Travere Therapeutics Presents Long-Term Open-Label Extension Data from the Phase 3 DUPLEX Study at the 63rd European Renal Association (ERA) 2026 Congress

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Patients in the study who initiated and remained on FILSPARI maintained durable and deepened proteinuria reductions, resulting in further achievement of clinically meaningful low proteinuria thresholds over time

Patients who transitioned from active control maximum labeled dose irbesartan to FILSPARI after the double-blind study period demonstrated rapid and sustained reductions in proteinuria

FILSPARI was generally well tolerated for up to five years of follow-up in the study

SAN DIEGO--(BUSINESS WIRE)-- Travere Therapeutics, Inc., (Nasdaq: TVTX) today announced long-term results from the ongoing Phase 3 DUPLEX Study open-label extension (OLE) of FILSPARI® (sparsentan) in the treatment of focal segmental glomerulosclerosis (FSGS). Patients who initiated FILSPARI in the double-blind period and remained on therapy in the OLE maintained durable reductions in proteinuria, resulting in further achievement of clinically meaningful low proteinuria thresholds over time. Patients who transitioned from active control maximum labeled dose irbesartan to FILSPARI at the start of the OLE subsequently demonstrated rapid and sustained reductions in proteinuria similar to those who initiated FILSPARI at the beginning of the double-blind period. The results were presented at the European Renal Association (ERA) 2026 Congress in Glasgow, Scotland June 3-6.

“These long-term open-label extension data continue to reinforce the meaningful and sustained impact FILSPARI can have for people living with FSGS without nephrotic syndrome,” said Jula Inrig, M.D., chief medical officer of Travere Therapeutics. “Patients experienced clinically meaningful reductions in proteinuria after initiating FILSPARI, whether treatment began during the double-blind period or after transition from irbesartan in the open-label extension. The continued response observed over approximately five years, including three years in the open-label extension, further validates the benefit of FILSPARI and adds to a growing body of evidence supporting its role as foundational care in FSGS.”

The Phase 3 DUPLEX Study is a global, randomized, multicenter, double-blind, parallel-arm, active-controlled clinical trial that assessed the efficacy and safety of FILSPARI in patients with biopsy-proven or genetic FSGS compared to maximum labeled dose irbesartan for up to 108 weeks. At the end of the double-blind period, all patients were eligible to enroll in the open-label extension portion of the trial following a 4-week washout period and receive FILSPARI for up to three additional years.

During the DUPLEX double-blind period, patients treated with FILSPARI achieved higher rates of complete and partial remission compared to maximum labeled dose irbesartan. Complete remission (urine protein-to-creatinine ratio, UPCR <0.3 g/g) was achieved by 18.5% of FILSPARI-treated patients compared to 7.5% of those who received irbesartan, while partial remission (UPCR <1.5 g/g) was achieved by 69.0% and 50.8% of patients, respectively.

Following transition to the OLE, patients who remained on FILSPARI maintained durable reductions in proteinuria, resulting in further achievement of clinically meaningful low proteinuria thresholds over time. Among these patients, 37.5% achieved complete remission at any time across the double-blind or OLE period, and 87.5% achieved partial remission. Patients who transitioned from irbesartan to FILSPARI in the OLE after washout experienced rapid and sustained reductions in proteinuria, consistent with the reductions observed among patients who began FILSPARI during the double-blind period. Among these patients, 28.9% achieved complete remission at any time across the double-blind or OLE period, and 74.6% achieved partial remission. FILSPARI was generally well tolerated during the long-term OLE follow-up in the study with a safety profile consistent with previous findings.

At the 2026 ERA meeting, the Company will also share preclinical gddY mouse model data identifying a mechanism demonstrating how FILSPARI blocks gdIgA deposition in the kidney.

More information on Travere’s presence at ERA can be found **here**.

About the DUPLEX Study

The Phase 3 DUPLEX Study is the largest interventional study to date in FSGS. It was a global, randomized, multicenter, double-blind, parallel-arm, active-controlled Phase 3 clinical trial that assessed the efficacy and safety of FILSPARI in 371 patients ages 8 to 75 years with biopsy-proven or genetic FSGS. After a two-week washout period, patients were randomized 1:1 to receive either FILSPARI or irbesartan, the active control, and subsequently dose titrated to the maximum dose of 800 mg of sparsentan or 300 mg of irbesartan, as tolerated. The primary efficacy endpoint at the final analysis was the rate of change in eGFR from baseline to Week 108. The two-year results from the study were published in the New England Journal of Medicine. Patients who completed the

DUPLEX double-blind portion of the study on treatment were eligible to participate in the open-label extension of the trial.

