Company Announcement

Italfarmaco Announces Health Canada Acceptance and Priority Review of New Drug Submission for Givinostat as a Duchenne Muscular Dystrophy Treatment

- Health Canada Priority Review targets an expedited 180-day review period for givinostat, reflecting Italfarmaco's commitment to Canadian DMD community
- NDS is based on Italfarmaco's Phase 3 EPIDYS trial data demonstrating meaningful treatment benefits in DMD patients

MILAN, Italy, June 10, 2026 – Italfarmaco S.p.A. today announced that Health Canada has accepted for review the New Drug Submission (NDS) for givinostat (Duvyzat®) for the treatment of Duchenne muscular dystrophy (DMD). Health Canada has granted givinostat Priority Review status, a designation reserved for drugs that may provide a significant improvement in the benefit-risk profile over existing therapies.

"Families affected by Duchenne muscular dystrophy in Canada currently have limited access to treatment options that can slow functional decline," said **Dr. Jean K. Mah, a Canadian investigator for the EPIDYS and OLE studies and Director of the Pediatric Neuromuscular Program at the Alberta Children's Hospital in Calgary, Alberta**. *"As a clinician treating DMD patients, I am encouraged by this positive step in the Canadian regulatory progress and givinostat's therapeutic potential demonstrated in the EPIDYS Phase 3 study."*

An estimated 1000 boys in Canada are living with DMD, one of the most severe and common forms of childhood muscular dystrophy.[1] As part of its commitment to the Canadian DMD community, Italfarmaco will establish a local Canadian affiliate to lead ongoing discussions with health authorities throughout the regulatory review process and to support patients and their families as well as healthcare providers. Subject to Health Canada's review, marketing authorisation could be granted before the end of 2026.

"Duchenne muscular dystrophy places an enormous burden on boys and their families, and we understand the urgency of bringing new treatment options to communities where significant unmet need remains," said **Francesco Di Marco, Chief Executive Officer of Italfarmaco Group.** *"Health Canada's acceptance of the New Drug Submission for givinostat with Priority Review is an encouraging step forward. As we expand our presence in Canada, we are committed to working with clinicians, patient organisations, and other stakeholders to support the Duchenne community and help advance access for appropriate patients, if approved."*

The submission builds on many years of clinical research, including contributions from Canadian patients, families, investigators, and three clinical trial sites in Canada. It is supported by data from the EPIDYS Phase 3 multicentre, randomized, double-blind, placebo-controlled trial (NCT02851797) evaluating givinostat in ambulant boys with DMD aged six and older. The study met its primary endpoint, demonstrating a statistically significant and clinically meaningful difference in time to complete the four-stair climb assessment in patients treated with givinostat twice daily, in addition to corticosteroids, compared to placebo and corticosteroids. During the study, the most common treatment-related adverse events (frequency ≥1/10 boys) associated with givinostat were decreased platelet count/thrombocytopenia, increased blood triglyceride/hypertriglyceridemia, diarrhoea and abdominal pain; none of the severe or serious adverse events were treatment-related or resulted in study withdrawal. givinostat tolerability was managed with appropriate monitoring and dose adjustments. No other safety concerns were observed.[2] Patients from the EPIDYS

study remain under observation in a long-term study assessing tolerability and efficacy, with follow-up extending up to eleven years (NCT03373968).

Givinostat has received regulatory approvals in multiple regions, including the US, the UK, the EU, and the UAE for the treatment of DMD. Additional regulatory submissions are ongoing in other geographies, reflecting Italfarmaco's commitment to enabling access for as many individuals living with DMD as possible.

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 loss of ambulation; eventually, 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

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] Givinostat is an investigational medicine in Canada. Its safety and efficacy are currently under investigation, and Health Canada has not yet granted market authorization for this product.

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 commercialisation with proven success in many therapeutic areas including immuno-oncology, gynaecology, neurology, cardiovascular disease and rare diseases. Italfarmaco's rare disease unit includes programmes in Duchenne muscular dystrophy, Becker muscular dystrophy, amyotrophic lateral sclerosis and polycythaemia vera.

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