Vera Therapeutics to Host In-Person R&D Day in New York to Present Week 72 Data from Phase 2b ORIGIN Clinical Trial of Atacicept in IgAN on January 25, 2024

January 8, 2024

BRISBANE, Calif., Jan. 08, 2024 (GLOBE NEWSWIRE) -- Vera Therapeutics, Inc. (Nasdaq: VERA), a late clinical-stage biotechnology company developing and commercializing transformative treatments for patients with serious immunologic diseases, today announced it will host an in-person R&D day featuring Richard Lafayette, M.D., FACP, from Stanford University Medical Center, who will join company management to present Phase 2b eGFR and proteinuria data from week 72 of the ORIGIN Phase 2b clinical trial of atacicept for the treatment of IgA nephropathy (IgAN), and Jonathan Barratt, Ph.D., FRCP, from the University of Leicester for a discussion of the results, on January 25, 2024. To register, click here.

Presentation Details:

Date:	Thursday, January 25, 2024
Time:	8:00 AM ET
Location:	Lotte New York Palace Hotel, 455 Madison Ave, New York, NY 10022 United States
Webcast:	https://lifescievents.com/event/veratx/

About Richard Lafayette, M.D., FACP

Dr. Lafayette is a Professor of Medicine (Nephrology) and Director of the Stanford Glomerular Disease Center at Stanford University Medical Center. Dr. Lafayette completed his medical education at New York Medical College and went on to complete his residency at the Long Island Jewish Medical Center, and his fellowship at Stanford University School of Medicine. Dr. Lafayette is board-certified in Internal Medicine and Nephrology. Dr. Lafayette served as the Associate Chair of the Stanford University Department of Medicine from 2002 to 2007, the Clinical Chief of Nephrology at Stanford University from 1999 to 2012, and currently serves as the Director of the Stanford Glomerular Disease Center since 2010. Dr. Lafayette was honored in America's Top Doctors, Best Doctors from 2004 to 2018, and received America's Top Doctors Award, Castle Connolly Medical Ltd. from 2014 to 2022. Dr. Lafayette has been part of the following boards and professional organizations: Editorial Board, Kidney News, American Society of Nephrology (2010 – 2021) Member, Glomerular Disease Advisory Committee, American Society of Nephrology (2013 – 2017) Member (ex-officio), Communications Committee, American Society of Nephrology (2015 – Present).

About Jonathan Barratt Ph.D., FRCP

Dr. Barratt leads the Renal Research Group within the College of Life Sciences, University of Leicester. His research is focused on a bench-to-bedside approach to improving our understanding of the pathogenesis of IgAN, a common global cause of kidney failure. Dr. Barratt is the IgAN Rare Disease Group lead for the UK National Registry of Rare Kidney Diseases (RaDaR), and a member of the steering committee for the International IgAN Network. He works closely with pharmaceutical companies interested in new treatments for IgAN, is Chief Investigator for a number of international randomized controlled Phase 2 and 3 clinical trials in IgAN, and was a member of the U.S. Food and Drug Administration and American Society of Nephrology Kidney Health Initiative: Identifying Surrogate Endpoints for Clinical Trials in IgAN Workgroup.

About the Phase 2b ORIGIN clinical trial

The Phase 2b ORIGIN clinical trial (NCT04716231) is a global, multicenter, randomized, double-blind, placebo-controlled trial evaluating the safety and efficacy of atacicept in 116 patients with IgAN who continue to have persistent proteinuria and remain at high risk of disease progression despite being on a stable prescribed regimen of RAASi for at least 12 weeks that is the maximum labeled or tolerated dose.

The objectives of the study are to determine the effect of atacicept on proteinuria and preservation of renal function compared to placebo to determine the appropriate dose(s) for further clinical development.

The primary endpoint is the change in proteinuria as evaluated by urine protein to creatinine ratio (UPCR) at week 24 and the key secondary endpoint is the change in proteinuria as evaluated by UPCR at week 36.

Additional exploratory endpoints include change in proteinuria as evaluated by UPCR at weeks 12, 48, and 96; change in estimated glomerular filtration rate (eGFR); change in serum immunoglobulin levels, and serum Gd-IgA1 levels; safety and tolerability; and serum pharmacokinetics (PK).

The Phase 2b ORIGIN clinical trial evaluated three dose strengths of atacicept versus placebo, administered weekly by prefilled syringe. Patients were randomized 2:2:1:2 to atacicept 150 mg, atacicept 75 mg, atacicept 25 mg, or matching placebo. Upon completion of the 36-week blinded treatment period, all patients are offered open-label atacicept 150 mg for an additional 60 weeks.

The trial met its primary and key secondary endpoints, with statistically significant and clinically meaningful proteinuria reductions and stabilization of eGFR versus placebo through week 36. Safety was comparable between atacicept and placebo.

For more information about the Phase 2b ORIGIN clinical trial, please visit www.clinicaltrials.gov.

About IgA nephropathy (IgAN), or Berger's disease

IgAN, also known as Berger's disease, is a serious and progressive autoimmune disease of the kidney, for which there remains a high unmet medical need. IgAN is driven by the production of immunogenic galactose-deficient IgA1 (Gd-IgA1), which triggers autoantibodies that lead to the formation of

pathogenic immune complexes, which become trapped in the kidney's glomeruli, causing inflammation and progressive damage. In up to 50 percent of patients, IgAN can lead to end-stage renal disease (ESRD) or kidney failure, which has considerable morbidity and impact on patients' lives.

About Atacicept

Atacicept is an investigational recombinant fusion protein that contains the soluble transmembrane activator and calcium-modulating cyclophilin ligand interactor (TACI) receptor that binds to the cytokines B-cell activating factor (BAFF) 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 and lupus nephritis. The Phase 2b ORIGIN clinical trial of atacicept in IgAN met its primary endpoint and showed a statistically significant reduction in mean proteinuria versus baseline at weeks 24 and 36. 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 1,500 patients in clinical studies across different indications.

About Vera Therapeutics

Vera Therapeutics is a late clinical-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-cell activating factor (BAFF) and A proliferation-inducing ligand (APRIL), which stimulate B cells and plasma cells to produce autoantibodies contributing to certain autoimmune diseases, including 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 (BKV), a polyomavirus that can have devastating consequences in certain settings such as kidney transplant. Vera retains all global developmental and commercial rights to atacicept and MAU868. For more information, please visit www.veratx.com.

Forward-looking Statement

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, Vera's anticipated presentation of additional data from the Phase 2b ORIGIN clinical trial, atacicept being positioned for best-in-class potential, the design and management of Vera's clinical trials, expectations regarding reporting longer term results from the Phase 2b ORIGIN clinical trial and 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," "will," "plan," 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, preliminary results may not be predictive of topline results, risks and uncertainties associated with Vera's business in general, the impact of macroeconomic and geopolitical events, 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.

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