Vera Therapeutics Initiates Pivotal Phase 3 (ORIGIN 3) Clinical Trial of Atacicept for the Treatment of IgA Nephropathy (IgAN)

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Pivotal Phase 3 Trial for Atacicept in IgA Nephropathy Initiated Today

Late-breaking results of ORIGIN Phase 2b trial supporting further evaluation of atacicept 150 mg as a potential disease-modifying treatment for IgAN will be presented at 60th European Renal Association (ERA) Congress

BRISBANE, Calif., June 07, 2023 (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 initiation of the pivotal Phase 3 clinical trial (ORIGIN 3) of atacicept for the treatment of IgA nephropathy (IgAN). ORIGIN 3 is a multinational, randomized, double-blind, placebo-controlled clinical trial evaluating the efficacy and safety of atacicept 150 mg in patients with IgAN who continue to have persistent proteinuria and remain at high risk of disease progression despite optimized angiotensin converting enzyme inhibitor (ACEi) or angiotensin II receptor blocker (ARB) therapy.

Atacicept is a potential best-in-class, disease-modifying dual inhibitor of the cytokines B lymphocyte stimulator (BLyS) and a proliferation-inducing ligand (APRIL). The ORIGIN 3 trial was initiated based on the results of the Phase 2b trial, which will be presented in a late-breaking session at the 60th European Renal Association (ERA) Congress in June 2023.

“Building upon positive data from our Phase 2b trial that show atacicept’s best-in-class potential, initiation of the pivotal ORIGIN 3 trial is a crucial milestone in the advancement of its clinical development,” said Marshall Fordyce, M.D., Chief Executive Officer of Vera Therapeutics. “Our Phase 2 results have shown that atacicept targets the source of IgA nephropathy and improves kidney function as measured by statistically and clinically significant reductions in proteinuria. As we enroll this pivotal Phase 3 trial, we plan to share longer term Phase 2 results later in 2023 and 2024.”

About the Phase 3 clinical trial (ORIGIN 3)
The ORIGIN 3 clinical trial (NCT04716231) is a global, multicenter, randomized, double-blind, placebo-controlled Phase 3 trial evaluating the safety and efficacy of atacicept 150 mg in 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 RASi (ACEi or ARB) for at least 12 weeks that is at the maximum labeled or tolerated dose. The objectives of the study trial are to determine the effect of atacicept on proteinuria and preservation of renal function compared to placebo.

The Phase 3 trial is composed of up to a 4-week screening period, a 104-week double-blind treatment period, a 52-week open-label extension and 26 weeks of follow-up. Participants will be randomized 1:1 to atacicept 150 mg once weekly subcutaneous injections (N=188) or placebo once weekly subcutaneous injections (N=188) for 104 weeks, followed by a 52-week open-label extension. The primary endpoint is the change in proteinuria as evaluated by urine protein to creatinine ratio (UPCR) at week 36. The key secondary endpoint is annualized rate of change in estimated glomerular filtration rate (eGFR) up to week 104. Additional secondary endpoints are the change in Gd-IgA1, change in eGFR up to week 52, and time from randomization to first occurrence of composite kidney failure endpoint event.

For more information about the ORIGIN 3 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 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. 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 24 weeks. 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
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. 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, atacicept's potential to be a transformational treatment for patients with IgAN and a best-in-class therapy, the design and management of Vera's pivotal Phase 3 clinical trial of atacicept for the treatment of IgAN, expectations regarding reporting Phase 2b data at in June 2023, and Vera's plans to share additional Phase 2 results in 2023 and 2024. 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 "advance," "expect," "will," "potential," "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, 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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