Retrophin Announces Presentation of Abstracts at ASN Kidney Week 2020 Reimagined

October 9, 2020

SAN DIEGO, Oct. 09, 2020 (GLOBE NEWSWIRE) -- Retrophin, Inc. (NASDAQ: RTRX) today announced that it will present new data from a post-hoc analysis examining the proportion of patients with focal segmental glomerulosclerosis (FSGS) that achieved complete remission of proteinuria in the Phase 2 DUET Study, at the American Society of Nephrology (ASN) Kidney Week 2020 Reimagined. The Company and its collaborators will also feature encore presentations of preclinical data supporting the potential for sparsentan to protect kidney function in additional rare glomerular diseases. ASN Kidney Week 2020 Reimagined is being held virtually October 19–25, 2020.

Oral Presentation:

Complete Remission of Proteinuria in Patients with FSGS Treated with Sparsentan, a Dual Endothelin and Angiotensin Receptor Antagonist, in the DUET Trial
Session #: OR1203
Session Title: Halfway Through the Marathon: Clinical Candidates in Development
Date & Time: Sunday, October 25, 2020, 5:00 p.m. – 7:00 p.m. ET

Poster Presentations:

Sparsentan Protects Against Development of Albuminuria and Glomerulosclerosis in the gddY Mouse Model of IgA Nephropathy
ePoster #: PO1808
Session: Glomerular Diseases: IgA, C3G, and FSGS
Session Release Date & Time: Thursday, October 22, 2020, 10:00 a.m. ET

The Dual Endothelin/Angiotensin II Receptor Antagonist Sparsentan Slows Renal Disease, Improves Lifespan, and Attenuates Hearing Loss in Alport Mice: Comparison with Losartan and Atrasentan
ePoster #: PO1897
Session: Glomerular Diseases: Clinical, Outcomes, and Trials
Session Release Date & Time: Thursday, October 22, 2020, 10:00 a.m. ET

About Sparsentan

Sparsentan is an investigational product candidate in Phase 3 clinical development that has a dual mechanism of action combining endothelin receptor type A blockade with angiotensin receptor blockade. Retrophin is developing sparsentan for the treatment of FSGS and IgAN, rare kidney disorders that often lead to end-stage kidney disease (ESKD). In several forms of chronic kidney disease, such as FSGS and IgAN, endothelin receptor blockade has been shown to have an additive beneficial effect on proteinuria in combination with renin-angiotensin blockade via angiotensin receptor blockers or angiotensin converting enzyme inhibitors. Sparsentan has been granted orphan drug designation for the treatment of FSGS by the FDA and European Commission.

The Phase 2 DUET Study of sparsentan in FSGS met its primary efficacy endpoint for the combined treatment group, demonstrating a greater than two-fold reduction in proteinuria compared to irbesartan, after the eight-week, double-blind treatment period. Irbesartan is part of a class of drugs used to manage FSGS and IgAN in the absence of an approved pharmacologic treatment. Retrophin is currently enrolling the pivotal Phase 3 DUPLEX Study of sparsentan for the treatment of FSGS (FSGSduplex.com), as well as the pivotal Phase 3 PROTECT Study of sparsentan for the treatment of IgAN (IgANprotect.com). Both studies contain 36-week proteinuria-based endpoints, which if achieved, are expected to support submission of a New Drug Application (NDA) under the Subpart H accelerated approval pathway in the U.S. as well as an application for Conditional Marketing Authorization (CMA) consideration in Europe. If approved for both indications, sparsentan could potentially be the first medicine approved for FSGS and IgAN.

About Retrophin

Retrophin is a biopharmaceutical company specializing in identifying, developing and delivering life-changing therapies to people living with rare disease. The Company's approach centers on its pipeline featuring sparsentan, a product candidate in late-stage development for focal segmental glomerulosclerosis (FSGS) and IgA nephropathy (IgAN), rare disorders characterized by progressive scarring of the kidney often leading to end-stage kidney disease. Research in additional rare diseases is also underway, including partnerships with leaders in patient advocacy and government research to identify potential therapeutics for NGLY1 deficiency and Alagille syndrome, conditions with no approved treatment options. Retrophin's R&D efforts are supported by revenues from the Company's commercial products Chenodal ®, Cholbam®, Thiola® and Thiola EC®.

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. 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, success of its commercial products as well as risks and uncertainties associated with the Company's preclinical and clinical stage pipeline. Specifically, the Company faces risks associated with market acceptance of its marketed products including efficacy, safety, price, reimbursement and benefit over competing therapies. The risks and uncertainties the Company faces with respect to its preclinical and clinical stage pipeline include risk that the Company's clinical candidates will not be found to be safe or effective and that current or future clinical trials will not proceed as planned. Specifically, the Company faces the risk that the Phase 3 clinical trial of sparsentan in FSGS will not demonstrate that sparsentan is safe or effective or serve as a basis for accelerated approval of sparsentan as planned; risk that the Phase 3 clinical trial of sparsentan in IgAN will not demonstrate that sparsentan is safe or effective or serve as the basis for accelerated approval of sparsentan as planned; and risk that sparsentan will not be approved for efficacy, safety, regulatory or other reasons, and for each of the programs, risk associated with enrollment of clinical trials for rare diseases and risk that ongoing or planned clinical trials may not succeed or may be delayed for safety, regulatory or other reasons. Also, there is no guarantee that the preclinical findings that are summarized in the abstracts that are a subject of this press release will translate to a viable therapeutic approach in patients or that the findings related to sparsentan from the post-hoc analysis of the DUET Study data will be seen in the currently ongoing Phase 3 DUPLEX study. The Company faces risk that it will be unable to raise additional funding that may be 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 exclusivity periods and intellectual property rights of third parties; risks associated with regulatory interactions; risks and uncertainties relating to competitive products, including potential generic competition with certain of the Company's 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 any 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 most recent Form 10-K, Form 10-Q and other filings with the Securities and Exchange Commission.

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