

Full FDA Approval of FILSPARI® (sparsentan), the Only Non-Immunosuppressive Treatment that Significantly Slows Kidney Function Decline in IgA Nephropathy

September 5, 2024



## **Forward-Looking Statements**

This presentation contains forward-looking statements, including but not limited to statements about: continued progress with the FILSPARI launch; the potential for FILSPARI to become a foundational treatment in IgAN; statements relating to the KDIGO guidelines; statements regarding potential future milestone and royalty payments; statements regarding estimates of potential addressable market sizes; and statements regarding financial metrics and expectations related thereto. These forward-looking statements may be accompanied by such words as "anticipate," "believe," "estimate," "expect," "forecast," "intend," "may," "plan," "project," "schedule," "target," "will," and other words and terms of similar meaning. You should not place undue reliance on these statements.

These statements involve risks and uncertainties that could cause actual results to differ materially from those reflected in such statements. 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, as well as risks and uncertainties associated with our business and finances in general, success of our commercial products, and risks and uncertainties associated with our preclinical and clinical stage pipeline. Specifically, we face risks associated with the ongoing commercial launch of FILSPARI, market acceptance of our commercial products including efficacy, safety, price, reimbursement, and benefit over competing therapies, as well as risks associated with the successful development and execution of commercial strategies for such products, including FILSPARI. The risks and uncertainties we face with respect to our preclinical and clinical stage pipeline include risk that our clinical candidates will not be found to be safe or effective and that current or anticipated future clinical trials will not proceed as planned. We also face the risk that we will not receive some or all of the potential future milestone and/or royalty payments described herein, the risk that our cash runway might not last as long as currently anticipated and the risk that we will be unable to raise additional funding that may be required to complete development of any or all of our product candidates, including as a result of macroeconomic conditions; risks relating to our 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 our products, and technological changes that may limit demand for our products. We also face 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, and the other risks and uncertainties that are described in the Risk Factors section of our most recent annual or quarterly report and in other reports we have filed with the SEC.

These statements are based on our current beliefs and expectations and speak only as of the date of this presentation. We do not undertake any obligation to publicly update any forward-looking statements.



### Full FDA Approval and Draft KDIGO Guidelines Pave the Way for FILSPARI as a Foundational Treatment in IgAN



**Expanded indication** and removal of proteinuria threshold



**Broadens** addressable patient population and enables earlier treatment



**Statistically significant benefit** on kidney function with accrual of benefit over two years



Positions FILSPARI as foundational in preserving kidney function in IgAN patients



