Company Announcement

Presentation of New Clinical Data on Givinostat in Duchenne Muscular Dystrophy at ICNMD 2026

- Phase 3 EPIDYS MRI data quantify givinostat's potential to preserve functional muscle tissue and reduce fat infiltration in patients with Duchenne muscular dystrophy[1]
- Updated open-label extension data contribute to the understanding of long-term outcomes and safety of givinostat with up to 10+ years of treatment in a clinical trial setting[3]

MILAN, Italy, July 7, 2026 – Italfarmaco S.p.A. today announced the presentation of new data from its clinical development programme for givinostat in patients with Duchenne muscular dystrophy (DMD) at the 19th International Congress on Neuromuscular Diseases (ICNMD) 2026, taking place from July 7-11 in Florence, Italy. The presentations highlight findings from the pivotal Phase 3 EPIDYS trial and its ongoing open-label extension (OLE) study, including quantitative magnetic resonance imaging (MRI) data and insights into long-term loss-of-ambulation (LoA) and safety.

"These analyses contribute to the growing body of evidence on givinostat in DMD," said **Scott Baver, Ph.D., VP, Head of Global Medical Affairs, Rare Diseases, Italfarmaco**. "The MRI findings and long-term observational data provide additional insights into disease progression and treatment outcomes in this patient population."

Key findings:

- Quantitative MRI measures of DMD disease progression from the Phase 3 EPIDYS trial were associated with statistically significant differences between treatment group vs. placebo in measures of muscle composition, including contractile cross-sectional area (cCSA) and fat fraction, across selected lower limb muscles[1]
  - Observed differences in cCSA, a measure of muscle tissue mass, ranged from 0.43 to 1.20 cm^2 between treatment group vs. placebo[1]
  - Differences in fat fraction, a measure of fat infiltration, ranged from -3.4% to -4.6% between treatment group vs. placebo[1]
- Interim analyses from the OLE study (n=225) describe long-term follow-up of patients treated with givinostat. Median age at persistent LoA was 17.3 years (95% CI: 15.5–18.1 years) in the study population, compared with previously published natural history data (11.0–13.4 years for corticosteroid-treated patients)[2]
- Long-term follow-up of patients treated with givinostat for up to 10+ years in the OLE study setting was generally consistent with the known safety profile, with no new safety signals[3]

For the complete scientific programme, visit icnmd.org.

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.

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 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. An HDAC inhibitor reduces decline of contractile cross-sectional area and decreases fat infiltration in Duchenne muscular dystrophy. Oral presentation at: 19th International Congress on Neuromuscular Diseases (ICNMD); July 7-11, 2026; Florence, Italy.
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. Bettica P. Interim safety results from an open-label extension study of givinostat treatment for Duchenne muscular dystrophy. Poster presented at: 19th International Congress on Neuromuscular Diseases (ICNMD); July 7-11, 2026; Florence, Italy.