Company Announcement

Italfarmaco Announces Managed Entry Agreement in Georgia for Givinostat as Treatment for Patients with Duchenne Muscular Dystrophy

MILAN, Italy, July 31, 2026 – Italfarmaco S.p.A. today announced a managed entry agreement with the Georgian Ministry of Health for givinostat (Duvyzat®) as a treatment for patients with Duchenne muscular dystrophy (DMD). Based on the European Commission (EC) approval in June 2025, givinostat will be available in Georgia under this agreement for patients aged six years and over who are ambulant at the start of treatment, when taken together with corticosteroids.

Managed entry is designed to support access to an innovative pharmaceutical product for eligible patients in Georgia and reflects the ongoing commitment by the Georgian Ministry of Health to provide treatments for rare diseases. Italfarmaco will continue to work with the Ministry to support launch readiness and enhance multidisciplinary care for DMD patients across the country.

"This milestone reflects the Georgian Ministry of Health's strong commitment to improving care for people living with rare diseases and the constructive collaboration between healthcare stakeholders, the Duchenne community and Italfarmaco throughout this process," said **Francesco Di Marco, PhD, CEO of Italfarmaco Group**. "We welcome this managed access agreement and thank the Ministry for its dedication to identifying practical solutions for eligible patients. Through our partnership, we look forward to continuing our efforts to support the Duchenne community in Georgia."

EC approval is based on the results of the EPIDYS Phase 3 multicentre, randomised, double-blind, placebo-controlled trial (NCT02851797). In the EPIDYS study, a total of 179 ambulant boys six years of age or older received either givinostat twice daily or placebo, in addition to corticosteroid treatment. The EPIDYS study met its primary endpoint demonstrating a statistically significant difference in time to complete the four-stair climb assessment. Givinostat also showed favourable results on key secondary endpoints including North Star Ambulatory Assessment (NSAA) and fat infiltration evaluation by magnetic resonance imaging. Specifically, givinostat treatment was associated with 40% less decline in cumulative loss of NSAA items, indicating givinostat's potential to delay disease progression in affected individuals. Most adverse effects observed with givinostat were mild to moderate in severity. Results from this study were published in *The Lancet Neurology* in March 2024.[1]

Long-term data from an interim analysis of the ongoing EPIDYS open-label extension (OLE) study reported that the median age at loss of ambulation was 17.3 years in the givinostat-treated group, compared with 11.0–13.4 years in previously published natural history cohorts of corticosteroid-treated patients.[2]

About Duchenne Muscular Dystrophy

Duchenne muscular dystrophy (DMD) is a rare, progressive neuromuscular disorder caused by mutations in the DMD gene. Mutations in the DMD gene prevent the production of functional dystrophin, causing the dystrophin-associated protein complex (DAPC) to break down. This makes muscle fibres more vulnerable to damage and increases histone deacetylase (HDAC) levels in the muscle cells, blocking the activation of important genes needed for muscle maintenance and repair. As a result, muscle fibres experience ongoing

damage, leading to chronic inflammation and poor regeneration. Over time, muscle cells die and are replaced by scar tissue and fat.[3-6] DMD primarily affects males, with symptoms typically appearing between the ages of two and five. As the condition progresses, muscle weakness worsens, leading to difficulty walking and eventually to loss of ambulation. Over time, the heart and respiratory muscles are also affected, which are the leading causes of premature death.[7] DMD is one of the most severe and common forms of childhood muscular dystrophy, with a global birth incidence of approximately 1 in 5,050 boys.[8]

About Givinostat (Duvyzat®)

Givinostat was discovered through Italfarmaco's research and development efforts in collaboration with Telethon and Duchenne Parent Project (Italy). Givinostat is an orally administered histone deacetylase (HDAC) inhibitor that regulates the excessive HDAC activity characteristic of DMD muscles. By doing so, it helps restore the expression of key genes and biological processes essential for muscle maintenance and repair. Its mechanism of action is independent of the specific dystrophin gene mutation causing the disease.[9,10]

The EPIDYS Phase 3 study is a randomized, placebo-controlled clinical trial designed to evaluate the efficacy and safety of givinostat in patients with DMD. MRI-based assessments of muscle composition were included as exploratory endpoints to better characterize disease progression.