About Focal Segmental Glomerulosclerosis

Focal segmental glomerulosclerosis (FSGS) is a rare proteinuric kidney disorder in both children and adults defined by progressive scarring of the kidney and often leads to kidney failure. FSGS is characterized by proteinuria, where protein leaks into the urine due to a breakdown of the normal filtration mechanism in the kidney. Once in the urine, protein is considered to be toxic to other parts of the kidney, especially the tubules, and is believed to contribute to further disease progression. FSGS without nephrotic syndrome spans all categories of the disorder.

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® (sparsentan) is indicated:

- To slow kidney function decline in adults with primary immunoglobulin A nephropathy (IgAN) who are at risk for disease progression.
- To reduce proteinuria in adult and pediatric patients aged 8 years and older with focal segmental glomerulosclerosis (FSGS) without nephrotic syndrome.

IMPORTANT SAFETY INFORMATION

BOXED WARNING: HEPATOTOXICITY AND EMBRYO-FETAL TOXICITY

Because of the risk of hepatotoxicity, 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 3.5% of FILSPARI-treated patients, including cases confirmed with rechallenge.

Measure transaminases and bilirubin before initiating treatment 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 is contraindicated for use during pregnancy because it may cause fetal harm if used by pregnant patients. Therefore, in patients who can become pregnant, exclude pregnancy prior to initiation of FILSPARI. Advise use of effective contraception before the initiation of treatment, during treatment, and for two weeks after discontinuation of treatment with FILSPARI. When pregnancy is detected, discontinue FILSPARI as soon as possible.

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 in up to 3.5% of FILSPARI-treated patients, including cases confirmed with rechallenge. While no concurrent elevations in bilirubin >2-times ULN or cases of liver failure were observed in FILSPARI-treated patients in clinical trials, some ERAs have caused elevations of aminotransferases, hepatotoxicity, and liver failure. To reduce the risk of potential serious hepatotoxicity, measure serum aminotransferase levels and total bilirubin prior to initiation of treatment and 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) because

monitoring hepatotoxicity in these patients may be more difficult and these patients may be at increased risk for serious hepatotoxicity

- FILSPARI REMS: Due to the risk of hepatotoxicity, FILSPARI is available only through a restricted program called the FILSPARI REMS. Prescribers, patients, and pharmacies must be enrolled in the REMS program and comply with all requirements (**www.filsparirems.com**).
- Embryo-Fetal Toxicity: Based on data from animal reproduction studies, FILSPARI may cause fetal harm when administered to a pregnant patient and is contraindicated during pregnancy. The available human data for ERAs do not establish the presence or absence of fetal harm related to the use of FILSPARI. Counsel patients who can become pregnant of the potential risk to a fetus. Exclude pregnancy before initiating treatment with FILSPARI. Advise patients who can become pregnant to use effective contraception prior to initiation of treatment, during treatment, and for two weeks after discontinuation of treatment with FILSPARI. Advise pre-pubertal females and/or their guardian(s) of the fetal risk and the need to use effective contraception once they reach reproductive potential. When pregnancy is detected, discontinue FILSPARI as soon as possible.
- Hypotension: Hypotension has been observed in patients treated with ARBs and ERAs and was observed in FILSPARI clinical studies. 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, despite elimination or reduction of other antihypertensive medications, consider a dose reduction or dose interruption of FILSPARI. A transient hypotensive response is not a contraindication to further dosing of FILSPARI, which can be given once blood pressure has stabilized.
- Acute Kidney Injury: Monitor kidney function periodically. Drugs that inhibit the renin-angiotensin system (RAS) can cause kidney injury. Patients whose kidney function may depend in part on the activity of the RAS (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 in clinical studies with FILSPARI. FILSPARI has not been evaluated in patients with heart failure. If clinically significant fluid retention develops, evaluate the patient to determine the cause and the potential need to initiate or modify the dose of diuretic treatment then consider modifying the dose of FILSPARI.

