

Company Announcement



ITF Therapeutics LLC Announces Multiple Data Presentations at 2026 MDA Clinical and Scientific Conference

Presenting ten abstracts including observations on long-term safety, disease progression, and decline in muscle contractile area with givinostat

Encore oral presentation also highlights analyses from the givinostat clinical development program on weight-based flexible dosing

CONCORD, Mass., February 23, 2026 – ITF Therapeutics LLC, the U.S. rare disease affiliate of Italfarmaco, today announced that one oral and nine poster presentations have been accepted at the Muscular Dystrophy Association (MDA) Clinical and Scientific Conference to be held March 8-11, 2026, in Orlando, Florida.

Poster presentations will include long-term safety observations, as well as new findings on disease progression and decline in muscle contractile area in patients with Duchenne muscular dystrophy (DMD) treated with givinostat.

In addition, an encore oral presentation delivered by Aravindhan Veerapandiyan, M.D., Associate Professor of Pediatrics, University of Arkansas for Medical Sciences and Arkansas Children's Hospital, includes analyses of functional outcomes with weight-based flexible dosing in the pivotal Phase 3 EPIDYS trial. Functional outcomes were evaluated based on time to complete the 4-stair climb test and North Star Ambulatory Assessment scores.

Encore poster presentations will 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.

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

"Since the launch of ITF Therapeutics just over two years ago, our progress has been shaped by the voices and experiences of people living with Duchenne and their families whom we are privileged to serve," said Matt Trudeau, President, ITF Therapeutics. "The MDA Clinical and Scientific Conference offers an essential opportunity for us to hear directly from community members to better understand their evolving needs and priorities. At this year's meeting, we look forward to presenting new data — including a range of perspectives on the safety and efficacy of DUVYZAT — that reflect our ongoing dialogue with the Duchenne community."

Encore Oral Presentation

- **Title:** Givinostat Weight-Based Flexible Dosing: Rationale and Efficacy at the Different Doses
Presenter: Aravindhan Veerapandiyan, M.D., Associate Professor of Pediatrics, University of Arkansas for Medical Sciences and Arkansas Children's Hospital
Date and time: Wednesday, March 11, 2026, at 1:30 p.m. ET



Company Announcement



De Novo Poster Presentations

- **Title:** Long-Term Safety of Givinostat in Patients with Duchenne Muscular Dystrophy: Interim Results from an Open-Label Extension Study
Presenter: John F. Brandsema, M.D., Pediatric Neurologist, Division of Neurology, Children's Hospital of Philadelphia
Poster number: 51S
- **Title:** Givinostat Reduces the Decline of Contractile Cross-Sectional Area and Decreases Fat Infiltration in Patients with Duchenne Muscular Dystrophy
Presenter: Sara Cazzaniga, R&D Senior Manager, Neuromuscular Area, Italfarmaco
Poster number: 37S
- **Title:** Open Label Extension Analysis Shows Potential Delay in Age at Loss of Ambulation in Patients with Duchenne Muscular Dystrophy Treated with Givinostat
Presenter: Paolo Bettica, M.D., Ph.D., Chief Medical Officer, Italfarmaco
Poster number: 64S
- **Title:** Givinostat Reprograms TGFβ-Induced Fibrotic Network in DMD Stromal Cells
Presenter: Monica Forino, M.D., Molecular Biologist, Italfarmaco
Poster number: 276T

Encore Poster Presentations

- **Title:** A Simplified Givinostat Dosing Regimen Minimizes Exposure Differences and Dose Reductions in Higher-Weight Patients
Presenter: Paolo Bettica, M.D., Ph.D., Chief Medical Officer, Italfarmaco
Poster number: 36S
- **Title:** Cardiac Safety Data for Givinostat in Ambulant Patients with Duchenne Muscular Dystrophy: Results from the EPIDYS Study
Presenter: Han C. Phan, M.D., Principal Investigator and Head of Research, Rare Disease Research
Poster number: 42S
- **Title:** Characterizing Thrombocytopenia in Patients with Duchenne Muscular Dystrophy Treated with Givinostat: Results from the Phase 3 EPIDYS Trial
Presenter: John F. Brandsema, M.D., Pediatric Neurologist, Division of Neurology, Children's Hospital of Philadelphia
Poster number: 50S
- **Title:** Characterizing Platelet Count Reductions Below $75 \times 10^9/L$ in Patients with Duchenne Muscular Dystrophy Treated with Givinostat from the Phase 3 EPIDYS Trial and LTSE Study
Presenter: Paolo Bettica, M.D., Ph.D., Chief Medical Officer, Italfarmaco
Poster number: 67S
- **Title:** Characterizing Gastrointestinal Adverse Events of Interest from a Phase 3 Study of Givinostat in Patients with Duchenne Muscular Dystrophy
Presenter: John F. Brandsema, M.D., Pediatric Neurologist, Division of Neurology, Children's Hospital of Philadelphia
Poster number: 49S



Company Announcement



ITF Therapeutics is also sponsoring the following educational program taking place during the conference:

- Industry Forum: Clinical Perspectives on HDAC Inhibition in Duchenne Muscular Dystrophy
 - **Presenters:** Omer A. Abdul Hamid, M.D., Neuromuscular Specialist, Pediatric Neurology, Nemours Children's Hospital, joined by a caregiver from the DMD community
 - **Date and time:** Tuesday, March 10, 2026, at 12:00-1:30 p.m. ET
 - **Room:** Florida 5-7

During the forum, Dr. Hamid will share perspectives on unmet needs in the DMD treatment landscape, the potential role of histone deacetylase (HDAC) inhibition in the treatment of DMD, and expanded findings from the Phase 3 clinical trial evaluating the safety and efficacy of givinostat including the latest open-label extension data. A caregiver will also share their personal experiences with DUVYZAT.

This is not an official event of the 2026 MDA Clinical and Scientific Conference. This event is not sponsored, endorsed, or accredited by MDA.

About DUVYZAT® (givinostat)

DUVYZAT is a U.S. FDA-approved histone deacetylase (HDAC) inhibitor indicated for the treatment of patients six 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.

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.

Company Announcement



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.

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.

Company Announcement



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.

U.S.A.

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