Travere Therapeutics and Vifor Pharma Announce Licensing Agreement for the Commercialization of Sparsentan in Europe, Australia and New Zealand

September 15, 2021

Vifor Pharma obtains exclusive commercialization rights for sparsentan in Europe, Australia and New Zealand

Travere receives a $55 million upfront payment and is eligible for additional regulatory and commercial milestones, as well as tiered royalties on net sales

Sparsentan is a potential first-in-class treatment to address significant unmet medical needs in rare kidney disorders focal segmental glomerulosclerosis (FSGS) and IgA nephropathy (IgAN)

SAN DIEGO and ST GALLEN, Switzerland, Sept. 15, 2021 (GLOBE NEWSWIRE) -- Travere Therapeutics, Inc. (NASDAQ: TVTX) and Vifor Pharma today announced the companies have entered into a joint collaboration and licensing agreement for the commercialization of sparsentan in Europe, Australia and New Zealand. Sparsentan is a novel investigational product candidate currently being evaluated in pivotal Phase 3 clinical studies for the treatment of FSGS and IgAN, two rare progressive kidney disorders and leading causes of end-stage kidney disease. There are currently no approved medicines indicated for FSGS or IgAN. Sparsentan has been granted Orphan Drug Designation for the treatment of FSGS and IgAN in the U.S. and Europe.

Under the terms of the agreement, Vifor Pharma will receive exclusive commercialization rights for sparsentan in Europe, Australia and New Zealand. Travere will receive an upfront payment of $55 million and be eligible for up to $135 million in payments tied to the achievement of certain regulatory and market access related milestones. Vifor Pharma will also make further payments in the form of sales milestones, and tiered double-digit royalties on net sales of sparsentan in Europe, Australia and New Zealand up to 40 percent at the high end of the royalty range.

“Our goal is for sparsentan to become the new global treatment standard for people living with FSGS and IgAN; this collaboration marks an important step forward in this journey,” said Eric Dube, Ph.D., chief executive officer of Travere Therapeutics. “Vifor Pharma is a global leader in nephrology with established commercialization expertise in Europe, Australia and New Zealand and this agreement aligns our two companies with the common goal of maximizing the number of people who can access sparsentan, if approved in these regions. In addition, this collaboration will further strengthen our financial foundation and allow our organization to focus on planned future launches of sparsentan in the U.S.”

“This agreement highlights that Vifor Pharma has become a company of choice for organizations committed to partnering innovative nephrology assets,” Abbas Hussain, chief executive officer of Vifor Pharma Group commented. “With sparsentan, we will further expand our growing nephrology pipeline into FSGS and IgAN. There are currently no effective or approved therapies for these two rare kidney disorders, resulting in a significant unmet medical need among these patient populations. We look forward to working closely with Travere, who is responsible for the ongoing clinical development program of sparsentan, and to leveraging our commercial expertise to bring this highly promising, innovative treatment option to more than 150,000 patients living with FSGS and IgAN in the licensed territories as soon as possible.”

Following the recently announced positive topline interim results from the ongoing pivotal Phase 3 PROTECT Study of sparsentan in IgAN, Travere and Vifor Pharma will further evaluate the regulatory strategy for sparsentan in Europe, including the potential to submit a joint marketing authorization application for both FSGS and IgAN in 2022. Ultimately, the responsibility for and control over marketing authorizations in the licensed territories will be transitioned to Vifor Pharma. If sparsentan is approved, Vifor Pharma will be responsible for all commercialization activities in the licensed territories. Travere remains responsible for the clinical development of sparsentan and will retain all rights to sparsentan in the United States and rest of world. Travere remains obligated to make payments to Ligand Pharmaceuticals upon achievement of certain regulatory and sales milestones, as well as an escalating annual royalty between 15 percent and 17 percent of global net product sales.

About Sparsentan

Sparsentan, a Dual Endothelin Angiotensin Receptor Antagonist (DEARA), is a novel investigational product candidate. Pre-clinical data have shown that blockade of both endothelin type A and angiotensin II type 1 pathways in forms of rare chronic kidney disease, reduces proteinuria, protects podocytes and prevents glomerulosclerosis and mesangial cell proliferation. Sparsentan has been granted Orphan Drug Designation for the treatment of FSGS and IgAN in the U.S. and Europe.

