



## Traverse Therapeutics to Present Abstracts at American Society of Nephrology (ASN) Kidney Week 2025

2025-10-17

Late-breaking poster from DUPLEX Study shows more FILSPARI® (sparsentan)-treated patients achieved proteinuria below 0.7 g/g compared with irbesartan, correlating with reduced kidney failure risk in FSGS

Data presentations highlight biomarker and cardiovascular safety data from SPARTAN Study of FILSPARI in patients with IgAN

SAN DIEGO--(BUSINESS WIRE)-- Traverse Therapeutics, Inc. (Nasdaq: TVTX) today announced that the Company will present 11 abstracts, including a late-breaking poster, at the upcoming American Society of Nephrology (ASN) Kidney Week 2025 in Houston, TX, November 6-9.

In focal segmental glomerulosclerosis (FSGS), the Company will present:

- A late-breaking analysis from the DUPLEX Study demonstrating that patients treated with FILSPARI® (sparsentan) were more likely to reach proteinuria levels under 0.7 g/g when compared with the maximum labeled dose of irbesartan, and achievement of this threshold correlated with reduced risk of kidney failure irrespective of treatment arm.
- An analysis evaluating the relationship between the magnitude of proteinuria reduction at two years with FILSPARI compared to the maximum labeled dose of irbesartan and long-term kidney outcomes in a subset of DUPLEX aligned participants in the UK National Registry of Rare Kidney Diseases (RaDaR).
- Data showing that FILSPARI-treated children and FILSPARI-treated individuals with COL4A3-5 mutations achieved rapid and sustained reductions in proteinuria compared with the maximum labeled dose of irbesartan in the DUPLEX Study.

Presentations in IgA nephropathy (IgAN) will include:

- New data from SPARTAN demonstrating that among RASI-naïve patients, FILSPARI induced anti-inflammatory and anti-fibrotic effects, regardless of disease severity, as well as favorable effects on cardiovascular risk factors.
- Real-world data reinforcing FILSPARI's ability to consistently lower proteinuria and preserve kidney function.
- Two new analyses from PROTECT showing that, irrespective of time from diagnosis or severity of disease based on kidney biopsy, FILSPARI demonstrated consistent, superior and sustained proteinuria reduction compared to maximum dose irbesartan.

"We look forward to presenting new clinical and real-world data further reinforcing FILSPARI as a foundational treatment for people living with IgA nephropathy and as a potential treatment for FSGS," said Julia Inrig, M.D., chief medical officer of Traverse Therapeutics. "Analyses from the DUPLEX Study in FSGS consistently show that FILSPARI achieves clinically meaningful reductions in proteinuria across the FSGS population, including children and genetically mutated forms of the disease. These data support FILSPARI's potential to preserve kidney function and are in alignment with findings from the PARASOL Project, which examined proteinuria as a key predictor of long-term outcomes in FSGS. In IgAN, biomarker data from the SPARTAN Study highlight FILSPARI's potential disease-modifying effect, underscoring its position as foundational therapy and highlighting the importance of early intervention."

More information on Traverse's presence at ASN can be found [here](#).

### Late-Breaking Poster Presentation

#### **Patients with Focal Segmental Glomerulosclerosis (FSGS) Reach Proteinuria <0.7 g/g More Often with Sparsentan vs. Irbesartan in DUPLEX: Implications for Kidney Failure Risk**

Poster: TH-PO1219

Session: Late-Breaking Science Posters

Exhibit Hall; November 6, 2025, 10:00 a.m.–12:00 p.m. CT

### Oral Presentations

#### **Estimating the Benefits of Proteinuria Reduction on Kidney Failure Risk in the DUPLEX Study Using an Aligned FSGS Cohort from the UK RaDaR Registry**

Oral: FR-OR031

Oral Abstract Session: Glomerular Disease Outcomes: Measuring What Matters  
Room 310A; November 7, 2025, 5:00–5:10 p.m. CT

**Impact of Histology on Efficacy of Sparsentan Therapy in IgA Nephropathy (IgAN): Central Biopsy Review of Patients in the PROTECT Trial**  
Oral: FR-OR032

Oral Abstract Session: Glomerular Disease Outcomes: Measuring What Matters  
Room 310A; November 7, 2025, 5:10–5:20 p.m. CT

**Outcomes of Renal Transplantation in Primary Glomerulonephritis Mapped to Post-Transplant Proteinuria in the UK RaDaR Registry**  
Oral: SA-OR080

Oral Abstract Session: Transplantation: Clinical Controversies in Donation, Access, Monitoring, and Treatment  
Room 370A; November 8, 2025, 5:40–5:50 p.m. CT

