MetrioPharm

PRESS RELEASE

MetrioPharm Receives Rare Pediatric Disease Designation (RPDD) for MP1032 from the U.S. FDA

- FDA grants RPDD for the treatment of Duchenne muscular dystrophy (DMD)
- MetrioPharm may be eligible for a priority review voucher with a market value in excess of USD 100 million
- MetrioPharm has recently raised CHF 18 million for the development of MP1032 in DMD in a Series D round and is targeting a second closing

Zurich, October 25, 2023 – MetrioPharm AG, a pharmaceutical company developing drugs for inflammatory and infectious diseases, announced today that the U.S. Food and Drug Administration (FDA) has granted Rare Pediatric Disease Designation (RPDD) for MP1032 for the treatment of Duchenne muscular dystrophy.

The FDA grants RPDD to serious and life-threatening diseases that primarily affect children and fewer than 200,000 patients in the United States. Duchenne is a genetic disease characterized by progressive muscle degeneration with onset of symptoms in early childhood, usually between two and three years of age. The disease primarily affects boys and causes severe muscle loss and heart failure. DMD significantly shortens life expectancy.

”In developing MP1032 for young patients with Duchenne we are in very close contact with patients, their families and with many international experts,” said MetrioPharm CSO and co-founder Dr. Wolfgang Brysch. “Our goal is to reduce the high doses of corticosteroids that patients receive over years, often decades, and to make long-term treatment safer and more efficient. The Rare Pediatric Disease Designation endorses our clinical development program, specifically our decision to make DMD our lead indication en route to market authorization for MP1032.”

The FDA's *Rare Pediatric Disease Priority Review Voucher Program* addresses the challenges of developing treatments for unique and small patient populations. Under the program, a sponsor that receives drug-approval for a rare pediatric disease may be eligible for a voucher that can be used to obtain priority review for marketing application. It can also be sold to another sponsor for priority review of their marketing application.

"The Rare Pediatric Disease Designation is a recognition of the medical potential of MP1032 for the treatment of patients suffering from Duchenne muscular dystrophy,” said Thomas Christély, CEO of MetrioPharm. "In addition, upon approval of MP1032, we may be eligible to receive an RPDD voucher valued and paid for by large pharmaceutical companies in excess of USD 100 million. This creates additional revenue potential and further supports a second closing of our

current financing round in which we already raised CHF 18 million for the development of MP1032 in DMD."

In May 2023, MetrioPharm received orphan drug designation from the FDA for MP1032 for the treatment of DMD.

About MetrioPharm

MetrioPharm AG is a Swiss biotech company developing first-in-class auto-regulated immune modulators targeting the pathologically dysregulated mitochondrial metabolism in macrophages. MetrioPharm's platform of oral small molecules has demonstrated preclinical & clinical efficacy (three Phase II studies) in several inflammatory and infectious diseases with an excellent safety profile.

As a monotherapy, MetrioPharm's lead candidate MP1032 produces therapeutic effects similar to corticosteroids (cortisone-based therapeutics), but without serious side effects.

MP1032 has demonstrated synergistic/supra-additive effects in combination with an ultra-low dose (10% of the normal dose) of corticosteroids, demonstrating the potential to create a new class of "super corticosteroids" that are more effective and have no serious side effects. For more than 60 years, there have been no major advances in achieving such corticosteroid-sparing therapy and thereby reducing corticosteroid-specific side effects.

In addition, MP1032 has demonstrated a broad host-directed antiviral and antibacterial activity in preclinical studies.

The Company is headquartered in Zurich and has a subsidiary for R&D activities in Berlin.

About MP1032 in Duchenne muscular dystrophy

MetrioPharm's drug candidate MP1032 represents a radically new concept in anti-inflammatory and corticosteroid-sparing therapy. MP1032 in combination with ultra-low dose corticosteroids has the potential to replace the current high dose corticosteroids (cortisone-based) therapy - with increased efficacy and reduced side effects.

MetrioPharm has conducted several preclinical studies in collaboration with the patient organization Duchenne UK. In these in vivo experiments, MP1032 was tested in an mdx model for DMD and compared to the effect of corticosteroids. MP1032 was able to increase muscle strength, comparable to the corticosteroid Prednisolone®, but without the serious side effects of the latter. In a second preclinical study, conducted by Eurofins, several biomarkers show that the combination of MP1032 with a 90% reduced dose of Prednisolone® increases the efficacy to more than two and a half times the normal dose of Prednisolone®. These supra-additive effects of MP1032 in combination with an ultra-low dose of corticosteroids show the potential to create a new class of "super corticosteroids" that are more effective and have significantly fewer side effects.

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 and are subject to numerous risks and uncertainties. No representations or warranty is made, and no reliance should be placed, expressively or impliedly, on the timeliness, accuracy or completeness of such data and information.

Contacts

MetrioPharm

Corporate Communications & Press Relations
T + 41 44 552 7198
E presse@metriopharm.com
W www.metriopharm.com

akampion
Dr. Ludger Wess / Ines-Regina Buth
Managing Partners
info@akampion.com
Tel. +49 40 88 16 59 64 /
Tel. +49 30 23 63 27 68

