Travere Therapeutics to Present Abstracts on FILSPARI® (sparsentan) in IgA Nephropathy at World Congress of Nephrology and the American Nephrology Nurses Association

April 3, 2024

Upcoming data presentations underscore the potential for FILSPARI to become a foundational treatment for IgAN and Travere's leadership and commitment to innovation in rare kidney disease (RKD)

SAN DIEGO, April 03, 2024 (GLOBE NEWSWIRE) -- Travere Therapeutics, Inc., (Nasdaq: TVTX) today announced that the Company will present nine abstracts in rare kidney disease at the World Congress of Nephrology (WCN) in Buenos Aires, Argentina, on April 13-16, 2024, and the American Nephrology Nurses Association (ANNA) National Symposium in Orlando, Florida, on April 14-17, 2024.

At WCN, the Company will present subgroup analyses of the Phase 3 PROTECT Study of FILSPARI® (sparsentan) in IgA nephropathy (IgAN) showing the treatment effect across participants with different levels of baseline proteinuria. Encore presentations will include preliminary findings from the SPARTAN Study supportive of FILSPARI as a first-line treatment for patients with IgAN, as well as the early clinical experience from the PROTECT open-label extension regarding the addition of sodium-glucose cotransporter-2 inhibitors (SGLT2i) to ongoing FILSPARI treatment in patients with IgAN. At ANNA, the Company will present additional insights from the HONUS trial, including health-related quality of life (HRQoL) data and the humanistic burden experienced by patients with IgAN and focal segmental glomerulosclerosis (FSGS).

"The data we are presenting at WCN and ANNA reinforce the wealth of evidence supporting FILSPARI's profile to become an effective foundational treatment replacing RAAS inhibition, with the potential to reduce the lifetime risk of kidney failure for patients with IgAN," said Jula Inrig, M.D., chief medical officer of Travere Therapeutics. "We are also looking forward to presenting data that address broader aspects of disease management, building upon Travere's holistic approach to improving patient outcomes in RKD."

WCN Late Breaking Abstract

Sparsentan vs Irbesartan in Patients with Immunoglobulin A Nephropathy (IgAN): Subgroup Analyses of 2-Year Results from the Pivotal Phase 3 PROTECT Trial
Oral Presentation: MON-296
Late Breaking Clinical Trial Session
Exhibition Hall and Main Foyer; April 15, 2024, 3:35-3:45 p.m. ART

WCN Poster Presentations

Sparsentan as First-Line Treatment of Incident Patients with IgA Nephropathy: Preliminary Findings from the SPARTAN Trial
Poster: SUN-042
Poster Session: Clinical Glomerulonephritis 2
Exhibition Hall and Main Foyer; April 14, 2024, 5:45-6:45 p.m. ART

Concomitant Sparsentan and Sodium-Glucose Cotransporter-2 Inhibitors (SGLT2i) in Patients with IgA Nephropathy (IgAN) in the PROTECT Open-Label Extension (OLE)
Poster: SUN-049
Poster Session: Clinical Glomerulonephritis 2
Exhibition Hall and Main Foyer; April 14, 2024, 5:45-6:45 p.m. ART

Sparsentan Receptor Occupancy Modeling, Clinical Actions, and Safety
Poster: SUN-045
Poster Session: Clinical Glomerulonephritis 2
Exhibition Hall and Main Foyer; April 14, 2024, 5:45-6:45 p.m. ART

Preliminary Findings from the Phase 2 EPPIK Study of Sparsentan in Pediatric Patients with Selected Proteinuric Glomerular Diseases
Poster: SUN-048
Poster Session: Clinical Glomerulonephritis 2
Exhibition Hall and Main Foyer; April 14, 2024, 5:45-6:45 p.m. ART

ANNA Poster Presentations

Sparsentan (SPAR), a Novel Non-immunosuppressive Therapy for Patients (pts) with Immunoglobulin A Nephropathy (IgAN): Pivotal Phase 3 PROTECT Trial Data
Exhibit Hall; April 15, 2024, 8:45-10:15 a.m. & 2:30-4 p.m.; April 16, 2024, 8:45-10:15 a.m. ET

Contextualizing the Humanistic Burdens of Focal Segmental Glomerular Sclerosis (FSGS) in HONUS Compared to External Controls in NHWS
Exhibit Hall; April 15, 2024, 8:45-10:15 a.m. & 2:30-4 p.m.; April 16, 2024, 8:45-10:15 a.m. ET

Indirect Comparisons of Humanistic Burdens Between Patients with Immunoglobulin A Nephropathy (IgAN) from HONUS and External Controls from NHWS
Exhibit Hall; April 15, 2024, 8:45-10:15 a.m. & 2:30-4 p.m.; April 16, 2024, 8:45-10:15 a.m. ET

Data in Kidney Failure (KF) Estimated by Treatment Effects on Proteinuria in Patients with Immunoglobulin A Nephropathy (IgAN)
Exhibit Hall; April 15, 2024, 8:45-10:15 a.m. & 2:30-4 p.m.; April 16, 2024, 8:45-10:15 a.m. ET

About IgA Nephropathy

IgA nephropathy (IgAN), also called Berger's disease, is a rare progressive kidney disease characterized by the buildup of immunoglobulin A (IgA), a protein that helps the body fight infections, in the kidneys. The deposits of IgA cause a breakdown of the normal filtering mechanisms in the kidney, leading to blood in the urine (hematuria), protein in the urine (proteinuria) and a progressive loss of kidney function. Other symptoms of IgAN may include swelling (edema) and high blood pressure.