Sparsentan is currently being evaluated in the pivotal Phase 3 DUPLEX Study for the treatment of FSGS and the pivotal Phase 3 PROTECT Study for the treatment of IgAN. In February 2021, the Company announced that the ongoing DUPLEX Study of sparsentan in FSGS achieved its pre-specified interim FSGS partial remission of proteinuria endpoint (FPRE) with statistical significance. FPRE is a clinically meaningful endpoint defined as urine protein-to-creatinine ratio (UP/C) ≤1.5 g/g and a >40 percent reduction in UP/C from baseline. After 36 weeks of treatment, 42.0 percent of patients receiving sparsentan achieved FPRE, compared to 26.0 percent of irbesartan-treated patients (p=0.0094). Preliminary results from the interim analysis suggest that at the time of the interim assessment, sparsentan had been generally well-tolerated and shown a comparable safety profile to irbesartan. In August of 2021, the Company announced that the ongoing PROTECT Study met its pre-specified interim primary efficacy endpoint with statistical significance, demonstrating a greater than threefold reduction of proteinuria from baseline after 36 weeks of treatment, compared to the active control irbesartan (p<0.0001). Preliminary results from the interim analysis suggest that at the time of the interim assessment, sparsentan had been generally well-tolerated and performed consistent with the observed safety profile to date. In the Phase 2 DUET Study of sparsentan in FSGS, the combined treatment group met its primary efficacy endpoint, demonstrating a greater than two-fold reduction in proteinuria compared to irbesartan, and was generally well tolerated after the eight-week, double-blind treatment period. Irbesartan is part of a class of drugs used to manage FSGS and IgAN in the absence of an approved pharmacologic treatment. If approved for both indications, sparsentan could potentially be the first medicine approved for both FSGS and IgAN.

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

About Vifor Pharma Group

Vifor Pharma Group is a global pharmaceuticals company. It aims to become the global leader in iron deficiency, nephrology and cardio-renal therapies. The company is a partner of choice for pharmaceuticals and innovative patient-focused solutions. Vifor Pharma Group strives to help patients around the world with severe and chronic diseases lead better, healthier lives. The company develops, manufactures and markets pharmaceutical products for precision patient care. Vifor Pharma Group holds a leading position in all its core business activities and consists of the following companies: Vifor Pharma and Vifor Fresenius Medical Care Renal Pharma (a joint company with Fresenius Medical Care). Vifor Pharma Group is headquartered in Switzerland, and listed on the Swiss Stock Exchange (SIX Swiss Exchange, VIFN, ISIN: CH0364749348).

For more information, please visit viforpharma.com.

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 "may", "might", "believes", "thinks", "anticipates", "plans", "expects", "intends" or similar expressions. In addition, expressions of our strategies, intentions or plans are also forward-looking statements. Such forward-looking statements include, but are not limited to, references to: Travere's goal for sparsentan to become the new global treatment standard for people living with FSGS and IgAN; the goal to maximize the number of people who can access sparsentan, if approved in the licensed regions; the ability of the collaboration to further strengthen Travere's financial foundation; planned future launches of sparsentan in the U.S.; the potential to submit a joint marketing authorization application for both FSGS and IgAN in 2022; Vifor's potential future achievement of regulatory, market-access and sales based milestones and Travere's potential future receipt of payments therefrom; statements regarding the projected patient population in the licensed territory if sparsentan is approved; references to the efficacy, safety and tolerability profile of sparsentan based on the preliminary data from the DUPLEX and PROTECT Studies' interim analyses; and the potential for sparsentan to become the first medicine approved for both FSGS and IgAN. 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 associated with the regulatory review and approval process, including the conditional marketing authorization pathway in Europe, and the pricing and reimbursement landscape in the licensed territories, as well as ongoing clinical development risk. There is no guarantee that regulatory authorities in the licensed territories will accept a marketing authorization application for sparsentan or that sparsentan will receive conditional marketing authorization or be approved at all. 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. Travere 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 as included in Travere's most recent Form 10-K, Form 10-Q and other filings with the Securities and Exchange Commission.

Contact:

Travere Therapeutics:
Chris Cline, CFA
Senior Vice President, Investor Relations & Corporate Communications
888-969-7879
IR@travere.com

Vifor Pharma:

Media Relations
Nathalie Ponnier
Global Head Corporate Communications
+41 79 957 96 73
media@viforpharma.com

Investor Relations
Julien Vignot
Head of Investor Relations
+41 58 851 66 90
investors@viforpharma.com

Source: Travere Therapeutics, Inc.