MetrioPharm

PRESS RELEASE

MetrioPharm Receives Orphan Drug Designation for the Treatment of Duchenne Muscular Dystrophy

- FDA grants orphan drug designation for MetrioPharm's lead compound MP1032 for the treatment of Duchenne muscular dystrophy (DMD)
- DMD is a designated orphan disease in both Europe and the U.S.
- MetrioPharm's development objectives: better tolerability of existing therapies and improved efficacy in long-term treatment of DMD patients

Zurich, May 30, 2023 – MetrioPharm AG, a pharmaceutical company developing drugs for inflammatory and infectious diseases, today announced that the U.S. Food and Drug Administration (FDA) has granted Orphan Drug Designation for MP1032 for the treatment of Duchenne muscular dystrophy.

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, while girls can show milder symptoms as well. DMD shortens life expectancy significantly. Existing standard therapies consist of treatment with high dose corticosteroids for decades that lead to serious side-effects and can only slow disease progression.

"Currently, DMD cannot be cured, but it can be treated," said MetrioPharm CSO and co-founder Dr. Wolfgang Brysch. "These treatments have serious side effects that heavily impact patients' quality of life. With MP1032 we aim to improve the tolerability of treatment while also further slowing down disease progression. Our goal is to improve both safety and efficacy in the long-term treatment of DMD patients."

"The orphan drug designation is granted by the FDA for drug candidates that the FDA considers a promising new treatment. In a designated orphan development, timelines are shorter, and costs are lower compared to indications with larger patient populations," said MetrioPharm CEO Thomas Christély. "The Orphan Drug Designation for MP1032 in DMD by the FDA is a very important achievement; it takes us one crucial step closer to obtaining an accelerated market approval of our lead compound for Duchenne patients. MetrioPharm plans to initiate a Phase II clinical trial in DMD in 2024."

DMD is classified as an orphan disease of high unmet medical need. FDA orphan drug designation is granted to investigational therapies addressing rare medical diseases (affecting fewer than 200,000 people in the U.S.). Orphan drug status provides benefits to drug developers,

including assistance in the development process, exemptions from FDA fees and seven years of post-approval marketing exclusivity.

About MP1032 in DMD

MetrioPharm has conducted preclinical studies in cooperation 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 enhance muscle strength, like the corticosteroid Prednisolone®, but without the serious side effects of the latter. In a second preclinical study, executed 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®. This supra-additive (synergistic) effect means that both substances, MP1032 plus Prednisolone®, are more effective in combination than either substance alone.

About MetrioPharm AG

MetrioPharm AG is a private, clinical-stage biotech company focused on therapies for inflammatory and infectious diseases.

MetrioPharm targets the modulation of immune metabolism with first-in-class self-regulating drug candidates. The Company´s platform has generated small-molecule metabolic modulators that have demonstrated pre-clinical and clinical efficacy in a wide range of inflammatory and infective diseases with an outstanding safety profile.

Based on this core technology, MetrioPharm has created a pipeline of disease-specific drug combinations targeting inflammatory, autoimmune, and degenerative diseases. Preclinical and clinical efficacy data have been obtained in multiple sclerosis, arthritis, sepsis, inflammatory bowel disease and psoriasis. The Company is currently exploring several orphan indications.

In a second line of development, MetrioPharm is developing its technology to target infectious diseases such as COVID-19 – also as a proof of concept to improve pandemic preparedness. Supported by a grant from the European Health Emergency Preparedness and Response Authority (HERA), a Phase IIa exploratory study evaluated the effect on hospitalized COVID-19 patients. The study confirmed the good clinical safety profile of MP1032 and demonstrated compelling efficacy data.

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

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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