



## CSL Vifor and Traverre Therapeutics Recognize Updated KDIGO Clinical Practice Guidelines for IgA Nephropathy

2025-09-26

FILSPARI® (sparsentan) suggested for IgA Nephropathy patients who are at risk of progressive kidney function loss

SAN DIEGO & ST. GALLEN, Switzerland--(BUSINESS WIRE)-- CSL Vifor and Traverre Therapeutics, Inc., (NASDAQ: TVTX) support the recent publication of the updated clinical practice guidelines for the treatment of IgA Nephropathy (IgAN), Kidney Disease: Improving Global Outcomes (KDIGO) 2025 clinical practice guideline for the management of IgA Nephropathy and Immunoglobulin A vasculitis. The updated guidelines define diagnostic criteria, treatment goals and treatment approaches, aiming for progress for people living with IgAN and the clinicians who treat them.

The 2025 update defines remission of proteinuria (<0.5 g/day, or ideally at <0.3 g/day) and slowing eGFR decline as key treatment goals. To achieve these goals, the guidelines recommend a treatment approach with therapies simultaneously targeting IgAN-induced nephron loss and IgA-formation.

Within the guidelines it is mentioned that treatment with FILSPARI® (sparsentan), the only Dual Endothelin Angiotensin Receptor Antagonist (DEARA), may be an appropriate first-line approach to manage the responses of IgAN-induced nephron loss in contrast to the RASi-first approach. The guidelines also highlight FILSPARI as the only therapy with proven efficacy compared to optimized RASi in clinical trials — with more patients enrolled in PROTECT than in all prior RASi trials combined.

"The updated KDIGO guidance represents an important step forward for the IgA Nephropathy community," said Prof. Dr. med. Jürgen Floege, Senior Professor, Div. Nephrology and Clinical Immunology at the University Hospital, RWTH Aachen, Germany. "For patients and clinicians, this provides greater clarity and confidence in navigating treatment decisions, with the ultimate goal of improving long-term kidney outcomes."

"The updated KDIGO guidelines mark an important milestone for the IgA nephropathy community, reflecting advances in disease understanding, more sophisticated risk assessment and therapies," said Julia Inrig, M.D., chief medical officer of Traverre Therapeutics. "The placement of FILSPARI underscores the strong clinical evidence supporting its role as a foundational treatment and offers clinicians with clear, evidence-based guidance to improve patient care."

"The new IgA Nephropathy management recommendations provide important guidance for clinicians treating this rare disease. The inclusion of FILSPARI in the KDIGO guidelines is a reflection of its benefit-risk profile and reinforces its role in helping eligible patients reduce proteinuria and slow kidney function loss, while being generally well-tolerated," said Dr. Achim Oberfell, Global Medical Head Nephrology Portfolio CSL Vifor.

The now published KDIGO clinical practice guidelines represent a focused update of Chapter 2: IgA Nephropathy/IgA Vasculitis from the KDIGO 2021 Clinical Practice Guideline for the Management of Glomerular Diseases. It sets out to provide a comprehensive and evidence-based framework for healthcare professionals to diagnose, treat, and manage these two types of glomerular diseases. The full guidance was presented at the International Symposium of IgA Nephropathy in September 2025 and will be published as a supplement to the **Official Journal of the International Society for Nephrology**.

FILSPARI is a non-immunosuppressive therapy for the treatment of IgA Nephropathy approved in the United States (U.S.) and Europe, and in addition to the U.S. has been launched in Germany, Austria, Switzerland, Luxembourg and UK.

### About the PROTECT Study

The PROTECT Study is one of the largest interventional studies to date in IgA nephropathy (IgAN) and the only Phase 3 head-to-head trial in this rare kidney disease. It is a global, randomized, multicenter, double-blind, parallel-arm, active-controlled clinical trial evaluating the safety and efficacy of 400 mg of FILSPARI (sparsentan), compared to 300 mg of irbesartan, in 404 patients ages 18 years and up with IgAN and persistent proteinuria despite receiving at least 50% of max label dose and maximally tolerated ACE or ARB therapy.

The trial met the pre-specified primary endpoint which showed that after 36 weeks patients receiving FILSPARI (n=202) achieved a mean reduction in proteinuria from baseline of 49.8%, compared to a mean reduction in proteinuria from baseline of 15.1% for irbesartan-treated patients (n=202, p<0.0001). In the final analysis conducted after two years, FILSPARI reduced the rate of decline in kidney function from baseline to Week 110 compared to irbesartan. Treatment emergent adverse events were well-balanced between FILSPARI and irbesartan, except for dizziness and hypotension.

### 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 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).

#### About CSL Vifor

**CSL Vifor** is a global partner of choice for pharmaceuticals and innovative, leading therapies in iron deficiency and nephrology. We specialize in strategic global partnering, in-licensing and developing, manufacturing and marketing pharmaceutical products for precision healthcare, aiming to help patients around the world lead better, healthier lives. Headquartered in St. Gallen, Switzerland, CSL Vifor also includes the joint company Vifor Fresenius Medical Care Renal Pharma (with Fresenius Medical Care). The parent company, **CSL** (ASX:CSL; USOTC:CSLLY), headquartered in Melbourne, Australia, employs 29,000+ people and delivers its lifesaving therapies to people in more than 100 countries.

For more information about CSL Vifor, visit [CSL.com](http://CSL.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 ( $>3\times$  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 ( $\geq 5\%$ ) 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 future progress for people living with IgAN and the clinicians who treat them; statements and expectations regarding the evolving treatment landscape and treatment approaches; statements and expectations regarding long-term kidney outcomes; statements and expectations regarding FILSPARI's role as a foundational treatment and improvements in patient care; 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.

Media:  
888-969-7879  
**mediarelations@travere.com**

Investors:  
888-969-7879  
**IR@travere.com**

Source: Travere Therapeutics, Inc.