Vera Therapeutics Announces Positive Week 36 Efficacy and Safety Results of Phase 2b ORIGIN Clinical Trial of Atacicept in IgAN in Late-Breaking Presentation at 60th European Renal Association (ERA) Congress

June 17, 2023

New data at week 36 shows atacicept 150 mg resulted in a delta of 43% versus placebo in mean proteinuria reduction in per-protocol analysis and demonstrated statistically significant stabilization of eGFR versus placebo in this high-risk population

Atacicept was well tolerated with safety profile similar to placebo

Positive results support atacicept 150 mg as a potential disease-modifying treatment for patients with IgA nephropathy; Phase 3 (ORIGIN 3) clinical trial initiated in June 2023

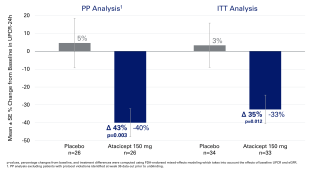
Conference call and webcast to take place on June 20th, 2023, at 8:00 a.m. ET to further discuss results

BRISBANE, Calif., June 17, 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 the Phase 2b ORIGIN clinical trial of atacicept for the treatment of IgA nephropathy (IgAN) met its primary and key secondary endpoints, with statistically significant and clinically meaningful reductions in proteinuria and stabilization of eGFR through week 36. The week 36 results of ORIGIN were presented as a late-breaking presentation at the 60th European Renal Association (ERA) Congress, taking place June 15-18, 2023, in Milan, Italy and virtually.

Atacicept is 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, randomized, double-blind, placebo-controlled clinical trial evaluating the efficacy and safety of atacicept in patients with IgAN who continue to have persistent proteinuria and remain at high risk of disease progression despite available ACEi or ARB therapy.

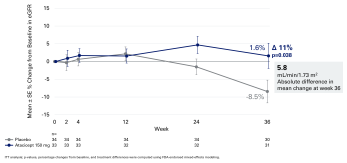
At week 36 in the prespecified per-protocol (PP) analysis, the atacicept 150 mg dose group showed a 43% placebo-adjusted reduction from baseline in proteinuria (p=0.003), compared to 35% in the intent-to-treat (ITT) analysis (p=0.012), as shown in Figure 1 below. In the ITT analysis of all randomized patients, patients receiving placebo had an expected decline in kidney function as measured by eGFR, while patients receiving atacicept 150 mg had stable eGFR through week 36, as shown in Figure 2. This difference in eGFR was statistically significant (delta 11%, p=0.038) and clinically significant (5.8 mL/min/1.73 m2). In addition, the atacicept 150 mg group achieved a 64% reduction from baseline at week 36 in Gd-IgA1 (p<0.0001).

