

**FOR IMMEDIATE RELEASE**



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**FDA allows Phrixus's IND for Carmeseal-MD™ (P-188 NF) in Duchenne muscular dystrophy (DMD)**

*- Carmeseal-MD™, the first disease-modifying agent with the potential to protect all three dystrophic target muscles: skeletal limb muscle as well as diaphragm and heart -*

**ANN ARBOR, MI – 7 September 2016** – Phrixus Pharmaceuticals is announcing that FDA allowed Phrixus's IND for Carmeseal-MD (P-188 NF) in Duchenne muscular dystrophy (DMD). The protocol that forms the basis of this IND includes a two-arm, randomized, double-blinded design with 120 patients in several centers in which one dose of P-188 NF will be evaluated against standard of care over 48 weeks. The primary endpoint will be forced vital capacity (FVC); a broad set of secondary endpoints will include cardiac endpoints and additional respiratory endpoints and measures of upper body strength in addition to safety measures. "This novel therapeutic strategy offers a unique opportunity to potentially favorably impact outcomes in boys and young men with Duchenne muscular dystrophy," stated Dr. John L. Jefferies, Director, Advanced Heart Failure and Cardiomyopathy, Professor, Pediatric Cardiology and Adult Cardiovascular Diseases, The Heart Institute, Professor, Division of Human Genetics, Cincinnati Children's Hospital Medical Center, who will be the Principal Investigator.

The IND-enabling studies were supported by the NIH's National Heart, Lung and Blood Institute and by Coalition Duchenne.

Carmeseal-MD is already available in Europe as part of Phrixus's European Access Program. Please contact Ethicor Pharma Ltd. at [enquiries@ethicorpharma.com](mailto:enquiries@ethicorpharma.com) or visit [www.ethicorpharma.com](http://www.ethicorpharma.com).

***About Carmeseal-MD™***

Carmeseal-MD (Poloxamer 188 NF or P-188 NF) is the first disease modifying agent in diseases characterized by membrane instability such as DMD, BMD, limb girdle muscular dystrophy and heart failure in the general population. In animal models of DMD and heart failure, it has been shown to improve the efficiency of damaged hearts. In animal models of DMD, it has also been shown to improve the performance of damaged diaphragms and to protect skeletal limb muscle.

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Carmeseal-MD is the first agent that has the potential to treat the three major aspects of DMD: loss of ambulation and limb muscle strength as well as respiratory dysfunction and heart disease, the last two being the leading causes of death. It is expected to have its effect in all patients with DMD regardless of the genetic defect.

***About Duchenne muscular dystrophy (DMD)***

DMD is the most devastating of the muscular dystrophies. It is a genetic disease that affects about 20,000 boys and young men in the United States and a comparable number in Europe. The hallmarks of DMD are skeletal muscle weakness, followed by respiratory distress and heart failure. As a degenerative disease, it inevitably leads to premature death, most commonly through heart failure, but also through respiratory failure.

***About Phrixus Pharmaceuticals, Inc.***

Phrixus Pharmaceuticals, Inc. is developing Carmeseal as Carmeseal-MD™ (P-188 NF for subcutaneous injection) for DMD and as Carmeseal-HF™ (P-188 NF for intravenous administration) for acute decompensated heart failure. Phrixus has assembled the leading global patent portfolio for the use of poloxamers in DMD, heart failure and respiratory dysfunction. For more information: Thomas A. Collet, [thomas.collet@phrixuspharmaceuticals.com](mailto:thomas.collet@phrixuspharmaceuticals.com) or [www.phrixuspharmaceuticals.com](http://www.phrixuspharmaceuticals.com) or [Phrixus on Facebook](#).

**Forward-Looking Statement Disclaimer**

This announcement may contain, in addition to historical information, certain forward-looking statements that involve risks and uncertainties. Such statements reflect management's current views and are based on certain assumptions. Actual results could differ materially from those currently anticipated as a result of a number of factors. The company is developing several products for potential future marketing. There can be no assurance that such development efforts will succeed, that such products will receive required regulatory clearance or that, even if such regulatory clearance were received, such products would ultimately achieve commercial success.

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