



Retrophin Receives Fast Track Designation for RE-024 for the Treatment of Pantothenate Kinase-Associated Neurodegeneration

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SAN DIEGO--(BUSINESS WIRE)-- Retrophin, Inc. (NASDAQ:RTRX) today announced the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for RE-024, the Company's novel investigational phosphopantothenate replacement therapy, for the treatment of pantothenate kinase-associated neurodegeneration (PKAN). PKAN is a rare and lethal autosomal recessive neurodegenerative disorder believed to affect approximately one to three persons per million worldwide, with no approved treatment currently available. Retrophin is currently enrolling healthy volunteers in its Phase 1 clinical trial evaluating the safety and tolerability of single oral doses of RE-024.

Fast Track designation is intended to aid the development of drugs to treat serious conditions with unmet medical needs, and expedite the review process with a goal of reaching patients earlier. A drug that receives Fast Track designation may be eligible for more frequent communication with the FDA to discuss development plans and clinical trial design, as well as Accelerated Approval and Priority Review. The developing company may also be eligible for Rolling Review, which enables the submission of completed sections of its New Drug Application (NDA) for review by the FDA before the company submits a complete application.

About Retrophin

Retrophin is a pharmaceutical company focused on the development, acquisition and commercialization of drugs for the treatment of serious, catastrophic or rare diseases for which there are currently no viable options for patients. The Company's approved products include Chenodal®, Cholbam™, and Thiola®, and its pipeline includes compounds for several catastrophic diseases, including focal segmental glomerulosclerosis (FSGS), pantothenate kinase-associated neurodegeneration (PKAN), infantile spasms, nephrotic syndrome and others. For additional information, please visit www.retrophin.com.

Forward-Looking Statements

This press release contains "forward-looking statements" as that term is defined in the Private Securities Litigation Reform Act of 1995, regarding the research, development and commercialization of pharmaceutical products. Without limiting the foregoing, these statements are often identified by the words "may", "might", "believes", "thinks", "anticipates", "plans", "expects", "intends" or similar expressions. In addition, expressions of our strategies, intentions or plans are also forward-looking statements. Such forward-looking statements are based on current expectations and involve inherent risks and uncertainties, including factors that could delay, divert or change any of them, and could cause actual outcomes and results to differ materially from current expectations. No forward-looking statement can be guaranteed. Among the factors that could cause actual results to differ materially from those indicated in the forward-looking statements are risks and uncertainties associated with the Company's business and finances in general, as well as risks and uncertainties associated with the Company's pre-clinical and clinical stage pipeline as well as its sales and marketing strategies. Specifically, the risks and uncertainties the Company faces with respect to its RE-024 program include risk that the Company will be unable to initiate and/or complete Phase 1 clinical trials, risk that RE-024 will not progress to Phase 2 clinical trials for safety, regulatory or other reasons; risk associated with enrollment of clinical trials for rare diseases; risk that the company's later stage RE-024 clinical studies will fail to demonstrate that RE-024 is safe and effective. The Company also faces risk that it will be unable to raise additional funding required to complete development of any or all of its product candidates; risk relating to the Company's dependence on contractors for clinical drug supply and commercial manufacturing; uncertainties relating to patent protection and intellectual property rights of third parties; risks and uncertainties relating to competitive products and technological changes that may limit demand for the Company's products. You are cautioned not to place undue reliance on these forward-looking statements as there are important factors that could cause actual results to differ materially from those in forward-looking statements, many of which are beyond our control. The Company undertakes no obligation to publicly update forward-looking statement, whether as a result of new information, future events, or otherwise. Investors are referred to the full discussion of risks and uncertainties as included in the Company's filings with the Securities and Exchange Commission.

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