Retrophin Provides Corporate Update and 2020 Outlook

January 13, 2020

SAN DIEGO, Jan. 13, 2020 (GLOBE NEWSWIRE) -- Retrophin, Inc. (NASDAQ: RTRX) today announced that, based on preliminary and unaudited financial data, the Company expects net product sales for the fourth quarter of 2019 to be approximately $47 million. For the fiscal year 2019, the Company expects total net product sales of approximately $175 million. The Company also provided a general update on its development programs, including anticipated milestones for 2020.

“Our outlook for 2020 is clear. We are focused on maximizing the potential for sparsentan, if approved, to change the treatment paradigm in the years to come for patients living with FSGS and IgA nephropathy,” said Eric Dube, Ph.D., chief executive officer of Retrophin. “With this objective, our R&D team is centering its efforts on patient enrollment and trial conduct to advance our pivotal DUPLEX and PROTECT studies and position us for the first NDA and CMA submissions for sparsentan next year. Our commercial organization will continue to focus on identifying and treating new patients with our approved products, and further strengthen our capabilities to support future product launches.”

Program Updates and Anticipated Upcoming Milestones

- The Company remains focused on advancing the development of sparsentan to become a potential new treatment standard in rare kidney conditions and anticipates the following upcoming milestones:
    - The Phase 3 DUPLEX Study is expected to reach enrollment of the first 190 patients with focal segmental glomerulosclerosis (FSGS) in the first half of 2020. Top-line efficacy data from the 36-week proteinuria endpoint analysis from the first 190 patients in the study remains on-track for the first half of 2021. Successful achievement of the proteinuria endpoint is expected to serve as the basis for submission of a New Drug Application (NDA) under the Subpart H accelerated approval pathway in the U.S. and Conditional Marketing Authorization (CMA) consideration in Europe.
    - The Phase 3 PROTECT Study is expected to reach enrollment of 280 patients with IgA nephropathy (IgAN) by early 2021. Top-line efficacy data from the 36-week proteinuria endpoint analysis from 280 patients in the study remains on-track for the first half of 2022. Successful achievement of the proteinuria endpoint is expected to serve as the basis for submission of an NDA under the Subpart H accelerated approval pathway in the U.S. and CMA consideration in Europe.
- In 2020, the Company expects continued organic growth of its rare nephrology and hepatology products.

In late February, the Company expects to announce complete full year 2019 financial results and provide a corporate update.

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 renal 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 commercial 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 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 for each of its development programs, risk associated with enrollment of clinical trials for rare diseases and risk that ongoing clinical trials may not proceed on expected timelines or may be delayed for safety, regulatory or other reasons and risk that the product candidates will not be approved for efficacy, safety, regulatory or other reasons. 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; and 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-Q, Form 10-K and other filings with the Securities and Exchange Commission.

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