The ongoing open-label extension (OLE) study is intended to provide additional information on longer-term outcomes in patients previously enrolled in clinical trials.

Givinostat is approved as a treatment of DMD in multiple regions, including the US, EU, UAE and UK, for patients aged 6 years and older, with differences across regions in ambulatory status criteria and subject to local prescribing information.

About ITALFARMACO

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, gynaecology, neurology, cardiovascular disease and rare diseases. Italfarmaco's rare disease unit includes programs in Duchenne muscular dystrophy, Becker muscular dystrophy, amyotrophic lateral sclerosis and polycythaemia vera. For more information visit www.italfarmaco.com.

Media inquiries:
Anja Heuer / Adolfo Luna | +49 (0) 151 106 199 05 | italfarmaco@trophic.eu

Other inquiries:
Samantha Parker | Patient Advocacy and Communications Lead | RDEnquiries@italfarmacogroup.com

References:

1. Mercuri, E, Vilchez, JJ, Boespflug-Tanguy, O, Zaidman, CM, Mah, JK, Goemans, N. Safety and efficacy of givinostat in boys with Duchenne muscular dystrophy (EPIDYS): a multicentre, randomised, double-blind, placebo-controlled, phase 3 trial. Lancet Neurol. 2024;23:393-403.
2. Sansone V. Open-label extension analysis suggests givinostat delays age at loss of ambulation in patients with DMD. Poster presented at: 19th International Congress on Neuromuscular Diseases (ICNMD); July 7-11, 2026; Florence, Italy.
3. Sandonà M, Cavioli G, Renzini A, et al. Histone Deacetylases: Molecular Mechanisms and Therapeutic Implications for Muscular Dystrophies. Int J Mol Sci. 2023;24(5):4306. https://doi.org/10.3390/ijms24054306.
4. Consalvi S, Saccone V, Giordani L, Minetti G, Mozzetta C, Puri PL. Histone Deacetylase Inhibitors in the Treatment of Muscular Dystrophies: Epigenetic Drugs for Genetic Diseases. Mol Med. 2011;17(5):457–465. https://doi.org/10.2119/molmed.2011.00049.
5. Bez Batti Angulski A, Hosny N, Cohen H, et al. Duchenne muscular dystrophy: disease mechanism and therapeutic strategies. Front Physiol. 2023;14:1183101. https://doi.org/10.3389/fphys.2023.1183101.
6. Giuliani G, Rosina M, Reggio A. Signaling pathways regulating the fate of fibro/adipogenic progenitors (FAPs) in skeletal muscle regeneration and disease. FEBS J. 2022;289(21):64846517. https://doi.org/10.1111/febs.16080.
7. Walter MC, Reilich P. Recent developments in Duchenne muscular dystrophy: facts and numbers. J Cachexia Sarcopenia Muscle. 2017;8(5):681–685. https://doi.org/10.1002/jcsm.12245.
8. Crisafulli S, Sultana J, Fontana A, Salvo F, Messina S, Trifirò G. Global epidemiology of Duchenne muscular dystrophy: an updated systematic review and meta-analysis. Orphanet J Rare Dis. 2020;15(1):141. https://doi.org/10.1186/s13023-020-01430-8.
9. Comi G, Bertini E, Vita G, et al. S22.008: Development of the histone deacetylases inhibitor Givinostat in Duchenne Muscular Dystrophy. Poster. Neurology. 2018;90(15 (Supplement)).
10. Licandro SA, Crippa L, Pomarico R, et al. The pan HDAC inhibitor Givinostat improves muscle function and histological parameters in two Duchenne muscular dystrophy murine models expressing different haplotypes of the LTBP4 gene. Skelet Muscle. 2021;11(1):19. https://doi.org/10.1186/s13395-021-00273-6.