**Two-year safety data** with no new safety signals, comparable to irbesartan

Updated draft **KDIGO** guidelines released for public comment



treatment FILSPARI in guidelines; lower proteinuria target and **earlier** 

combination use in simultaneous

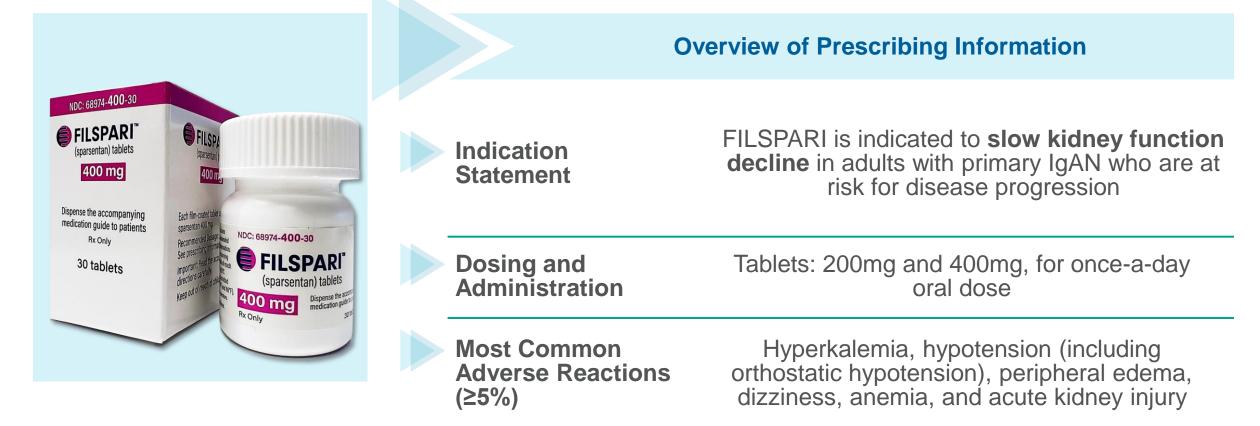
Only non-immunosuppressive

treatment approved; ability for

treatment recommended



### The Only Non-Immunosuppressive Treatment Proven to Significantly Slow Kidney Function Decline in IgA Nephropathy



For full prescribing information including boxed warning, visit filspari.com



### IgA Nephropathy (IgAN)

### is a Serious Unmet Rare Kidney Disease (RKD)

IgAN is the most prevalent primary glomerulonephritis worldwide<sup>1</sup> Often uncontrolled, progressive IgAN is a major cause of kidney failure<sup>2,3</sup>

>70k

Addressable IgAN patients for FILSPARI in the U.S.<sup>4</sup> ~11 years

median time to kidney failure in high-risk adult patients<sup>5</sup>

25-39 peak incidence age of IgAN<sup>6</sup> 30-40%

of transplants fail due to disease recurrence<sup>7</sup>



<sup>1</sup>Le W, et al. *Nephrol Dial Transplant* 2012; 27:1479–1485; <sup>2</sup>McGrogan A, et al. *Nephrol Dial Transplant*. 2011;26:414-430; <sup>3</sup>Nasri H, et al. *J Nephrol*. 2015; 4:1-5; <sup>4</sup>Source: independent market research, data on file <sup>5</sup>Barratt J, et al. "Natural History of IgA Nephropathy: Analysis of a UK National RaDaR IgA Nephropathy Cohort." ASN 2021; Poster presentation (Abstract P01577); , <sup>6</sup>Nair R & Walker PD. *Kidney Int* 2006; 69:1455–1458; <sup>7</sup>Uffing A et al. *Clin J Am Soc Nephrol*. 2021 Aug;16(8):1247-1255.

### **Draft KDIGO Guidelines: The IgAN Treatment Paradigm is Evolving** Earlier Treatment, Lower Proteinuria Targets and Simultaneous Therapy



The only validated early biomarker to help guide clinical decision-making is **proteinuria**, which should be maintained at <0.5 g/d, preferably <0.3 g/d. Earlier **diagnosis** and earlier **treatment** is recommended (*proteinuria at*  $\geq$ 0.5 g/d).



Simultaneous combination therapy recommended to target both IgAN-induced nephron loss and immune complex formation.



FILSPARI is included in the treatment algorithm as the **only drug to have shown efficacy beyond maximum-labeled dose RASi**; recommend using FILSPARI to target kidney injury, thereby positioning FILSPARI as foundational.

FILSPARI is the only oral non-immunosuppressive, long-term treatment positioned to become foundational in preserving kidney function in IgAN patients\*

