

PRESS RELEASE

MetrioPharm's MP1032 Receives EMA Orphan Drug Designation in Duchenne Muscular Dystrophy

- European Medicines Agency recognizes potential of lead compound MP1032 in addressing a high unmet medical need in Duchenne Muscular Dystrophy (DMD)
- Designation is paving the way for safer long-term therapy
- MP1032 has demonstrated ability to preserve muscle function and reduce inflammation without disrupting normal cellular processes

Zurich, July 29, 2025 – MetrioPharm AG, a pharmaceutical company developing drugs for inflammatory and infectious diseases, announced today that the European Medicines Agency has granted Orphan Drug Designation (ODD) to its lead compound, MP1032 for the treatment of children affected by Duchenne muscular dystrophy (DMD). This milestone follows the U.S. FDA's ODD, underscoring MP1032's potential as a first-in-class therapy that could minimize reliance on high-dose corticosteroids, which cause severe side effects like osteoporosis, growth stunting, and metabolic issues.

The EMA's ODD provides key incentives, including protocol assistance from the EMA, fee waivers, and up to 12 years of market exclusivity in the EU (extended from 10 years due to DMD's pediatric focus) upon approval. This regulatory validation builds on compelling preclinical data showing MP1032's ability to preserve muscle function and reduce inflammation without disrupting normal cellular processes.

"This dual ODD from the FDA and EMA as well as the already received Rare Pediatric Disease Designation from the FDA are game changers for MetrioPharm and the DMD community," said CEO Thomas Christély. "MP1032's unique mechanism – modulating mitochondrial ROS in overactive immune cells – could transform long-term DMD management by slashing corticosteroid doses and side effects. We're accelerating MP1032 towards Phase II trials, collaborating with patient groups, and exploring partnerships to bring this to children who need safer options. Beyond DMD, our platform's host-directed approach has shown promise in autoimmune diseases and even pandemics, as evidenced by our HERA-funded COVID-19 Phase IIa study."

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About MP1032

MetrioPharm's lead candidate MP1032 is a unique small molecule targeting overshooting reactions of activated immune cells by addressing a central, natural metabolic process occurring in activated immune cells. The mitochondria of these cells react to the activation by boosting their energy metabolism, which in turn leads to the generation of excessive reactive oxygen species (ROS). MP1032 is a first-in-class anti-inflammatory drug that reduces excessive ROS without interfering with the physiological ROS levels of other cells, that are essential for normal cell function, resulting in an excellent safety profile. As a monotherapy, MP1032 produces

therapeutic effects similar to corticosteroids (cortisone-based therapeutics), but without serious side effects. Unlike traditional anti-inflammatories, it mimics corticosteroid benefits as a monotherapy but avoids their toxicities, as demonstrated in preclinical models of DMD, multiple sclerosis, arthritis, and more. Its host-directed nature also positions it for infectious diseases, with Phase IIa data in 131 hospitalized COVID-19 patients (published in [The Lancet Regional Health – Europe](#)) confirming safety and efficacy against viral inflammation—regardless of the pathogen.

About DMD

DMD is the most common form of muscular dystrophy. It is a genetic disorder characterized by progressive muscle degeneration; symptom onset is in early childhood, usually between the ages of two and three. The disease primarily affects boys causing severe muscle loss and heart failure. DMD shortens life expectancy significantly. Existing standard therapies consist of treatment with high dose corticosteroids for decades that lead to serious side-effects but can significantly slow down disease progression.

About MetrioPharm AG

Headquartered in Zurich, Switzerland, with a R&D subsidiary in Berlin, Germany, MetrioPharm is a private biotech pioneering small-molecule therapies for inflammatory, autoimmune, and infectious diseases. Its ROS-modulating platform has generated a robust pipeline, including disease-specific combinations for multiple sclerosis, arthritis, sepsis, inflammatory bowel disease, psoriasis, and orphan indications like DMD as the lead.

In infectious diseases, MetrioPharm is advancing pandemic preparedness based on its successful COVID-19 Phase IIa study financed by a €7.9 million grant from the European Health Emergency Preparedness and Response Authority (HERA). MP1032's host-directed mechanism targets immune overreactions rather than specific viruses, offering a rapid-response tool for emerging threats. With a strong safety profile across preclinical and clinical studies, MetrioPharm is poised for strategic collaborations and further milestones.

Forward-looking statements

This press release contains forward-looking statements that involve risks and uncertainties and are consistent with MetrioPharm AG's assessment as of the date of this release. Such forward-looking statements are neither promises nor guarantees but are subject to numerous risks and uncertainties. No liability or warranty, and no claim, if any, is made with respect to the timeliness, accuracy or completeness of such data and information, and no reliance should be placed on such data and information, either explicitly or impliedly.

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