulatory authorities around the world to assess data.

We will continue to closely monitor, investigate, and report data to ensure we maintain a deep understanding of the safety profile of DUVYZAT. We are grateful for the trust of the DMD community and acknowledge that we need to earn that trust every day.

Sincerely,

Scott Baver
Vice President Head of Medical Affairs, Italfarmaco

Paolo Bettica
Chief Medical Officer, Italfarmaco