Figure 1



UPCR % Change With Atacicept 150 mg at Week 36

Figure 2

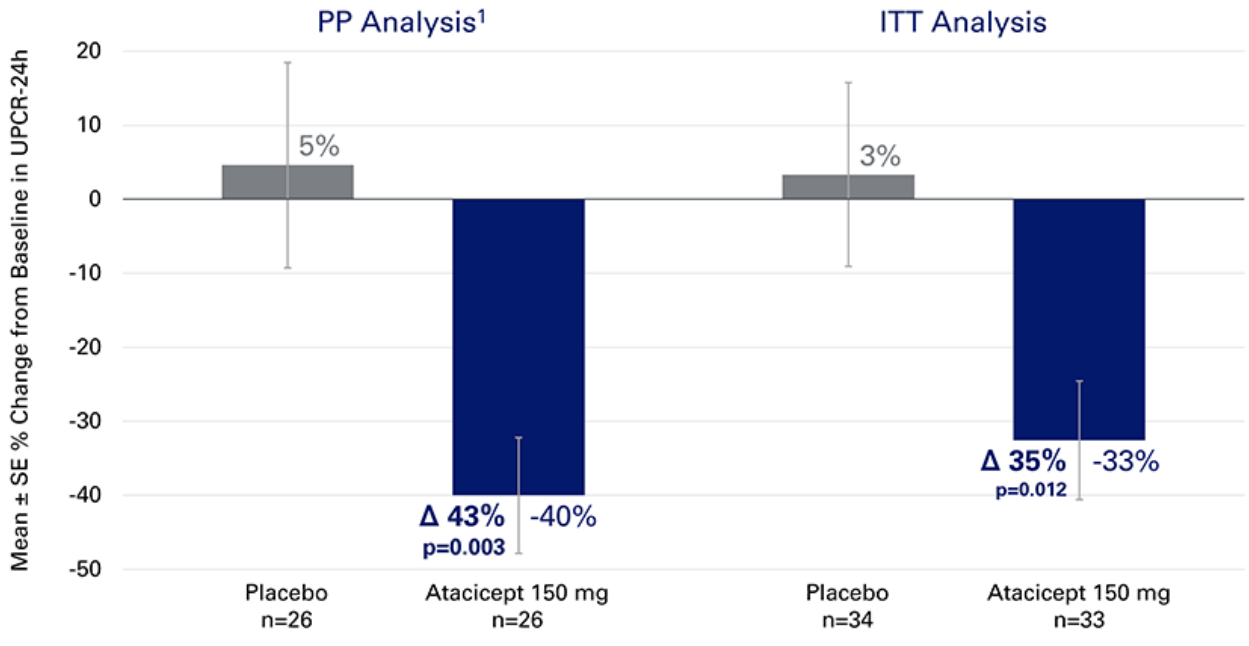


eGFR % Change With Atacicept 150 mg Through Week 36

"The week 36 results of the Phase 2b ORIGIN clinical trial build on a growing body of data that demonstrates atacicept's potential to modify and delay disease progression in IgAN. We believe this is best characterized by the early signs of eGFR stabilization and a significant 43% reduction in proteinuria for the atacicept 150 mg group compared to placebo," said Richard Lafayette, M.D., F.A.C.P., Professor of Medicine, Nephrology and Director of the Stanford Glomerular Disease Center at Stanford University Medical Center. "These data also demonstrate the therapeutic potential of the BLyS and APRIL dual inhibitor approach to treating the root cause of IgAN."

