

Italfarmaco Announces Exclusive Distribution Agreement with Multicare Pharma for DMD Treatment Givinostat in Brazil

- Italfarmaco has entered into an agreement with Multicare for the regulatory approval and distribution of givinostat as a treatment for Duchenne muscular dystrophy in Brazil.

MILAN, Italy, September 16, 2025 – [Italfarmaco S.p.A.](#) today announced an exclusive agreement with [Multicare Pharma](#), a prominent pharmaceutical company in Latin America. Multicare Pharma will support the regulatory approval in Brazil and distribute givinostat (Duvyzat®), Italfarmaco's novel histone deacetylase (HDAC) inhibitor to treat Duchenne muscular dystrophy (DMD). According to the terms of the agreement, Multicare will manage supply and distribution operations for the drug within Brazil. No financial terms were disclosed.

"At Italfarmaco, our commitment to rare diseases drives every decision we make. Access to givinostat can have a meaningful impact for patients in Brazil living with DMD," said **Antonio Nardi, Vice President and Head of Business & Portfolio Development of Italfarmaco**. "Partnering with Multicare, a leader in the field of rare and highly complex diseases with extensive reach across Brazil, allows us to bring this innovative treatment to those who need it most."

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.¹⁻⁴ 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.⁵ 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.⁶

About Givinostat

Givinostat (Duvyzat®) 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.^{7,8}

Givinostat is approved as a treatment of DMD in multiple regions, including the US, EU and UK.

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.

About Multicare Pharma

Multicare Pharma is a leading pharmaceutical company with over 40 years of experience in Latin America. Specializing in the licensing, marketing authorization, promotion, importation, and distribution of innovative treatments, Multicare Pharma focuses on addressing the unmet needs of patients with rare and complex diseases. The company offers a comprehensive range of products and services, from regulatory evaluation to drug distribution, ensuring timely access to essential therapies across the region. With a commitment to improving patient outcomes, Multicare Pharma partners with global pharmaceutical companies to enhance healthcare delivery in Latin America.

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