Sarcomatrix Renews United States Orphan Drug Designation for LAMA2-Related Muscular Dystrophy Program

RENO, NV, UNITED STATES, April 9, 2025 /EINPresswire.com/ -- Sarcomatrix Therapeutics, a privately held biopharmaceutical company advancing transformative therapies for severe muscle diseases, today announced the renewal of its Orphan Drug Designation (ODD) from the U.S. Food and Drug Administration (FDA) for its Laminin-111 replacement therapy targeting LAMA2-Related Dystrophy (LAMA2-RD).

Sarcomatrix Therapeutics Logo

LAMA2-RD, also known as merosin-deficient congenital muscular dystrophy type 1A (MDC1A), is a rare and progressive neuromuscular disorder caused by mutations in the LAMA2 gene, leading to severe muscle weakness, delayed motor milestones, and early loss of ambulation. The disease currently has no approved treatments.

The renewed designation reinforces Sarcomatrix's leadership in the development of protein replacement therapies for rare muscular dystrophies and underscores the FDA's continued recognition of the urgent medical need in this underserved patient population.

"This renewed Orphan Drug status is an important regulatory milestone that further supports our commitment to developing life-changing treatments for individuals and families affected by LAMA2-RD," said David Craig, CEO of Sarcomatrix Therapeutics. "We are actively preparing for advanced preclinical studies and pursuing strategic partnerships to accelerate our path toward the clinic."

Orphan Drug Designation in the U.S. provides important incentives including tax credits for qualified clinical trials, exemption from user fees, and seven years of market exclusivity upon regulatory approval.

In parallel, Sarcomatrix continues to expand its therapeutic pipeline, including exploratory

research into Laminin-111’s potential to treat Duchenne muscular dystrophy and other neuromuscular disorders.

For more information about Sarcomatrix’s research and development programs, please visit www.sarcomatrix.com.

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