

Statement on Imprimis Pharmaceuticals' Announcement Regarding Thiola®

February 10, 2016

SAN DIEGO, Feb. 10, 2016 (GLOBE NEWSWIRE) -- Retrophin, Inc. (NASDAQ:RTRX) has issued the following statement in response to Imprimis Pharmaceuticals' announcement of its intention to make a compounded alternative to Thiola[®]:

Thiola is an U.S. Food and Drug Administration (FDA) approved therapy, and as such has met the rigorous standards of the regulatory and manufacturing process that ensure safety and efficacy for patients. Before Retrophin acquired Thiola and invested in increasing the availability of the drug, the therapy was so low in inventory that virtually all patients were unable to fill their prescriptions. Since acquiring the product, Retrophin has more than doubled historical access to Thiola for people suffering from cystinuria and has worked closely with patient advocates to ensure any patient requiring treatment has affordable access to Thiola.

Imprimis Pharmaceuticals' proposed compounded form of tiopronin, the active ingredient in Thiola, in combination with potassium citrate has no safety or efficacy data supported by clinical trials and should not be considered a valid substitute for Thiola. Compounded therapies are not subjected to the same level of safety and efficacy evaluation and may not offer the same therapeutic outcome for patients. Specific to Imprimis' projected co-formulation, there is no clinical data to support the compatibility of fixed dosing of tiopronin with potassium citrate. Fixed-dose combinations of therapies containing potassium are generally avoided due to the potential for fluctuations in serum potassium, which may cause serious adverse outcomes including cardiac events. Additionally, compounded therapies have recently come under increased regulatory scrutiny due to poor outcomes. As noted in recent comments and testimony by Dr. Janet Woodcock, Director of the FDA's Center for Drug Evaluation and Research, compounding raises safety concerns and people have been harmed.

It is also important to note that the cystinuria community has been extremely supportive of the increased investment in, and access to Thiola that Retrophin has continuously provided, and we do not believe there will be demand from patients or physicians to treat with any compounded version that could potentially jeopardize therapeutic outcome.

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.

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