IgAN is the most common type of primary glomerulonephritis worldwide and a leading cause of kidney failure due to glomerular disease. IgAN is estimated to affect up to 150,000 people in the U.S. and is one of the most common glomerular diseases in Europe and Japan.

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

FILSPARI® (sparsentan) U.S. Indication

FILSPARI is an endothelin and angiotensin II receptor antagonist indicated to reduce proteinuria in adults with primary immunoglobulin A nephropathy (IgAN) at risk of rapid disease progression, generally a UPCR ≥1.5 g/g.

This indication is granted under accelerated approval based on reduction in proteinuria. It has not been established whether FILSPARI slows kidney function decline in patients with IgAN. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory clinical trial.

FILSPARI® (sparsentan) Important Safety Information

BOXED WARNING: HEPATOTOXICITY AND EMBRYO-FETAL TOXICITY
Because of the risks of hepatotoxicity and birth defects, FILSPARI is available only through a restricted program called the FILSPARI REMS. Under the FILSPARI REMS, prescribers, patients and pharmacies must enroll in the program.

Hepatotoxicity
Some Endothelin Receptor Antagonists (ERAs) have caused elevations of aminotransferases, hepatotoxicity, and liver failure. In clinical studies, elevations in aminotransferases (ALT or AST) of at least 3-times the Upper Limit of Normal (ULN) have been observed in up to 2.5% of FILSPARI-treated patients, including cases confirmed with rechallenge.

Measure transaminases and bilirubin before initiating treatment and monthly for the first 12 months, and then every 3 months during treatment. Interrupt treatment and closely monitor patients who develop aminotransferase elevations more than 3x ULN.

FILSPARI should generally be avoided in patients with elevated aminotransferases (>3x ULN) at baseline because monitoring for hepatotoxicity may be more difficult and these patients may be at increased risk for serious hepatotoxicity.

Embryo-Fetal Toxicity
FILSPARI can cause major birth defects if used by pregnant patients based on animal data. Therefore, pregnancy testing is required before the initiation of treatment, during treatment and one month after discontinuation of treatment with FILSPARI. Patients who can become pregnant must use effective contraception before the initiation of treatment, during treatment, and for one month after discontinuation of treatment with FILSPARI.

Contraindications: FILSPARI is contraindicated in patients who are pregnant. Do not coadminister FILSPARI with angiotensin receptor blockers (ARBs), ERAs, or aliskiren.

Warnings and Precautions

Hepatotoxicity: Elevations in ALT or AST of at least 3-fold ULN have been observed. To reduce the risk of potential serious hepatotoxicity, measure serum aminotransferase levels and total bilirubin prior to initiation of treatment, monthly for the first 12 months, then every 3 months during treatment.

Advise patients with symptoms suggesting hepatotoxicity (nausea, vomiting, right upper quadrant pain, fatigue, anorexia, jaundice, dark urine, fever, or itching) to immediately stop treatment with FILSPARI and seek medical attention. If aminotransferase levels are abnormal at any time during treatment, interrupt FILSPARI and monitor as recommended.

Consider re-initiation of FILSPARI only when hepatic enzyme levels and bilirubin return to pretreatment values and only in patients who have not experienced clinical symptoms of hepatotoxicity.

Avoid initiation of FILSPARI in patients with elevated aminotransferases (>3x ULN) prior to drug initiation.

Embryo-Fetal Toxicity: FILSPARI can cause fetal harm. Advise patients who can become pregnant of the potential risk to a fetus. Obtain a pregnancy test and advise patients who can become pregnant to use effective contraception prior to, during, and one month after discontinuation of FILSPARI treatment.

FILSPARI REMS: FILSPARI is available only through a restricted program under a REMS called the FILSPARI REMS. Important requirements include:

- Prescribers must be certified with the FILSPARI REMS by enrolling and completing training.
- All patients must enroll in the FILSPARI REMS prior to initiating treatment and comply with monitoring requirements.
- Pharmacies that dispense FILSPARI must be certified with the FILSPARI REMS and must dispense only to patients who are authorized to receive FILSPARI.

Further information is available at www.filsparirems.com or 1-833-513-1325.

Hypotension: There was a greater incidence of hypotension-associated adverse events, some serious, including dizziness, in patients treated with FILSPARI compared to irbesartan. In patients at risk for hypotension, consider eliminating or adjusting other antihypertensive medications and maintaining appropriate volume status. If hypotension develops, consider a dose reduction or dose interruption of FILSPARI.

