Vera Therapeutics Presents New Analysis of Phase 2a JANUS Trial of Atacicept in IgA Nephropathy and Positive Final Phase 2 Results of MAU868 in Kidney Transplant Recipients with Reactivated BK Virus Infection at the American Society of Nephrology Kidney Week 2022 Annual Meeting

November 5, 2022

- *New analysis of Phase 2a JANUS clinical trial showed atacicept reduced immune complex levels in patients with IgA nephropathy (IgAN)*
- *Atacicept is the first therapeutic to show reduction in all of the three first hits of IgAN pathogenesis – serum galactose-deficient IgA1 (Gd-IgA1), anti-Gd-IgA1, and now immune complex levels*
- *Final results from the Phase 2 clinical trial of MAU868 versus placebo showed MAU868 was well tolerated and demonstrated clinically meaningful BK antiviral activity through 36 weeks in kidney transplant patients with BK viremia*

Table: Antiviral Effect of MAU868 vs. Placebo at Week 36

	Week 16		Week 36	
	MAU868 (N=20)	Placebo (N=8)	MAU868 (N=20)	Placebo (N=8)
Patients VL decreased by ≥1 $\log_{10}$ BKV DNA copies/ml vs baseline	8 (40%)	1 (13%)	15 (75%)	4 (50%)
Patients with VL < lower limit of detection (LOD)	3 (15%)	0	6 (30%)	0
Patients with VL <10^4 $\log_{10}$ BKV DNA copies/ml	13 (65%)	3 (38%)	15 (75%)	5 (63%)
BKV VL reduction - median log10 BKV DNA copies/ml (interquartile range [IQR])	-0.97(-2.6, 0.8)	-0.38 (-2.3,0.5)	-1.31 (-3.3,0.6)	-0.85 (-2.3,1.3)
Change in estimated glomerular filtration rate (eGFR)- median ml/min/1.73m² (Min,Max)	-4.5 (-28.0,13.0)	-6.0 (-11,2.0)	-0.5 (-51.0,25.0)	-5.5 (-27,12)

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BRISBANE, Calif., Nov. 05, 2022 (GLOBE NEWSWIRE) -- Vera Therapeutics, Inc. (Nasdaq: VERA), a late-stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunological diseases, today announced new clinical data presented on the Company's two product candidates, atacicept in immunoglobulin A nephropathy (IgAN) and MAU868 in kidney transplant. These data were presented in poster and oral presentations, respectively at the American Society of Nephrology (ASN) Kidney Week 2022 Annual Meeting, held November 3-6, 2022 in Orlando, Florida.

The poster presentation on atacicept included a new analysis of previously presented clinical data from the Phase 2a JANUS clinical trial evaluating atacicept in patients with IgAN that showed atacicept reduced immune complex levels in patients with IgAN. Atacicept is the first therapeutic to show reduction in all of the first three hits of IgAN pathogenesis – serum galactose-deficient IgA1 (Gd-IgA1), anti-Gd-IgA1, and now immune complex levels. The oral presentation on MAU868 included final results from the Phase 2 clinical trial of MAU868 versus placebo to treat BK Virus (BKV) in kidney transplant patients that showed MAU868 was well tolerated and demonstrated clinically meaningful BK antiviral activity through 36 weeks in kidney transplant patients with BK viremia.

Details of the presentations are as follows:

Title:	Atacicept Reduces Serum Immune Complex Levels in Patients with Immunoglobulin A Nephropathy (IgAN)
Presenter:	Jonathan Barratt, Ph.D., FRCP, The Mayer Professor of Renal Medicine, University of Leicester, U.K.
Abstract Number:	SA-PO655 (poster presentation)

IgA nephropathy (IgAN) is an autoimmune disease driven by a multi-hit pathogenesis that involves B-cell priming. Gd-IgA1 plays a central role in IgAN pathogenesis and as the intrinsic antigen is the first hit in the disease pathogenesis. The second hit is the development of antibodies to the hinge region of Gd-IgA1, which then leads to formation of immune complexes (third hit). These circulating immune complexes then deposit in the kidney and cause progressive renal injury (fourth hit). The Phase 2a randomized, placebo-controlled JANUS trial showed that atacicept was the first therapeutic to decrease circulatory Gd-IgA1 in IgAN patients and further analysis of these results showed that atacicept reduced anti-Gd-IgA1 antibodies. This analysis investigated whether atacicept can also reduce serum immune complexes.