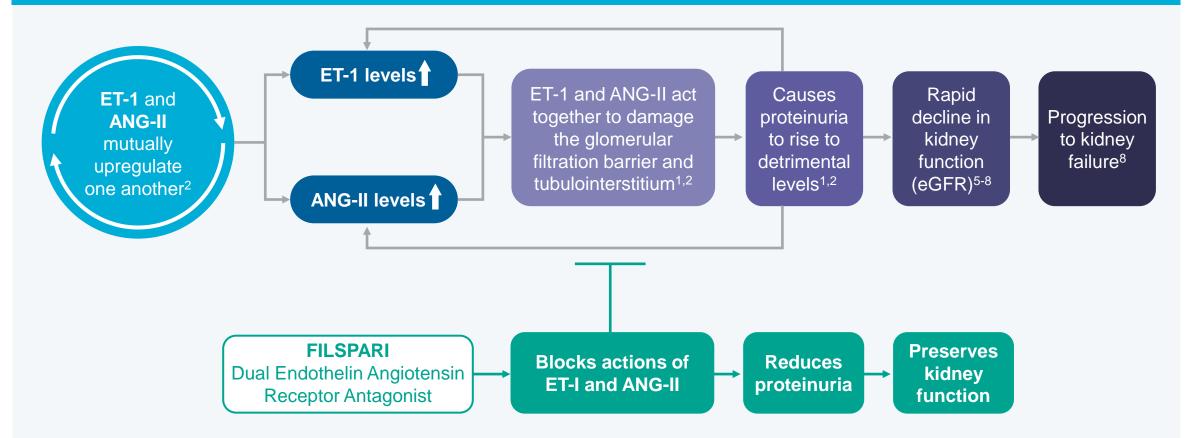
Abbreviations: KDIGO: Kidney Disease Improving Global Outcomes, RASi: renin-angiotensin system inhibitor.

Source: KDIGO 2024 Clinical Practice Guideline for the Management of Immunoglobulin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV), public review draft, 8/30/2024.

\* Indicated to slow kidney function decline in adults with primary IgAN who are at risk for disease progression.

### IgAN Induced Nephron Loss is Driven by Two Critical Pathways -Endothelin-1 (ET-1) and Angiotensin II (ANG-II)<sup>1-3</sup>

Galactose-deficient, IgA-containing immune complexes are deposited in the mesangium<sup>4</sup>



Abbreviations: Ang II: angiotensin II, ET-1: endothelin-1; IgAN, Immunoglobulin A Nephropathy.

Figure adapted from Lai K, et al. Nat Rev Dis Primers. 2016;16001

<sup>1</sup> Komers R, et al. Am J Physiol Regul Integr Comp Physiol. 2016;310(10):R877-R884. <sup>2</sup> Kohan DE, et al. Kidney Int. 2014;86(5):896-904. <sup>3</sup> Raina R, et al. Kidney Dis. 2020;6(1):22-34. <sup>4</sup> Ebefors K, Bergwall L, Nyström J. Front Med (Lausanne). 2022;8:740527. doi:10.3389/fmed.2021.740527. <sup>5</sup> Zoja C, Morigi M, Figliuzzi M, et al. Am J Kidney Dis. 1995;26(6):934-941. <sup>6</sup> Morigi M, Buelli S, Angioletti S, et al. Am J Pathol. 2005;166(5):1309-1320. <sup>7</sup> Tejera N, Gómez-Garre D, Lázaro A, et al. Am J Pathol. 2004;164(5):1817-1826. <sup>8</sup> Lai K, et al. Nat Rev Dis Primers. 2016;2:160001.



### The Only Head-to-Head, Active-Controlled Trial in IgAN to Date: Phase 3 PROTECT Study

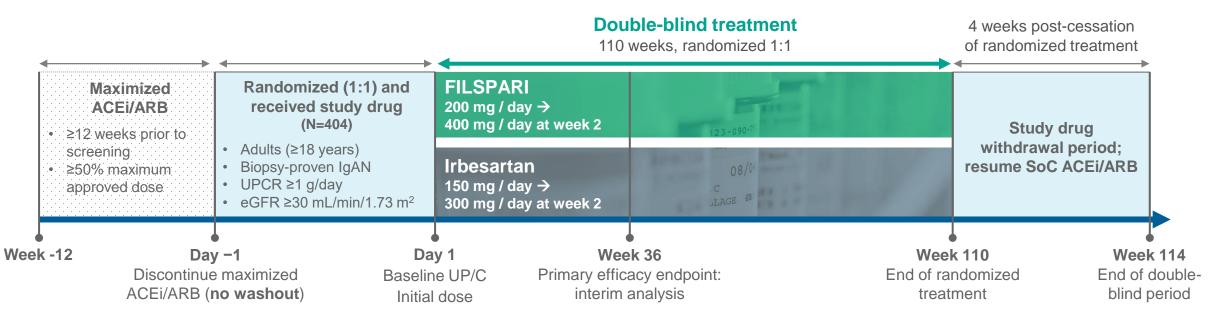


Test the efficacy and safety of FILSPARI vs. active control (irbesartan) in a global, multicenter, double-blind, randomized study of 404 patients with IgAN, ages 18+

