Company Announcement

ITF Therapeutics LLC Presents New Data and Analyses on Givinostat for Treatment of Duchenne Muscular Dystrophy at 2026 MDA Clinical and Scientific Conference

Long-term observations from the givinostat clinical development program further characterize safety profile in patients with Duchenne muscular dystrophy

Additional analyses highlight new findings related to decline in muscle contractile area and median age at loss of ambulation with givinostat

CONCORD, Mass., March 9, 2026 – ITF Therapeutics LLC, the U.S. rare disease affiliate of Italfarmaco, today announced the presentation of ten abstracts at the Muscular Dystrophy Association (MDA) Clinical and Scientific Conference held March 8-11, 2026. Poster presentations include long-term safety observations based on data from the company's ongoing open-label extension study in patients with Duchenne muscular dystrophy (DMD) treated with givinostat. In addition, analyses from the givinostat clinical development program include findings on decline in muscle contractile area and median age at loss of ambulation.

Please see the Indication and Important Safety Information for DUVYZAT® (givinostat) below.

"These presentations at the 2026 MDA Clinical and Scientific Conference reflect our continued commitment to deepening the understanding of long-term treatment with DUVYZAT, supported by analyses from our Phase 3 EPIDYS trial and ongoing open-label extension study," said Scott Baver, Ph.D., VP, Head of Global Medical Affairs, Rare Diseases, Italfarmaco. "By further evaluating safety, efficacy outcomes, and dosing considerations, we are focused on providing people living with DMD, their families, and clinicians with information to support informed treatment decisions regarding DUVYZAT."

Data presented at the 2026 MDA Clinical and Scientific Conference include:

POSTER #51S Long-Term Safety of Givinostat in Patients with Duchenne Muscular Dystrophy: Interim Results from an Open-Label Extension Study

The safety and efficacy of givinostat were assessed in the multicenter, randomized, double-blind, placebo-controlled, Phase 3 EPIDYS clinical trial. This poster presents findings from an interim analysis of safety data observed through the December 31, 2023 data cutoff in an ongoing open-label extension study in patients with DMD who completed, or were screened but not randomized into, prior givinostat studies.

POSTER #37S Givinostat Reduces the Decline of Contractile Cross-Sectional Area and Decreases Fat Infiltration in Patients with Duchenne Muscular Dystrophy

Contractile cross-sectional area (cCSA) and fat fraction are known quantitative measures of DMD disease progression, reflecting the amount of functional muscle tissue available for force generation and the extent of muscle tissue replacement by fat, respectively. This poster includes an evaluation of cCSA and fat fraction in patients with a baseline vastus lateralis fat fraction >5% to ≤30% measured by magnetic resonance spectroscopy from the Phase 3 EPIDYS trial.

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In the analysis, cCSA and fat fraction were determined via magnetic resonance imaging. Data were evaluated with a mixed model for repeated measures to determine change over time.

POSTER #64S Open Label Extension Analysis Shows Potential Delay in Age at Loss of Ambulation in Patients with Duchenne Muscular Dystrophy Treated with Givinostat

This analysis evaluates the effect of longer-term givinostat treatment, in combination with standard-of-care corticosteroids, on loss of ambulation (i.e., permanent inability to walk independently), in patients with DMD aged ≥6 years using data through the 2023 cutoff. This extension provided a larger patient population and an additional 2 years of follow-up since the previous interim analysis.

POSTER #276T Givinostat Reprograms TGFβ-Induced Fibrotic Network in DMD Stromal Cells

DMD features progressive muscle degeneration with replacement by fibrotic matrix, driven mainly by fibro-adipogenic progenitor cells (FAPs) and skeletal muscle fibroblasts (SMFs). Histone deacetylase (HDAC) enzymes regulate these pathogenic stromal responses and their inhibition restores homeostatic conditions. This poster reports findings from integrated RNA-seq and ATAC-seq analyses to define how givinostat modulates TGFβ-induced fibrotic programs in DMD-derived FAPs and SMFs.

Encore poster presentations also cover findings related to cardiac safety data in ambulant patients from the EPIDYS study, additional insights on the simplified givinostat dosing regimen, and the characterization of thrombocytopenia and gastrointestinal adverse events.

For additional details, see abstracts 51S, 37S, 64S, 276T, 36S, 42S, 50S, 67S, and 49S published here.

"Collectively, these findings presented during the MDA Clinical and Scientific Conference underscore the value of longer-term follow-up and complementary analyses in characterizing the clinical experience of givinostat," said Aravindhan Veerapandiyan, M.D., Associate Professor of Pediatrics, Division of Pediatric Neurology at the University of Arkansas for Medical Sciences and Arkansas Children's Hospital. "Ongoing evaluation of these data provides important context as clinicians consider appropriate, individualized treatment approaches for patients with DMD."