JANUS patients were evaluated for serum IgA-IgG immune complex levels by ELISA at baseline, weeks 4, 12, 24, 48, and 72. Results showed a decrease in serum IgA-IgG immune complex levels was observed in both atacicept 25 mg and 75 mg groups over time. The 150 mg dose was not evaluated in the JANUS trial. At 24 weeks, the mean percent change from baseline was a 17 percent decrease for atacicept 25 mg and a 21 percent decrease for atacicept 75 mg, and a three percent decrease for placebo. At 72 weeks, a 29 percent decrease for atacicept 25 mg, 26 percent decrease for atacicept 75 mg, and 13 decrease for placebo was observed.

"The ability of atacicept to decrease serum immune complex levels, as well as both circulatory Gd-IgA1 and anti-Gd-IgA1 antibodies, both of which are central to the pathogenesis and progression of IgAN, support its potential as a disease-modifying therapy for patients with IgAN," said Dr. Barratt.

Celia Lin, M.D., Chief Medical Officer at Vera Therapeutics, commented, "IgAN represents a high unmet medical need in the world, with an estimated 400,000 patients in the U.S., the European Union, and Japan – up to half of whom will develop end-stage renal disease within 20 years from initial diagnosis, requiring dialysis or kidney transplant. Research has shown that immune complex is a key component in the pathogenesis of IgAN. This is the first time we are seeing any investigational or approved therapy result in reduced immune complex levels in IgAN patients, and further shows that atacicept can target the upstream sources of disease in IgAN. We look forward to sharing new data of atacicept in IgAN – the topline results of our Phase 2b ORIGIN clinical trial – in early Q1 2023."

Title:	A Randomized Phase 2 Study of MAU868 vs. Placebo to Treat BK Viremia in Kidney Transplant Recipients
Presenter:	Stanley C. Jordan, M.D., FASN, FAST, Director of Nephrology & Transplant Immunology, Cedars-Sinai Medical Center, Professor of Pediatrics and Medicine at the David Geffen School of Medicine at University of California, Los Angeles
Abstract Number:	SA-OR43 (oral presentation)

BK Virus (BKV) is a polyoma virus that can be reactivated in settings of immunosuppression, such as in kidney transplant. It is a leading cause of kidney transplant loss and transplant-associated morbidity; there are currently no approved treatments for BKV.

This Phase 2, randomized, double-blind, placebo-controlled clinical trial evaluated the safety and efficacy of MAU868 in patients who received a kidney transplant within one year of enrollment and, within 10 days of enrollment, had BK viremia. Patients received MAU868 or placebo intravenously (IV) every 28 days for 12 weeks, with 24 weeks follow-up. In this clinical trial, 20 patients received MAU868 and eight patients received placebo; all patients completed 12 weeks of treatment. Baseline characteristics were comparable between groups. The primary endpoint was safety and tolerability; antiviral activity was assessed in secondary and post-hoc analyses.

This analysis reported efficacy results at 16 and 36 weeks for two cohorts: MAU868 1350 mg IV x4 doses, and MAU868 6750 mg IV followed by MAU868 1350 mg IV x3 doses. Results showed that the antiviral effect was higher in the MAU868 group than the placebo group at week 16 and sustained through week 36 (see Table below). Further, MAU868 was well tolerated, with a comparable frequency of adverse events and serious adverse events between groups through week 36. There were two deaths in the MAU868 group due to COVID-19 infection deemed unrelated to study drug.

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“Reactivation of BKV infections can cause kidney disease in immunocompromised patients, leading to increased morbidity and mortality factors in kidney transplant recipients. BKV nephropathy is a leading cause of allograft loss in kidney transplant recipients and there are no approved effective or BKV-specific therapies,” said Dr. Jordan. “These final results from the Phase 2 clinical trial showed that MAU868 was well tolerated and demonstrated significant BK antiviral activity in kidney transplant recipients with BK viremia up to week 36. These data support the further development of MAU868 as a therapy for BK viremia.”

