Travere Therapeutics to Present Abstracts at American Society of Nephrology Kidney Week 2021

November 2, 2021

SAN DIEGO, Nov. 02, 2021 (GLOBE NEWSWIRE) -- Travere Therapeutics, Inc. (NASDAQ: TVTX) today announced that the Company and its collaborators will present abstracts based on non-clinical data describing the potential for sparsentan, an investigational product candidate, to protect kidney function in models of rare glomerular diseases, including a potential anti-inflammatory role in IgA nephropathy (IgAN), at the American Society of Nephrology (ASN) Kidney Week 2021. Sparsentan is a Dual Endothelin Angiotensin Receptor Antagonist (DEARA) currently in Phase 3 clinical development for the treatment of IgAN and focal segmental glomerulosclerosis (FSGS). The company will also present data from natural history studies highlighting the challenges associated with managing IgAN and FSGS, as well as data indicating poor renal survival in children and adults living with these rare kidney disorders. In addition, an analysis of the association between achieving complete or partial remission of proteinuria and delaying the progression to end-stage kidney disease (ESKD) in FSGS will be presented. ASN Kidney Week 2021 is being held virtually November 4-7, 2021.

All ePosters will be made available to ASN Kidney Week 2021 participants on November 4, 2021 at 10:00 a.m. PT, and will be accessible on-demand through January 7, 2022.

The Dual Endothelin Angiotensin Receptor Antagonist (DEARA) Sparsentan Protects from Glomerular Hypercellularity and Associated Immune/Inflammatory Gene-Network-Activity in a Model of IgA Nephropathy (IgAN)
ePoster #: PO1454
Session: Glomerular Diseases: Immunology and Inflammation in IgANP, C3GP, TMA, and Nephrotic Diseases

Clinicopathological Characteristics of Adult IgA Nephropathy: A Retrospective Cohort Study
ePoster #: PO1576
Session: Glomerular Diseases: Clinicopathological Features and Outcomes in IgAN, Lupus Nephritis, and Vasculitis

Natural History of IgA Nephropathy: Analysis of a UK National RaDaR IgA Nephropathy Cohort
ePoster #: PO1577
Session: Glomerular Diseases: Clinicopathological Features and Outcomes in IgAN, Lupus Nephritis, and Vasculitis

An International Delphi Survey on IgA Nephropathy: Results from the DEFINE Physicians Study
ePoster #: PO1641
Session: Glomerular Diseases: Treatment and Outcomes

Proteinuria End Points and Association With Renal Survival in FSGS: Analysis of the UK National RaDaR Idiopathic Nephrotic Syndrome Cohort
ePoster #: PO1530
Session: Glomerular Diseases: Clinical Features and Outcomes in Nephrotic Syndromes and Complement-Mediated Diseases

Clinicopathological Characteristics of Adult Patients in the United States with Focal Segmental Glomerulosclerosis (FSGS)
ePoster #: PO1531
Session: Glomerular Diseases: Clinical Features and Outcomes in Nephrotic Syndromes and Complement-Mediated Diseases

Clinicopathological Characteristics of Focal Segmental Glomerulosclerosis (FSGS) in a Pediatric Patient Population
Publication#: PUB261
Session: ASN Kidney Week 2021 Abstract Supplement

Natural History of Focal Segmental Glomerulosclerosis (FSGS): The UK National RaDaR Idiopathic Nephrotic Syndrome Cohort
ePoster #: PO1529
Session: Glomerular Diseases: Clinical Features and Outcomes in Nephrotic Syndromes and Complement-Mediated Diseases

DEFINE Physicians: An International Delphi Survey to Identify Consensus in the Care of Patients with FSGS or Idiopathic Nephrotic Syndrome
ePoster #: PO1643
Session: Glomerular Diseases: Treatment and Outcomes

Humanistic Burden of Rare Kidney Diseases; Understanding the Impact of FSGS and IgAN on Patients and Caregivers: The HONUS Rationale and Study Design
ePoster #: PO1479
Session: Glomerular Diseases: Immunology and Inflammation in IgANP, C3GP, TMA, and Nephrotic Diseases

Sparsentan for Treatment of Pediatric Patients With Selected Proteinuric Glomerular Diseases: Design of the Phase 2 EPPIK Study
ePoster #: PO1980
Session: Pediatric Nephrology: AKI, Dialysis, Transplant, CKD, and Nephrotic Syndrome

Sparsentan, the Dual Endothelin Angiotensin Receptor Antagonist (DEARA), Improves Kidney Function and Life Span and Protects Against Hearing Loss in Alport Mice With Developed Renal Structural Changes
Poster #: PO1299

Session: Genetic Diseases of the Kidneys: Non-Cystic – I

About Sparsentan
Sparsentan, a Dual Endothelin Angiotensin Receptor Antagonist (DEARA), is a novel investigational product candidate. 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 focal segmental glomerulosclerosis (FSGS) and the pivotal Phase 3 PROTECT Study for the treatment of IgA nephropathy (IgAN). In February 2021, the Company announced that the ongoing 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. 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. 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 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.

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