About DUVYZAT® (givinostat)

DUVYZAT is a U.S. FDA-approved histone deacetylase (HDAC) inhibitor indicated for the treatment of patients 6 years of age and older with Duchenne muscular dystrophy (DMD). The therapy was discovered through the research and development efforts of Italfarmaco in collaboration with Telethon and Duchenne Parent Project (Italy).

HDACs are enzymes located in the body's cells that play a key role in maintaining and repairing muscles. In DMD, the HDAC enzymes become overactive, leading to chronic muscle inflammation, decreased muscle repair, and replacement of muscle with fat and scar tissue. DUVYZAT inhibits HDAC overactivity and is thought to help reduce inflammation, increase the body's ability to repair muscles, and slow muscle loss. For more information visit www.DUVYZAT.com.

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About ITF Therapeutics LLC

ITF Therapeutics was established in January 2024 as the United States affiliate of Italfarmaco Group to develop and commercialize treatments for rare diseases. The company combines end-to-end execution with close listening to learn directly from advocates, researchers, clinicians, and families, ensuring their perspectives help shape the design of innovative and potentially life-changing solutions. With deep expertise across regulatory, commercial operations, access, and community partnerships, ITF Therapeutics is focused on delivering proven therapies with urgency, ambition, and compassion to each rare disease community it serves. For more information visit www.itftherapeutics.com.

About Italfarmaco S.p.A.

Founded in 1938 in Milan, Italy, Italfarmaco is a private global pharmaceutical company that has led the successful development and approval of many pharmaceutical products around the world. The Italfarmaco group has operations in more than 90 countries through directly controlled or affiliated companies. The company is a leader in pharmaceutical research, product development, production, and commercialization with proven success in many therapeutic areas including immuno-oncology, gynecology, neurology, cardiovascular disease, and rare diseases. Italfarmaco's rare disease unit includes programs in Duchenne muscular dystrophy, Becker muscular dystrophy, amyotrophic lateral sclerosis, and polycythemia vera. For more information visit www.italfarmaco.com.

Indication and Important Safety Information for DUVYZAT® (givinostat)

INDICATION

DUVYZAT is a histone deacetylase inhibitor indicated for the treatment of Duchenne muscular dystrophy (DMD) in patients 6 years of age and older.

IMPORTANT SAFETY INFORMATION

Warnings and Precautions

Hematological Changes: DUVYZAT can cause dose-related thrombocytopenia and other signs of myelosuppression. Monitor blood count every 2 weeks for the first 2 months, at month 3, and every 3 months thereafter. Modify the dosage for confirmed thrombocytopenia. Discontinuation may be needed if abnormalities worsen.

Increased Triglycerides: DUVYZAT can cause elevations in triglycerides. Monitor triglycerides at 1 month, 3 months, 6 months, and then every 6 months thereafter. Modify the dosage if fasting triglycerides are verified >300 mg/dL. Treatment with DUVYZAT should be discontinued if triglycerides remain elevated despite adequate dietary intervention and dosage adjustment.

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Gastrointestinal Disturbances: Gastrointestinal disturbances, including diarrhea, nausea/vomiting, and abdominal pain were common adverse reactions in DUVYZAT clinical trials. Antiemetics or antidiarrheal medications may be considered during treatment with DUVYZAT. Modify the dosage of DUVYZAT in patients with moderate or severe diarrhea and discontinue treatment if significant symptoms persist.

QTc Prolongation: DUVYZAT can cause prolongation of the QTc interval. Avoid use of DUVYZAT in patients who are at an increased risk for ventricular arrhythmias (including torsades de pointes), such as those with congenital long QT syndrome, coronary artery disease, electrolyte disturbance or in patients taking concomitant medicinal products known to cause QT prolongation. Obtain ECGs prior to initiating treatment with DUVYZAT in patients with underlying cardiac disease or in patients who are taking concomitant medications that cause QT prolongation.

Adverse Reactions

The most common adverse reactions reported in >5% of patients treated with DUVYZAT are diarrhea (37%), abdominal pain (34%), thrombocytopenia (33%), nausea/vomiting (32%), hypertriglyceridemia (23%), pyrexia (13%), myalgia (9%), rash (9%), arthralgia (8%), fatigue (8%), constipation (7%), and decreased appetite (7%).

Drug Interactions

Closely monitor when DUVYZAT is used in combination with an oral CYP3A4 sensitive substrate or a sensitive substrate of the OCT2 transporter, for which a small change in substrate plasma concentrations may lead to serious toxicities.

Avoid concomitant use with other drugs that prolong the QTc interval; monitor ECG if concomitant use cannot be avoided. If concomitant use cannot be avoided, obtain ECGs when initiating, during concomitant use, and as clinically indicated. Withhold DUVYZAT if the QTc interval is >500 ms or the change from baseline is >60 ms.

To report SUSPECTED ADVERSE REACTIONS, contact ITF Therapeutics LLC at 1-833-582-4312 or FDA at 1-800-FDA-1088 or www.fda.gov/medwatch.

Please see full Prescribing Information for additional safety information.

DUVYZAT is a registered trademark of Italfarmaco S.p.A.

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