#### Endpoints



- Primary efficacy endpoint: change in UPCR from baseline to week 36
- Key secondary efficacy endpoint: eGFR slope: total (day 1 - week 110) and chronic (week 6 - 110)



Abbreviations: UPCR: urine protein/creatinine ratio, g/day: grams per day, eGFR: estimated glomerular filtration rate, ACEs: Angiotensin converting enzyme inhibitors, ARBs: angiotensin receptor blockers, SoC: standard of care \* ClinicalTrials.gov ID: NCT03762850

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### Active Control is Not Placebo: Matching-Adjusted Indirect Comparisons Show Irbesartan Significantly Outperformed Standard of Care in Other Studies

Rate of kidney function decline: maximally dosed irbesartan vs standard of care in real-world setting



Maximally tolerated irbesartan was associated with slower decline in kidney function vs real-world SoC treatment in RaDaR and physician defined, optimized SoC in NefIgArd\*

Source: Cheung et al, NKF 2024, Matching-Adjusted Indirect Comparisons of eGFR slopes in the PROTECT study with UK RaDaR IgA Nephropathy population and the control arm of NeflgArd. Abbreviations: eGFR: estimated glomerular filtration rate; SE: standard error; SoC: standard of care, RaDaR: The UK National Registry of Rare Kidney Diseases.

\* NefIgArd is a randomized, double-blind, placebo-controlled clinical trial recruiting a total of 360 patients across 155 nephrology clinics in 20 countries.

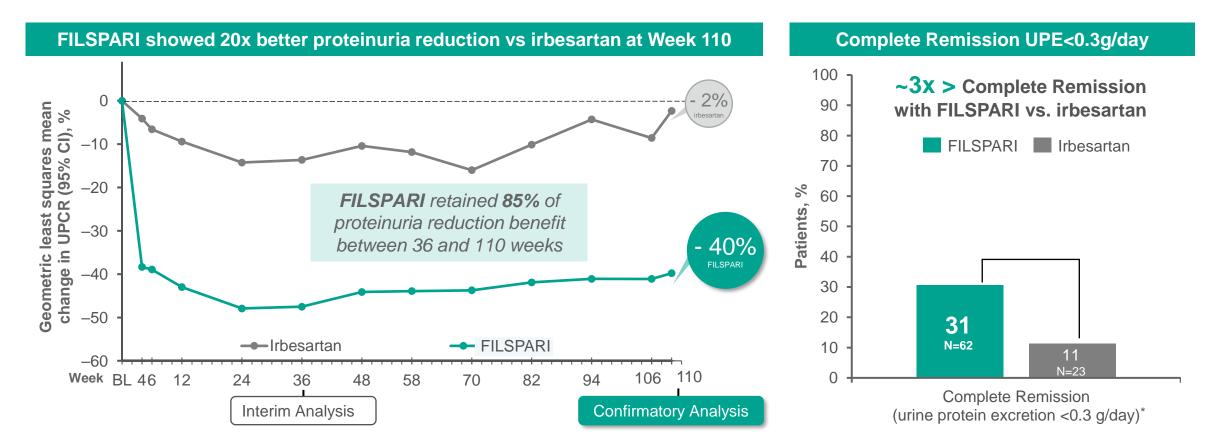


Rate of kidney function decline: maximally dosed

irbesartan vs standard of care in clinical trial setting

# FILSPARI Showed Superior Proteinuria Reduction in a Phase 3 Study vs. Active Control, Sustained Over Two Years

FILSPARI demonstrated a statistically significant reduction in proteinuria of ~40% after 110 weeks of treatment



Abbreviations: UP/C: urine protein/creatinine ratio, UPCR: urine protein/creatinine ratio, BL: baseline, UPE: urinary protein excretion.

