Travere Therapeutics Announces Presentations of Abstracts at the 59th ERA Congress

May 17, 2022

SAN DIEGO, May 17, 2022 (GLOBE NEWSWIRE) -- Travere Therapeutics, Inc. (NASDAQ: TVTX) today announced presentations including baseline characteristics for patients enrolled in the ongoing pivotal Phase 3 PROTECT and DUPLEX studies of sparsentan in IgA nephropathy (IgAN) and focal segmental glomerulosclerosis (FSGS), respectively, at the 59th European Renal Association (ERA) Congress. The Company and its collaborators will also present nonclinical data examining the renal protective effects of sparsentan compared to controls. ERA is being held live in Paris, France, and virtually May 19-22, 2022.

Mini-Oral Presentations:

Baseline Characteristics of Adults Enrolled in the Ongoing Phase 3 Randomized, Double-Blind, Active-Control Trial of Sparsentan for the Treatment of Immunoglobulin A Nephropathy (PROTECT)
Presentation #: MO209
Session Title: Glomerulonephritis
Date & Time: Thursday, May 19, 2022, 8:00-12:45 CEST

Baseline Characteristics of Patients Enrolled in the Ongoing Phase 3 Randomized, Double-Blind, Active-Control Trial of Sparsentan for the Treatment of Focal Segmental Glomerulosclerosis (DUPLEX)
Presentation #: MO254
Session Title: Glomerulonephritis
Date & Time: Thursday, May 19, 2022, 8:00-12:45 CEST

Sparsentan Protects the Glomerular Basement Membrane and Glycocalyx, and Attenuates Proteinuria in a Rat Model of Focal Segmental Glomerulosclerosis (FSGS)
Presentation #: MO255
Session Title: Glomerulonephritis
Date & Time: Thursday, May 19, 2022, 8:00-12:45 CEST

Sparsentan, the Dual Endothelin Angiotensin Receptor Antagonist (DEARA), Attenuates Albuminuria and Protects from the Development of Renal Injury to a Greater Extent Than Losartan in the gddY Mouse Model of IgA Nephropathy: A 16-Week Study
Presentation #: MO261
Session Title: Quick Fire Session 1
Date & Time: Friday, May 20, 2022, 16:30-18:00 CEST

About the PROTECT Study

The ongoing PROTECT Study is a global, randomized, multicenter, double-blind, parallel-arm, active-controlled clinical trial evaluating the safety and efficacy of 400mg of sparsentan, compared to 300mg of irbesartan, in 404 patients ages 18 years and up with IgAN and persistent proteinuria despite available ACE or ARB therapy. In August 2021, the Company announced the PROTECT Study met its pre-specified interim primary efficacy endpoint with statistical significance. After 36 weeks of treatment, patients receiving sparsentan achieved a mean reduction in proteinuria from baseline of 49.8 percent, compared to a mean reduction in proteinuria from baseline of 15.1 percent for irbesartan-treated patients ($p<0.0001$). The Company believes that preliminary eGFR data available at the time of the interim analysis are indicative of a potential clinically meaningful treatment effect after two years of treatment. Preliminary results at the time of the interim assessment suggested that sparsentan had been generally well-tolerated to date in the study and consistent with its overall observed safety profile. The PROTECT Study is fully enrolled and is scheduled to continue as planned on a blinded basis to assess the treatment effect on eGFR slope over 110 weeks in the confirmatory endpoint analysis. Topline results from the confirmatory endpoint analysis are expected in the second half of 2023.

About the DUPLEX Study

The ongoing DUPLEX Study is the largest interventional study to date in FSGS. It is a global, randomized, multicenter, double-blind, parallel-arm, active-controlled Phase 3 clinical trial assessing the efficacy and safety of sparsentan in 371 patients ages 8 to 75 years with primary FSGS. In February 2021, the Company announced that the ongoing pivotal Phase 3 DUPLEX Study of sparsentan in FSGS achieved its pre-specified interim FSGS partial remission of proteinuria (FPRE) endpoint with statistical significance. FPRE is a clinically meaningful endpoint defined as urine protein-to-creatinine ratio (UP/C) ≤1.5 g/g and a >40 percent reduction in UP/C from baseline. After 36 weeks of treatment, 42.0 percent of patients receiving sparsentan achieved FPRE, compared to 26.0 percent of irbesartan-treated patients ($p=0.0094$). Preliminary results from the interim analysis suggest that at the time of the interim assessment, sparsentan had been generally well-tolerated and shown a comparable safety profile to irbesartan. The DUPLEX Study is fully enrolled and is scheduled to continue as planned on a blinded basis to assess the confirmatory estimated glomerular filtration rate (eGFR) endpoint after 108 weeks of treatment. Topline results from the confirmatory endpoint are expected in the first half of 2023.

About Sparsentan

Sparsentan, a Dual Endothelin Angiotensin Receptor Antagonist (DEARA), is a novel investigational product candidate selectively targeting the endothelin A receptor (ETAR) and the angiotensin II subtype 1 receptor (AT1R). Pre-clinical data have shown that blockade of both endothelin type A and angiotensin II type 1 pathways in forms of rare chronic kidney disease, reduces proteinuria, protects podocytes and prevents glomerulosclerosis and mesangial cell proliferation. Sparsentan has been granted Orphan Drug Designation for the treatment of IgAN and FSGS in the US and Europe. A

New Drug Application (NDA) for accelerated approval of sparsentan in IgAN is currently being evaluated by the U.S. Food and Drug Administration (FDA) under Priority Review designation. If approved for both indications, sparsentan could potentially be the first medicine approved for both FSGS and IgAN.

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 efficacy, safety and tolerability profile of sparsentan based on the preliminary data from the PROTECT and DUPLEX Studies' interim analyses; the Company's belief that preliminary eGFR data available at the time of the interim analysis from the PROTECT Study are indicative of a potential clinically meaningful treatment effect after two years of treatment; expectations regarding the future conduct of the ongoing PROTECT and DUPLEX studies and timing for topline results from the confirmatory endpoint analyses; and the potential for sparsentan to become the first medicine approved for both FSGS and IgAN.. 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 regulatory review and approval process, including the Subpart H accelerated approval pathway in the United States and the conditional marketing authorization (CMA) pathway in Europe. Specifically, the Company faces the risk that the Phase 3 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 Phase 3 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 Company's 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. 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 current and potential future 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-Q, Form 10-K and other filings with the Securities and Exchange Commission.

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