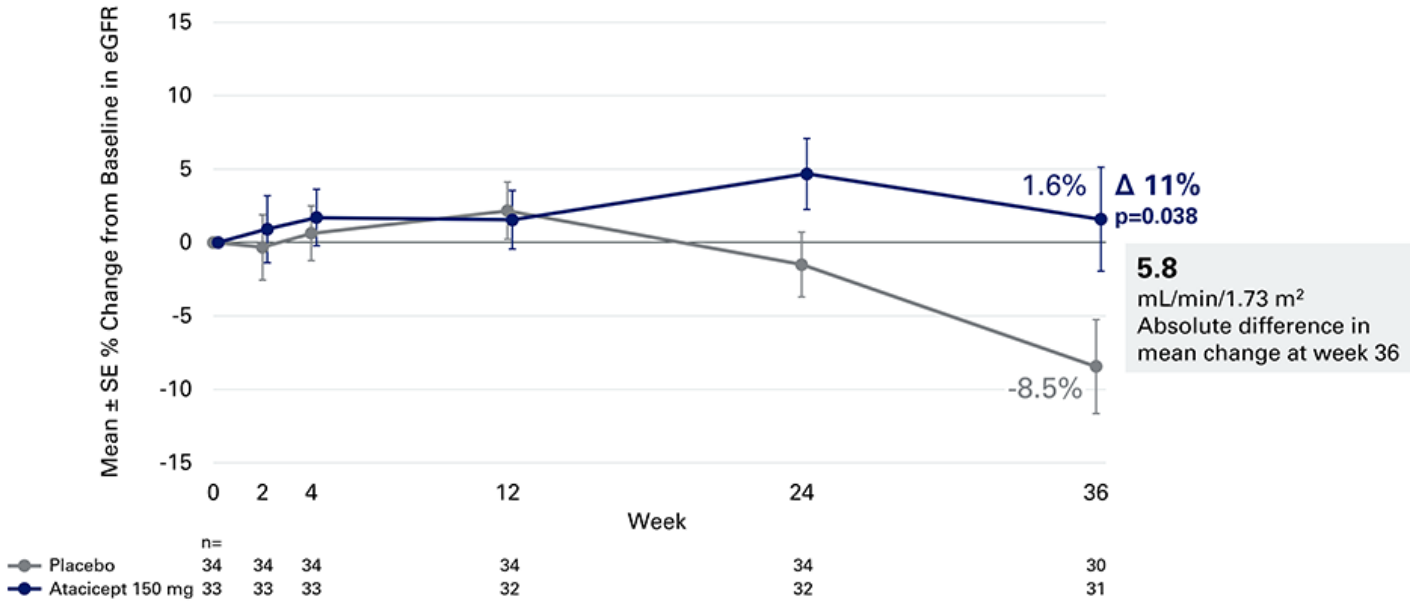
"With these results from the Phase 2b ORIGIN clinical trial at week 36, we believe the clinical results we have generated support atacicept as a potentially disease-modifying therapy for patients with IgAN," said Marshall Fordyce, M.D., Chief Executive Officer of Vera Therapeutics. "With our confirmatory Phase 3 ORIGIN 3 clinical trial already recruiting, we are working to bring this potentially transformative therapy to patients with IgAN as quickly as possible with guidance from regulators and look forward to sharing future updates on our progress."

Figure 1. UPCR % Change With Atacicept 150 mg at Week 36



p-values, percentage changes from baseline, and treatment differences were computed using FDA-endorsed mixed-effects modeling which takes into account the effects of baseline UPCR and eGFR.
1. PP analysis excluding patients with protocol violations identified at week 36 data-cut prior to unblinding.

Figure 2. eGFR % Change With Atacicept 150 mg Through Week 36



ITT analysis; p-values, percentage changes from baseline, and treatment differences were computed using FDA-endorsed mixed-effects modeling.

Safety results indicated that atacicept was generally well-tolerated and were consistent with the previously observed safety profile of atacicept, with no increased rate of infections compared to placebo, a low rate (2%) of serious adverse events overall, and no drug discontinuations or interruptions due to hypogammaglobulinemia. Serious treatment-emergent adverse events (TEAEs) were observed in 3% of patients receiving atacicept 150 mg and in 9% of placebo patients. These results build upon the prior integrated analysis of atacicept in randomized, double-blind, placebo-controlled clinical trials in over 1,500 patients to date across different indications – in which atacicept was well-tolerated.

The full presentation from the ERA 2023 congress will be available on the Company's website at https://ir.veratx.com/news-events/presentations.

Advancing Development of Atacicept
Longer term results, including the ongoing eGFR data, from the Phase 2b ORIGIN clinical trial are planned for presentation later in 2023 and 2024. Vera is continuing to advance the pivotal Phase 3 development of atacicept 150 mg. The ORIGIN 3 clinical trial was initiated in June 2023. Learn more on clinicaltrials.gov (NCT04716231).

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 being offered open-label atacicept 150 mg for an additional 60 weeks. For more information about the ORIGIN clinical trial, please visit www.clinicaltrials.gov.

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 the maximum labeled or tolerated dose. The objectives of the 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 from baseline 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 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
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 therapeutic potential of atacicept's dual inhibitor approach to treating the cause of IgAN, Vera's plans to enroll and complete the pivotal Phase 3 ORIGIN 3 trial, the design and management of such trial, and expectations regarding reporting longer term results from Vera's Phase 2b ORIGIN clinical trial. 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," "look," "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, 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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