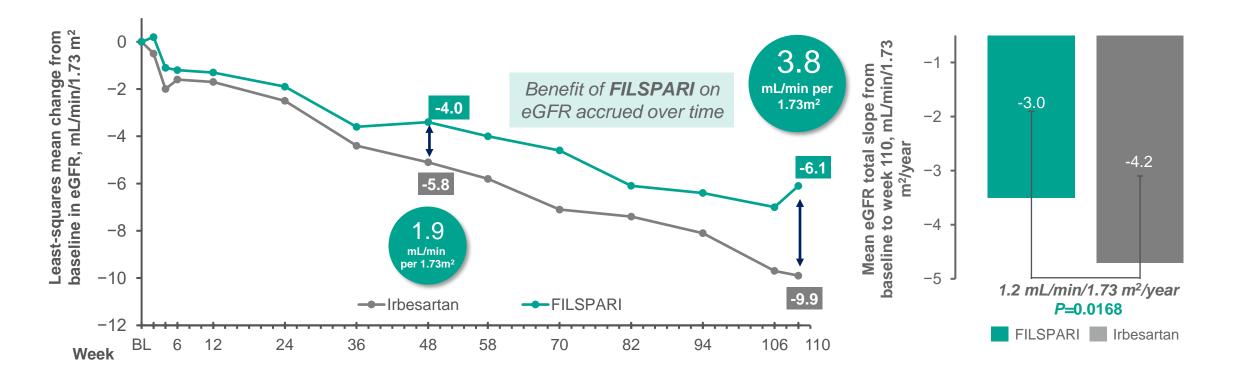
MMRM analysis including on-treatment data through week 110 with multiple imputation.

\* Achieved complete remission at any time while on study medication during the double-blind period.

### FILSPARI Demonstrated Significant Long-Term Kidney Function Preservation in IgAN Patients

Long-term FILSPARI treatment showed significant preservation of kidney function that accrued over time

Annual rate of decline in kidney function from baseline to Week 110

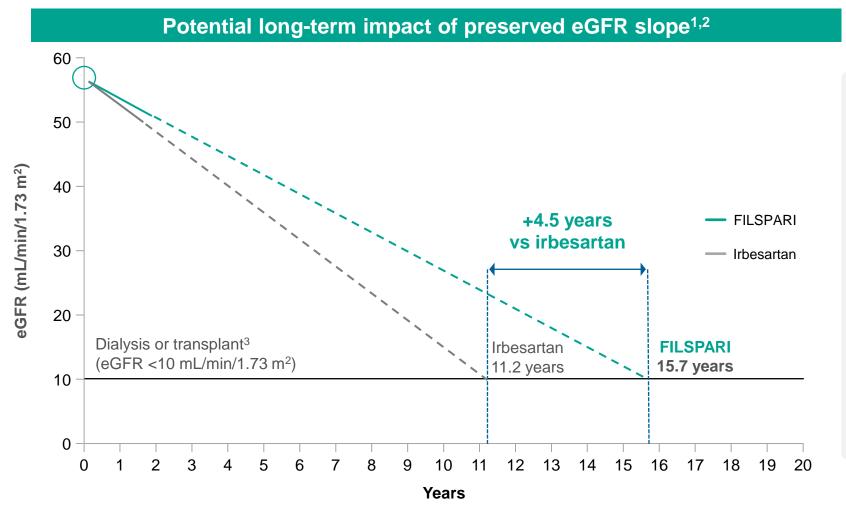


\* The analysis includes eGFR data during the double-blind period up to Week 110 regardless of treatment discontinuation or immunosuppressive therapy initiation.