#### Poster Presentations

**Sparsentan vs. Irbesartan in Pediatric Patients with Focal Segmental Glomerulosclerosis (FSGS) in the Phase 3 DUPLEX Trial**

Poster: FR-PO0746

Poster Session: Pediatric Nephrology: CKD, ESKD, and Glomerular Diseases

Exhibit Hall; November 7, 2025, 10:00 a.m.–12:00 p.m. CT

**Sparsentan in Participants with Focal Segmental Glomerulosclerosis (FSGS) and Collagen Type IV Alpha 3-5 Chain (COL4A3-5) Variants**

Poster: FR-PO0839

Poster Session: Glomerular Clinical Trials: From Data to Impact

Exhibit Hall; November 7, 2025, 10:00 a.m.–12:00 p.m. CT

**Efficacy of Sparsentan vs. Irbesartan in Patients with IgA Nephropathy (IgAN)  $\leq 12$  mo vs.  $>12$  mo From Kidney Biopsy**

Poster: FR-PO0807

Poster Session: Glomerular Clinical Trials: From Data to Impact

Exhibit Hall; November 7, 2025, 10:00 a.m.–12:00 p.m. CT

**The Effect of Sparsentan on Proteinuria and Urinary Inflammatory and Profibrotic Biomarkers by Baseline Proteinuria Strata in SPARTAN Study Participants with IgA Nephropathy (IgAN)**

Poster: FR-PO0809

Poster Session: Glomerular Clinical Trials: From Data to Impact

Exhibit Hall; November 7, 2025, 10:00 a.m.–12:00 p.m. CT

**Evaluation of Cardiovascular Risk Factors, Structure and Function in an Interim Analysis of the SPARTAN Study: Sparsentan as First-Line Treatment of Incident Patients with IgA Nephropathy (IgAN)**

Poster: FR-PO0810

Poster Session: Glomerular Clinical Trials: From Data to Impact

Exhibit Hall; November 7, 2025, 10:00 a.m.–12:00 p.m. CT

**Proteinuria Reductions with Sparsentan Combined with Sodium-Glucose Cotransporter-2 Inhibitors (SGLT2is) in Adults with IgA Nephropathy (IgAN) at a Single Site**

Poster: SA-PO0888

Poster Session: Glomerular Case Reports: ANCA, IgA, IgG, and More

Exhibit Hall; November 8, 2025, 10:00 a.m.–12:00 p.m. CT

**Real-World Data on Low Proteinuria with Sparsentan in Patients with IgA Nephropathy (IgAN): A Case Series**

Poster: SA-PO0889

Poster Session: Glomerular Case Reports: ANCA, IgA, IgG, and More

Exhibit Hall; November 8, 2025, 10:00 a.m.–12:00 p.m. CT

#### **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 Focal Segmental Glomerulosclerosis**

Focal segmental glomerulosclerosis (FSGS) is a rare proteinuric kidney disorder in both children and adults that is estimated to affect more than 40,000 patients in the U.S. with similar prevalence in Europe. The disorder is 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. Other common symptoms include swelling in parts of the body, known as edema, as well as low blood albumin levels, abnormal lipid profiles and hypertension. Sparsentan is not approved for use in FSGS. There is currently no approved pharmacologic indicated for the treatment of FSGS.

## About Travele Therapeutics

At Travele 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 [travele.com](http://travele.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.

## 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](http://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. When pregnancy is detected, discontinue FILSPARI as soon as possible.

- **Hypotension:** Hypotension has been observed in patients treated with ARBs and ERAs. 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.

### Most common adverse reactions

The most common adverse reactions (≥5%) are hyperkalemia, hypotension (including orthostatic hypotension), peripheral edema, dizziness, anemia, and acute kidney injury.

### 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.
- **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. Sparsentan exhibits pH-dependent solubility. Antacids or acid reducing agents may decrease 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.
- **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 decreases exposure of these substrates, which may reduce efficacy related to these substrates.
- **P-gp and BCRP Substrates:** Avoid concomitant use of sensitive substrates of P-gp and BCRP with FILSPARI. Sparsentan may increase exposure of these transporter substrates which may increase the risk of adverse reactions related to these substrates.
- **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 and data described herein; statements and expectations regarding FILSPARI’s role as a foundational treatment in IgAN, its potential disease-modifying effect, and the potential to preserve kidney function; statements regarding FILSPARI as a potential treatment for FSGS; and statements related to the estimated sizes of patient populations. 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 Company's sNDA for FILSPARI in FSGS, including the timing and outcome thereof. There is no guarantee that the FDA will grant approval of FILSPARI for FSGS on the anticipated timeline, or at all. 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 ongoing commercial launch of FILSPARI 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 new 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, 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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