Vera Therapeutics Completes Patient Enrollment in Phase 2b ORIGIN Clinical Trial of Atacicept for the Treatment of IgA Nephropathy

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Topline results anticipated fourth quarter of 2022

BRISBANE, Calif., July 06, 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 disease, today announced completion of patient enrollment in the Phase 2b ORIGIN clinical trial of atacicept, the Company's potential best-in-class, disease-modifying dual inhibitor of the cytokines B lymphocyte stimulator (BLyS) and a proliferation-inducing ligand (APRIL). ORIGIN is a multinational dose-ranging study evaluating the efficacy and safety of atacicept in patients with IgA nephropathy (IgAN) who continue to have persistent proteinuria and remain at high risk of disease progression despite being on a stable prescribed regimen of renin-angiotensin-aldosterone system inhibition (RAASi) with an angiotensin converting enzyme inhibitor (ACEi) or angiotensin II receptor blocker (ARB).

"We have been seeking a disease modifying therapy for IgAN to potentially slow or reverse disease progression," said Richard Lafayette, M.D., FACP, Professor of Medicine, Director, Stanford Glomerular Disease Center, Stanford University School of Medicine, and a clinical investigator in the trial. "Recently, new data analysis from the Phase 2a JANUS clinical trial in patients with IgAN, showed atacicept is the first known investigational therapeutic to reduce IgG autoantibodies as well as its autoantigen, Gd-IgA1 – the source of immune complexes that cause disease. This builds on the already compelling disease-modifying dose-dependent activity and well-tolerated safety profile for atacicept. We look forward to the results of the ORIGIN trial which will be a first for the field."

"We are excited to complete enrollment in the Phase 2b ORIGIN trial and reach this significant milestone for atacicept as we work diligently amidst a global pandemic and geopolitical crises to provide a much-needed treatment option for patients with IgAN," said Celia Lin, M.D., Chief Medical Officer at Vera Therapeutics. "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. We believe atacicept could have a profound benefit for patients with IgAN and look forward to topline results of this study expected to be announced later this year."

The ORIGIN clinical trial (NCT04716231) is a global, multicenter, randomized, double-blind, placebo-controlled Phase 2b trial evaluating the safety and efficacy of atacicept in 115 patients with IgAN who continue to have persistent proteinuria and remain at high risk of disease progression despite being on a stable prescribed regiment 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 ORIGIN trial is designed to evaluate three dose strengths of atacicept versus placebo, administered weekly by prefilled syringe, and their impact on the reduction of proteinuria as evaluated by urine protein to creatinine ratio (UPCR). Subjects 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 subjects will be offered open-label atacicept 150 mg for an additional 60 weeks.

The primary endpoint is the change in proteinuria as evaluated by UPCR at week 24 and the key secondary endpoint is the change in proteinuria as evaluated by UPCR at week 36. Additional secondary and exploratory endpoints include change in proteinuria as evaluated by UPCR at weeks 12, 48, and 96; rate of change in estimated glomerular filtration rate (eGFR); change in serum immunoglobulin levels, and serum Gd-IgA1 levels; safety and tolerability; and serum pharmacokinetics (PK). For more information about the ORIGIN clinical trial, please visit www.clinicaltrials.gov.

About IgA nephropathy (IgAN), or Berger's disease
IgAN is a serious and progressive autoimmune disease of the kidney, which currently has no approved treatments. 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 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 and lupus nephritis. Atacicept showed a dose-dependent effect on key biomarkers and clinical markers in a Phase 2a clinical study. 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 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 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, research and clinical development plans and timing, the scope, progress, and results of developing Vera's product candidates, including the timing and results of the ORIGIN trial, strategy, and regulatory matters, including the timing and likelihood of success of obtaining drug approvals. 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 "could," "will," "expects," "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 the COVID-19 pandemic, and the other risks described in Vera's filings with the Securities and Exchange Commission, including in its latest Form 10-Q filed with the Securities and Exchange Commission on May 16, 2022, particularly under the caption "Risk Factors." 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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