\*\* LS Means and 95% CI from a random coefficient analysis including available on-treatment eGFR data through week 110 with multiple imputation; mL/min/1.73m<sup>2</sup> per year



### Treatment with FILSPARI May Potentially Delay Dialysis or Transplant



Based on extrapolation of eGFR slope data from PROTECT,

### FILSPARI may potentially delay dialysis or transplant by 4.5 years

when compared to maximum-labeled dose irbesartan<sup>1-3</sup>

Abbreviations: eGFR: estimated glomerular filtration rate, ESKD: end-stage kidney disease.

<sup>1</sup> FILSPARI Prescribing Information. San Diego, CA: Travere Therapeutics, Inc.

<sup>2</sup> Data on file, Travere Therapeutics, Inc.

<sup>3</sup> United States Renal Data System. 2023 USRDS Annual Data Report: Epidemiology of kidney disease in the United States. NIH, NIDDK, Bethesda, MD, 2023.



### Launch Fundamentals Positioning FILSPARI To Potentially Become the Foundational Treatment in IgAN

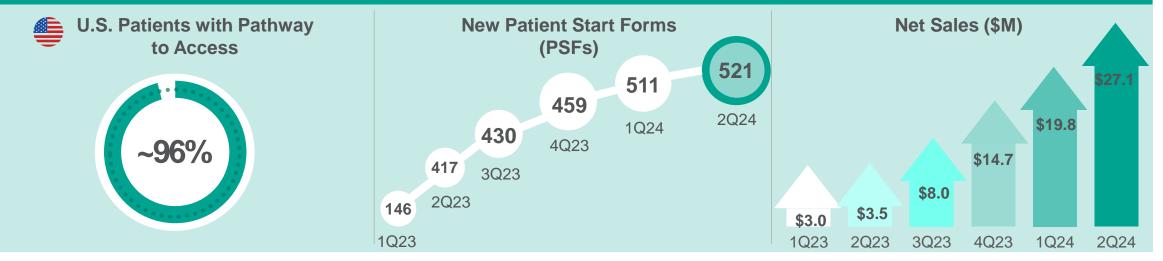
Cross-functional team of 80+ active in the field and executing on our commercial launch

#### Takeaways from the field...

FILSPARI is well established in payer plans and formularies, reflected in payer approval claims

Consistently growing demand quarter-over-quarter since launch On track to outperform benchmark nephrology launches in year two

### FILSPARI launch metrics reflect strong demand and broadening reimbursement: As of June 30, 2024





## Full FDA Approval Has the Potential to Significantly Increase the Number of Patients Benefiting from FILSPARI

Broader label allows for greater number of patients to benefit from FILSPARI

Draft KDIGO guidelines<sup>2</sup> to drive earlier intervention, strengthen FILSPARI's foundational positioning

Opportunity to broaden and deepen FILSPARI's prescriber base

Continue to engage payers to further strengthen coverage / access

Addressable IgAN Patients for FILSPARI in the U.S.<sup>1</sup>

>70k

Evolving treatment landscape and IgAN awareness to support further growth in addressable patient population

<sup>1</sup> Source: independent market research, data on file

<sup>2</sup> KDIGO 2024 Clinical Practice Guideline for the Management of Immunoglobulin A Nephropathy (IgAN) and Immunoglobulin A Vasculitis (IgAV), public review draft, 8/30/2024. © 2024 Travere Therapeutics, Inc.



### Paving a Path to Global Access for FILSPARI with Established Commercial Partners



## Travere eligible to receive up to \$910 million in potential milestone payments<sup>\*\*</sup> + tiered double-digit royalties on global net sales of FILSPARI

Abbreviations: EC: European Commission, CMA: conditional marketing authorization.

<sup>1</sup> Source: independent market research, data on file.

\* License to CSL Vifor also covers other territories including the United Kingdom, Switzerland, Australia, and New Zealand, with potential to expand, \*\* Potential milestone payments include achievements for both IgAN and FSGS indications.





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