Travere Therapeutics Provides Corporate Update and 2021 Outlook

January 11, 2021

Pipeline of potential first-in-class therapies on track to deliver two pivotal readouts in 2021

SAN DIEGO, Jan. 11, 2021 (GLOBE NEWSWIRE) -- Travere Therapeutics (NASDAQ: TVTX) today announced that, based on preliminary and unaudited financial data, the Company expects net product sales for the fourth quarter of 2020 to be approximately $51 million. For the fiscal year 2020, the Company expects total net product sales of approximately $199 million. The Company also provided a general update on its development programs, including anticipated milestones for 2021.

"We are entering 2021 with great momentum as we continue on our path to potentially delivering new, first-in-class treatment options for people living with rare disease," said Eric Dube, Ph.D., chief executive officer of Travere Therapeutics. "Our focus remains clear on maximizing the potential for sparsentan, if approved, to shape the treatment paradigm for patients living with rare kidney conditions FSGS and IgA nephropathy. The pivotal DUPLEX and PROTECT studies of sparsentan remain on track to report topline results from the interim proteinuria assessments, potentially positioning us for accelerated approval regulatory submissions in FSGS this year, followed by IgA nephropathy as early as next year. Additionally, we expect proof-of-concept data from the ongoing Phase 1/2 clinical trial of TVT-058 later this year, as we look to develop the first disease modifying therapy for people living with classical homocystinuria."

Program Updates and Anticipated Upcoming Milestones

- The Company continues to advance sparsentan, an investigational product candidate that is an innovative, single molecule that selectively inhibits both endothelin type A and angiotensin type II receptors, with the goal of having it ultimately become a new treatment standard in rare kidney conditions. The following upcoming milestones in the pivotal DUPLEX and PROTECT studies are anticipated in 2021:
    - The Phase 3 DUPLEX Study of sparsentan in focal segmental glomerulosclerosis (FSGS) is on track to report topline efficacy data from the 36-week interim proteinuria endpoint analysis in February 2021.
    - Successful achievement of the interim proteinuria endpoint in the DUPLEX Study 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. Contingent on the upcoming data read-out, the Company anticipates being in position to submit these applications for the treatment of FSGS in the second half of 2021.
    - The Phase 3 PROTECT Study of sparsentan in IgA nephropathy (IgAN) is expected to complete enrollment in 2021. Topline efficacy data from the 36-week interim proteinuria endpoint analysis are anticipated in the third quarter of 2021. Successful achievement of the interim proteinuria endpoint is expected to support submission of an NDA under the Subpart H accelerated approval pathway in the U.S., as well as an application for CMA consideration in Europe.
- The Phase 1/2 study of TVT-058 in patients with classical homocystinuria (HCU) continues to advance and topline data are anticipated in 2021. TVT-058 is an investigational human enzyme replacement therapy with the potential to become the first disease modifying therapy for people living with HCU.
- The Company expects continued organic growth of its approved rare nephrology and hepatology products in 2021. The Company also anticipates continuing to build upon its existing commercialization capabilities to support the potential future launch of sparsentan, contingent on the upcoming data read-outs and if approved.

In late February, the Company expects to announce complete full year 2020 financial results and provide a corporate update.

About Travere Therapeutics

At Travere Therapeutics we are in rare for life. We are a biopharmaceutical company that comes together every day to help patients, families and caregivers of all backgrounds as they navigate life with a rare disease. On this path, we know the need for treatment options is urgent – that is why our global team works with the rare disease community to identify, develop and deliver life-changing therapies. In pursuit of this mission, we continuously seek to understand the diverse perspectives of rare patients and to courageously forge new paths to make a difference in their lives and provide hope – today and tomorrow. For more information, visit travere.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 include, but are not limited to, references to the Company's expectations regarding net product sales for the fourth quarter of 2020 and fiscal year 2020 based on preliminary and unaudited financial data; the Company's current expectations around the timeline for reporting top-line data from the proteinuria endpoints in the DUPLEX and PROTECT studies; expectations regarding potential regulatory submissions for sparsentan under the Subpart H accelerated approval pathway in the U.S. and CMA consideration in Europe; references to the Company's path to potentially delivering new, first-in-class treatment options for people living with rare disease; the ability of the Company to shape the treatment paradigm for patients living with rare kidney conditions FSGS and IgA nephropathy, if sparsentan is approved; the goal of having sparsentan ultimately become a new treatment standard in rare kidney conditions; the potential future regulatory approval of sparsentan for FSGS and IgAN; the expected timing for the proof-of-concept data read-out from the Phase 1/2 trial of TVT-058; and the potential for OT-58 to ultimately become a new treatment option for HCU. 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 DUPLEX Study 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 PROTECT Study 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 positive results from the DUET Study of sparsentan in FSGS will be repeated 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. The Company faces additional risks associated with the potential impacts the COVID-19 pandemic may have on its business, including, but not limited to (i) the Company's ability to continue its ongoing development activities and clinical trials, (ii) the timing of such clinical trials and the release of data from those trials, (iii) the Company's and its suppliers' ability to successfully manufacture its commercial products and product candidates, and (iv) the market for and sales of its commercial 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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