Acute Kidney Injury: Monitor kidney function periodically. Patients whose kidney function may depend in part on the activity of the renin-angiotensin system (e.g., patients with renal artery stenosis, chronic kidney disease, severe congestive heart failure, or volume depletion) may be at particular risk of developing acute kidney injury on FILSPARI. Consider withholding or discontinuing therapy in patients who develop a clinically significant decrease in kidney function while on FILSPARI.

Hyperkalemia: Monitor serum potassium periodically and treat appropriately. Patients with advanced kidney disease, taking concomitant potassium-increasing drugs (e.g., potassium supplements, potassium-sparing diuretics), or using potassium-containing salt substitutes are at increased risk for developing hyperkalemia. Dosage reduction or discontinuation of FILSPARI may be required.

Fluid Retention: Fluid retention may occur with ERAs, and has been observed with FILSPARI. If clinically significant fluid retention develops, after evaluation, consider modifying the dose of FILSPARI.

Most common adverse reactions (5%) with FILSPARI are peripheral edema, hypotension (including orthostatic hypotension), dizziness, hyperkalemia, and anemia.

Drug interactions

- **Renin-Angiotensin System (RAS) Inhibitors and ERAs:** Do not coadminister FILSPARI with angiotensin receptor blockers (ARBs), ERAs, or aliskiren.
- **Strong and Moderate CYP3A Inhibitors:** Avoid concomitant use of FILSPARI with strong CYP3A inhibitors. Monitor blood pressure, serum potassium, edema, and kidney function regularly when used concomitantly with moderate CYP3A inhibitors.
- **Strong CYP3A Inducers:** Avoid concomitant use with a strong CYP3A inducer.
- **Antacids and Acid Reducing Agents:** Administer FILSPARI 2 hours before or after administration of antacids. Avoid concomitant use of acid reducing agents (histamine H2 receptor antagonist and PPI proton pump inhibitor) with FILSPARI.
- **Non-Steroidal Anti-Inflammatory Agents (NSAIDs), Including Selective Cyclooxygenase-2 (COX-2) Inhibitors:** Monitor for signs of worsening renal function.
- **CYP2B6, 2C9, and 2C19 Substrates:** Monitor for efficacy of the concurrently administered CYP2B6, 2C9, and 2C19 substrates and consider dosage adjustment in accordance with the Prescribing Information.
- **P-gp and BCRP Substrates:** Avoid concomitant use of sensitive substrates of P-gp and BCRP with FILSPARI.
- **Agents Increasing Serum Potassium:** Monitor serum potassium frequently. Concomitant use of FILSPARI with potassium-sparing diuretics, potassium supplements, potassium-containing salt substitutes, or other drugs that raise serum potassium levels may result in hyperkalemia.

Use in specific populations

- **Pregnancy / Females and Males of Reproductive Potential:** FILSPARI can cause fetal harm, including birth defects and fetal death, when administered to a pregnant patient and is contraindicated during pregnancy.
    - **Pregnancy Testing / Contraception:** Verify the pregnancy status and effective method of contraception prior to, during, and one month after discontinuation of FILSPARI treatment. The patient should contact their physician immediately for pregnancy testing if onset of menses is delayed or pregnancy is suspected.
- **Lactation:** Advise patients not to breastfeed during treatment with FILSPARI.
- **Hepatic Impairment:** Avoid use of FILSPARI in patients with any hepatic impairment (Child-Pugh class A-C).

Please see Full Prescribing Information for FILSPARI here.

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 “anticipate,” “believe,” “expect,” “intend,” “may,” “might,” “objective,” “plan,” “will” 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, statements regarding the potential for FILSPARI to become a foundational treatment for IgAN replacing RAAS inhibition, and its potential to reduce the lifetime risk of kidney failure for patients with IgAN; and statements regarding the studies described herein, including but not limited to future expectations, preliminary findings and early clinical experience. 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, risks associated with enrollment of clinical trials for rare diseases, and risks that ongoing or planned clinical trials may not succeed or may be delayed for safety, regulatory or other reasons. The Company faces risks related to its business and finances in general; risks related to the commercial launch of a new product; risks associated with market acceptance of FILSPARI and other current and future products, including efficacy, safety, price, reimbursement and benefit over competing therapies; and the risk that the Company’s clinical candidates will not be found to be safe or effective and that current or anticipated future clinical trials will not proceed as planned. Specifically, the Company faces risks related to the timing and potential outcome of the FDA’s potential acceptance for filing and review of the sNDA submission for full approval of FILSPARI in IgAN, and the timing and potential outcome of the European Commission’s decision regarding conditional marketing authorization of sparsentan for IgAN. There is no guarantee that the FDA will accept the sNDA submission for filing, that the European Commission will grant conditional marketing authorization of sparsentan for IgAN, or that regulators will grant full approval of sparsentan for IgAN or FSGS. The Company also faces the 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, including as a result of macroeconomic conditions; risks 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 also faces additional risks associated with global and macroeconomic conditions, including health epidemics and pandemics, including risks related to potential disruptions to clinical trials, commercialization activity, supply chain, and manufacturing operations. 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, including under the heading “Risk Factors”, 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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