Travere Therapeutics Announces Presentations and Posters at American Society of Nephrology Kidney Week 2022

October 26, 2022

Data support the Company's lead investigational product candidate sparsentan

SAN DIEGO, Oct. 26, 2022 (GLOBE NEWSWIRE) -- Travere Therapeutics, Inc. (NASDAQ: TVTX) today announced that the Company and its collaborators will present data from its sparsentan programs, including long-term clinical data from the ongoing Phase 2 DUET Study in focal segmental glomerulosclerosis (FSGS), as well as non-clinical data exploring the potential for sparsentan to protect kidney function at the American Society of Nephrology (ASN) Kidney Week 2022. The company will also present data on the role of proteinuria in IgA nephropathy (IgAN) and on the humanistic burden of IgAN on patients and caregivers. ASN Kidney Week 2022 is being held November 3-6, 2022, in Orlando, Florida.

Oral Presentations

Sparsentan Improves Glomerular Endothelial and Podocyte Functions and Augments Protective Tissue Repair in a Mouse Model of Focal Segmental Glomerulosclerosis (FSGS)
Session: Glomerular Diseases: From Bench to Bedside
Oral Presentation: FR-OR56
Location: Session Room: W414 (Orange County Convention Center, West Building)
Date & Time: November 4, 2022, from 5:15 to 5:24 p.m. ET

Long-Term Efficacy and Safety of Sparsentan in FSGS: 240-Week Analysis of the DUET Open-Label Extension (OLE)
Session: Glomerular Diseases: From Bench to Bedside
Oral Presentation: FR-OR57
Location: W414 (Orange County Convention Center, West Building)
Date & Time: November 4, from 5:24 to 5:33 p.m. ET

Poster Presentations

Evaluating the Predictors of Structural Features in Kidney Biopsies from Adults with Focal Segmental Glomerulosclerosis
Poster #: TH-PO478
Session: Glomerular Diseases: Clinical, Outcomes, Trials – I
Date, Time & Location: November 3, 2022, from 10 a.m. to 12 p.m. ET, Hall E

Proteinuria and Its Association With Disease Progression in IgA Nephropathy: Analysis of the UK National RaDaR IgA Nephropathy Cohort
Poster #: TH-PO494
Session: Glomerular Diseases: Clinical, Outcomes, Trials - I
Date, Time & Location: November 3, 2022, from 10 a.m. to 12 p.m. ET, Hall E

Health State Utility Values for Immunoglobulin A Nephropathy (IgAN)
Poster #: TH-PO496
Session: Glomerular Diseases: Clinical, Outcomes, Trials – I
Date, Time & Location: November 3, 2022, from 10 a.m. to 12 p.m. ET, Hall E

Effect of Multiple Doses of Sparsentan on the Single-Dose Pharmacokinetics of Dapagliflozin: Open-Label Drug-Drug Interaction Study in Healthy Adults
Poster #: FR-PO217
Session Title: Pharmacology
Date, Time & Location: November 4, 10 a.m. to 12 p.m. ET, Hall E

Predictors of Progression to Kidney Failure in Patients with Focal Segmental Glomerulosclerosis
Poster #: FR-PO662
Session: Glomerular Diseases: Clinical, Outcomes, Trials - II
Date, Time & Location: November 4, 10 a.m. to 12 p.m. ET, Hall E

Development of a Treatment Response Prediction Strategy for Sparsentan in Glomerular Disease
Poster #: FR-PO724
Session: Glomerular Diseases: Podocyte Biology – I
Date, Time & Location: November 4, 10 a.m. to 12 p.m. ET, Hall E

Differentiating Primary and Secondary FSGS Using Non-Invasive Urine Biomarkers
Poster #: FR-PO913
Session: CKD: Epidemiology, Risk Factors, Prevention – II
Date, Time & Location: November 4, 10 a.m. to 12 p.m. ET, Hall E

Humanistic Burden of Patients with Immunoglobulin A Nephropathy (IgAN) in the United States (US): Preliminary Results from HONUS Study

Poster Board #: SA-PO699
Session: Glomerular Diseases: Clinical, Outcomes, Trials - III
Date, Time & Location: November 5, 2022, from 10 a.m. to 12 p.m. ET, Hall E

A Retrospective Analysis of Cardiovascular Disease (CVD) Events in Prevalent Patients with Focal Segmental Glomerulosclerosis (FSGS) in the US
Poster #: SA-PO702
Session: Glomerular Diseases: Clinical, Outcomes, Trials - III
Date, Time & Location: November 5, 2022, from 10 a.m. to 12 p.m. ET, Hall E

About Sparsentan

Sparsentan, a Dual Endothelin Angiotensin Receptor Antagonist (DEARA), is a novel investigational product candidate selectively targeting the endothelin A receptor (ET_AR) and the angiotensin II subtype 1 receptor (AT_1R). 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 FSGS and IgAN in the U.S. and Europe.

Sparsentan is currently being evaluated in the pivotal Phase 3 DUPLEX Study for the treatment of FSGS and the pivotal Phase 3 PROTECT Study for the treatment of IgAN. 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 endpoint (FPRE) 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. In August of 2021, the Company announced that the ongoing PROTECT Study in IgAN met its pre-specified interim primary efficacy endpoint with statistical significance, demonstrating a greater than threefold reduction of proteinuria from baseline after 36 weeks of treatment, compared to the active control irbesartan (p<0.0001). Preliminary results from the interim analysis suggest that at the time of the interim assessment, sparsentan had been generally well tolerated and performed consistent with the observed safety profile to date. In the Phase 2 DUET Study of sparsentan in FSGS, the combined treatment group met its primary efficacy endpoint, demonstrating a greater than two-fold reduction in proteinuria compared to irbesartan, and was generally well tolerated 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. An NDA for accelerated approval of sparsentan in IgAN is currently being evaluated by the 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 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. 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 DUPLEX and PROTECT Studies' interim analyses and the potential for sparsentan to be the first medicine approved for both FSGS and IgAN, if approved for both indications. 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 the European Union, as well as risks and uncertainties associated with the Company's business and finances in general. Specifically, the Company faces the risk that the Phase 3 clinical trial of sparsentan in IgAN 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 FSGS will not demonstrate that sparsentan is safe or effective or serve as the basis for traditional 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 non-clinical data that are summarized in the abstracts that are a subject of this press release will translate to a viable therapeutic approach in patients. 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 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. 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.

Contact:

Investors:
Investor Relations
888-969-7879
IR@travere.com

Media:
Nivi Nehra
Vice President, Corporate Communications
888-969-7879
mediarelations@travere.com

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