

**NEWS RELEASE** 

# Ligand Partner Travere Therapeutics Receives Full FDA Approval for FILSPARI® (sparsentan), the Only Non-Immunosuppressive Treatment that Significantly Slows Kidney Function Decline in IgA Nephropathy

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FDA approves expanded indication making FILSPARI available to patients with IgA nephropathy (IgAN) at risk of progression; updated label includes data showing long-term durable benefit on proteinuria and kidney function preservation that accrued over two years

Conversion to full approval based on results from the PROTECT Study, where FILSPARI delivered superior long-term kidney function preservation compared to the active comparator irbesartan in the only Phase 3 head-to-head trial conducted in IgAN

As an oral, non-immunosuppressive and dual acting, once-daily medicine with superior long-term results vs. irbesartan, FILSPARI has the potential to become foundational care in IgAN

Ligand is entitled to a 9% royalty on worldwide net sales of FILSPARI

JUPITER, Fla.--(BUSINESS WIRE)-- Ligand Pharmaceuticals Incorporated (Nasdaq: LGND) today announced that its partner Travere Therapeutics, Inc. (Nasdaq: TVTX) has received full approval from the U.S. Food and Drug Administration (FDA) for FILSPARI® (sparsentan) to slow kidney function decline in adults with primary IgAN who are at risk of disease progression. Ligand is entitled to milestone payments and a 9%

royalty on worldwide net sales of FILSPARI.

FILSPARI was granted accelerated approval in February 2023 based on the surrogate marker of proteinuria. Full approval is based on positive long-term confirmatory results from the PROTECT Study demonstrating that FILSPARI significantly slowed kidney function decline over two years compared to irbesartan.

"This announcement is a momentous milestone for Travere and a positive development for people living with this rare kidney disease," said Todd Davis, CEO of Ligand. "We are encouraged by Travere's progress to drive adoption of FILSPARI in the U.S. and look forward to the European launch over the coming months. FILSPARI is a core part of Ligand's commercial-stage royalty portfolio, and we believe this treatment will be a significant driver of revenue for us over the next several years."

FILSPARI is the only oral, once-daily, non-immunosuppressive medication that directly targets glomerular injury in the kidney by blocking two critical pathways of IgAN disease progression (endothelin-1 and angiotensin II).

The two-year efficacy data contained in the FDA-approved label is a modified intention to treat (ITT) analysis, and as preferred by the FDA, evaluates data from all patients regardless of treatment discontinuation. In the final analysis of the 404 randomized patients, FILSPARI significantly reduced the rate of decline in kidney function from baseline to Week 110 compared to irbesartan. In the ITT analysis included in the label, the mean eGFR slope from baseline to Week 110 was -3.0 mL/min/1.73 m2/year for FILSPARI and -4.2 mL/min/1.73 m2/year for irbesartan, corresponding to a statistically significant treatment effect of 1.2 mL/min/1.73 m2/year (p=0.0168). The positive treatment effects on proteinuria compared to the active control irbesartan that were observed at Week 36 were durable out to the two-year measurement period. Additional results from the PROTECT Study demonstrated the benefit of FILSPARI on absolute eGFR accrued over time and by Week 110 resulted in a 3.8 mL/min/1.73 m2 difference in the mean change from baseline between FILSPARI and irbesartan.

Results from the PROTECT Study showed that FILSPARI was well tolerated with a clearly defined safety profile that has been consistent across all clinical trials conducted to date. Following engagement with the FDA, the Company expects to submit an sNDA for a potential modification to the liver-monitoring REMS.

# 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 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 primary efficacy endpoint for the interim analysis was the change from baseline in urine protein/creatinine ratio at Week 36. The key secondary efficacy endpoint for the final analysis was the rate of change in eGFR over a 110-week period following initiation of randomized therapy.

The trial met the pre-specified primary endpoint which showed that after 36 weeks patients receiving FILSPARI 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 (p<0.0001).

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Patients who completed the PROTECT double-blind portion of the study on treatment were eligible to participate in the open-label extension of the trial.

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## **About Ligand Pharmaceuticals**

Ligand is a biopharmaceutical company enabling scientific advancement through supporting the clinical development of high-value medicines. Ligand does this by providing financing, licensing our technologies or both. Its business model seeks to generate value for stockholders by creating a diversified portfolio of biopharmaceutical product revenue streams that are supported by an efficient and low corporate cost structure. Ligand's goal is to offer investors an opportunity to participate in the promise of the biotech industry in a profitable and diversified manner. Its business model focuses on funding programs in mid- to late-stage drug development in return for economic rights, purchasing royalty rights in development stage or commercial biopharmaceutical products and licensing its technology to help partners discover and develop medicines. Ligand partners with other pharmaceutical companies to leverage what they do best (late-stage development, regulatory management and commercialization) in order to generate its revenue. Ligand's Captisol® platform technology is a chemically modified cyclodextrin with a structure designed to optimize the solubility and stability of drugs. Ligand has established multiple alliances, licenses and other business relationships with the world's leading biopharmaceutical companies including Amgen, Merck, Pfizer, Jazz, Takeda, Gilead Sciences, and Baxter International. For more information, please visit at www.ligand.com . Follow Ligand on X @Ligand\_LGND.

We use our investor relations website and X as a means of disclosing material non-public information and for complying with our disclosure obligations under Regulation FD. Investors should monitor our website and our X account, in addition to following our press releases, SEC filings, public conference calls and webcasts.

### Forward-Looking Statements

This news release contains forward-looking statements by Ligand that involve risks and uncertainties and reflect Ligand's judgment as of the date of this release. Words such as "plans," "believes," "expects," "anticipates," "potential," "will" and similar expressions are intended to identify forward-looking statements. These forward-looking statements include, without limitation, statements regarding: the timing of the commercial launch of FILSPARI by Travere and the potential contribution it is expected to bring to Ligand; the timing and amount of milestone payments in connection with FILSPARI that Ligand expects; and the potential royalties to be paid on sales of FILSPARI by Travere. Actual events or results may differ from Ligand's or its partner's expectations due to risks and uncertainties inherent in Ligand's and its partner's business, including, without limitation: Travere may not be able to successfully commercialize FILSPARI which will depend on a number of factors including coverage and reimbursement levels from governmental authorities and health insurers as well as market acceptance by healthcare providers; the market size for

FILSPARI may be smaller than estimated; Ligand is dependent on Travere for the commercialization of FILSPARI; and other risks described in Ligand's prior press releases and filings with the Securities and Exchange Commission available at www.sec.gov. The failure to meet expectations with respect to any of the foregoing matters may reduce Ligand's stock price. Ligand disclaims any intent or obligation to update these forward-looking statements beyond the date of this release. This caution is made under the safe harbor provisions of the Private Securities Litigation Reform Act of 1995.

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