Adverse Reactions

- IgAN patients receiving FILSPARI: The most common adverse reactions (≥5%) are hyperkalemia, hypotension (including orthostatic hypotension), peripheral edema, dizziness, anemia, and acute kidney injury.
- FSGS patients receiving FILSPARI: The most common adverse reactions (≥5%) are peripheral edema, hypotension (including orthostatic hypotension), hyperkalemia, dizziness, and anemia.

Drug Interactions

- Renin-Angiotensin System (RAS) Inhibitors and ERAs: Do not coadminister FILSPARI with ARBs, ERAs, or aliskiren due to increased risks of hypotension, syncope, hyperkalemia, and changes in renal function (including acute renal failure).
- Strong and Moderate CYP3A Inhibitors: Avoid concomitant use of FILSPARI with strong CYP3A inhibitors. If a strong CYP3A inhibitor cannot be avoided, interrupt FILSPARI treatment. When resuming treatment with FILSPARI, consider dose titration. Monitor blood pressure, serum potassium, edema, and kidney function regularly when used concomitantly with moderate CYP3A inhibitors. Concomitant use with a strong CYP3A inhibitor increases sparsentan exposure which may increase the risk of FILSPARI adverse reactions.
- Strong CYP3A Inducers: Avoid concomitant use with a strong CYP3A inducer. Concomitant use with a strong CYP3A inducer decreases sparsentan exposure which may reduce FILSPARI efficacy.
- Non-Steroidal Anti-Inflammatory Agents (NSAIDs), Including Selective Cyclooxygenase-2 (COX-2) Inhibitors: Monitor for signs of worsening renal function with concomitant use with NSAIDs (including selective COX-2 inhibitors). In patients with volume depletion (including those on diuretic therapy) or with impaired kidney function, concomitant use of NSAIDs (including selective COX-2 inhibitors) with drugs that antagonize the angiotensin II receptor may result in deterioration of kidney function, including possible kidney failure. These effects are usually reversible.
- CYP2B6, 2C9, and 2C19 Substrates: Monitor for efficacy of concurrently administered CYP2B6, 2C9, and 2C19 substrates and consider dosage adjustment in accordance with the Prescribing Information. Sparsentan is a weak inducer of CYP2B6 and 2C9, and a moderate inducer of 2C19. Sparsentan decreases exposure of these substrates, which may reduce efficacy related to these substrates.
- P-gp Substrates: Monitor for adverse reactions and consider dose reduction of P-gp substrates with narrow therapeutic indices when co-administered with FILSPARI. FILSPARI is a weak P-gp inhibitor and may increase plasma concentrations of P-gp substrate drugs.
- Agents Increasing Serum Potassium: Monitor serum potassium frequently in patients treated with FILSPARI and other agents that increase serum potassium. 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.

Please see the full Prescribing Information, including BOXED WARNING, for additional Important Safety Information.

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 “on-track,” “positioned,” “look forward to,” “will,” “would,” “may,” “might,” “believes,” “anticipates,” “plans,” “expects,” “intends,” “potential,” or similar expressions. In addition, expressions of strategies, intentions or plans are also forward-looking statements. Such forward-looking statements include, but are not limited to, references to: statements relating to the clinical studies, models and data described herein; and statements regarding the sustained impact FILSPARI can have for people living with FSGS without nephrotic syndrome and the evidence supporting FILSPARI’s role as foundational care in FSGS. 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 related to the studies and data described herein. The Company also faces risks and uncertainties related to its business and finances in general, the success of its commercial products, risks and uncertainties associated with its preclinical and clinical stage pipeline, risks and uncertainties associated with the regulatory review and approval process, risks and uncertainties 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. Specifically, the Company faces risks associated with the commercial launch of FILSPARI in FSGS and the ongoing commercialization in IgAN, the timing and potential outcome of its and its partners’ clinical studies, market acceptance of its commercial products including efficacy, safety, price, reimbursement, and benefit over competing therapies, risks related to the challenges of manufacturing scale-up, risks associated with the successful development and execution of commercial strategies for such products, including FILSPARI, and risks and uncertainties related to the current administration, including but not limited to risks and uncertainties related to tariffs and the funding, staffing and prioritization of resources at government agencies including the FDA. 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, including potential ANDA filings or patent challenges, 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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