Dr. Lin commented, “MAU868 is a first-in-class targeted therapy specifically designed to neutralize BKV. We plan to initiate a Phase 2b or Phase 3 clinical trial of MAU868 in kidney transplant patients with BK Virus viremia in 2023, so that we can bring patients a treatment option as rapidly as possible.”

The posters presented during the American Society of Nephrology Kidney Week 2022 Annual Meeting will be available on the Company’s website at https://ir.veratx.com/news-events/presentations.

About Atacicept
Atacicept is an investigational recombinant fusion protein self-administered as a subcutaneous injection once weekly that contains the soluble transmembrane activator and calcium-modulating cyclophilin ligand interactor (TACI) receptor that binds to the cytokines B lymphocyte stimulator (BlyS) and a proliferation-inducing ligand (APRIL). These cytokines are members of the tumor necrosis factor family that promote B-cell survival and autoantibody production associated with certain autoimmune diseases, including IgA nephropathy (IgAN) and lupus nephritis. Atacicept showed a dose-dependent effect on key biomarkers and clinical markers in a Phase 2a clinical study in patients with IgAN. Vera believes atacicept is positioned for best-in-class potential, targeting B cells and plasma cells to reduce autoantibodies and having been administered to more than 1,400 patients in clinical studies across different indications.

About MAU868
MAU868, a first-in-class monoclonal antibody, has the potential to neutralize infection by blocking BK Virus (BKV) virions from binding to host cells. BK Virus is a polyoma virus that can be reactivated in settings of immunosuppression, such as in kidney transplant. It is a leading cause of kidney transplant loss and transplant-associated morbidity; there are currently no approved treatments for BKV. Vera holds an exclusive worldwide license from Amplyx Pharmaceuticals, Inc., a wholly owned subsidiary of Pfizer Inc., for the development and commercialization of MAU868 in all indications.

About Vera
Vera Therapeutics is a late-stage biotechnology company focused on developing treatments for serious immunological diseases. Vera’s mission is to advance treatments that target the source of immunologic diseases in order to change the standard of care for patients. Vera’s lead product candidate is atacicept, a fusion protein self-administered as a subcutaneous injection once weekly that blocks both B lymphocyte stimulator (BLyS) and a proliferation inducing ligand (APRIL), which stimulate B cells and plasma cells to produce autoantibodies contributing to certain autoimmune diseases, including IgA nephropathy (IgAN), also known as Berger’s disease, and lupus nephritis. In addition, Vera is evaluating additional diseases where the reduction of autoantibodies by atacicept may prove medically useful. Vera is also developing MAU868, a monoclonal antibody designed to neutralize infection with BK Virus, a polyomavirus that can have devastating consequences in certain settings such as kidney transplant. For more information, please visit www.veratx.com.

Forward-looking Statements

Statements contained in this press release regarding matters, events or results that may occur in the future are "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995. Such forward-looking statements include statements regarding, among other things, the initiation of a Phase 2b or Phase 3 clinical trial of MAU868 in kidney transplant patients with BK Virus viremia, the results of Vera's Phase 2b ORIGIN trial, the potential for MAU868 to be a first-in-class targeted therapy specifically designed to neutralize BKV, and other statements regarding Vera's product candidates, strategy, and regulatory matters. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "potential," and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Vera's current expectations and involve assumptions that may never materialize or may prove to be incorrect. Actual results could differ materially from those anticipated in such forward-looking statements as a result of various risks and uncertainties, which include, without limitation, risks related to the regulatory approval process, results of earlier clinical trials may not be obtained in later clinical trials, risks and uncertainties associated with Vera's business in general, the impact of geopolitical and macroeconomic events, including the COVID-19 pandemic, and the other risks described in Vera's filings with the Securities and Exchange Commission. All forward-looking statements contained in this press release speak only as of the date on which they were made and are based on management's assumptions and estimates as of such date. Vera undertakes no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

For more information, please contact:

Investor Contact:
Joyce Allaire
LifeSci Advisors
212-915-2569
jallaire@lifesciadvisors.com

Media Contact:
Kathy Vincent
Greig Communications, Inc.
kathy@greigcommunications.com

A photo accompanying this announcement is available at https://www.globenewswire.com/NewsRoom/AttachmentNg/e9c7e19e-2da0-44ff-8969-a22d6e928182