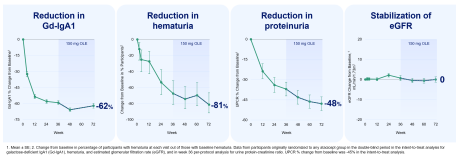
Vera Therapeutics Presents 72-week eGFR Stabilization and Rapid Hematuria Improvement in Phase 2b ORIGIN Study of Atacicept in IgAN at the 61st European Renal Association Congress

May 25, 2024

- *72-week data consistent with disease modification in IgAN, selected as a best-ranked abstract;*
- *Rapid and sustained improvements in hematuria over 36 weeks, with resolution in significantly greater percentage of participants than placebo;*

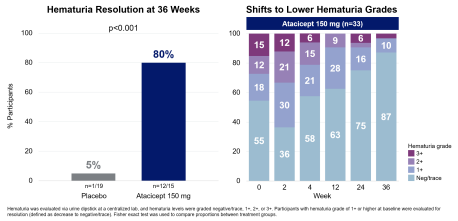
BRISBANE, Calif., May 25, 2024 (GLOBE NEWSWIRE) -- Vera Therapeutics, Inc. (Nasdaq: VERA), a late clinical-stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunological diseases, today announced data presentations from its Phase 2b ORIGIN trial of atacicept in immunoglobulin A nephropathy (IgAN), showing that atacicept stabilized kidney function through 72 weeks and led to rapid improvements in hematuria. These data were presented at the 61st European Renal Association Congress (ERA24) being held in Stockholm.

Figure 1



Atacicept 72 Week Results Are Consistent With a Disease-Modifying IgAN Profile

Figure 2

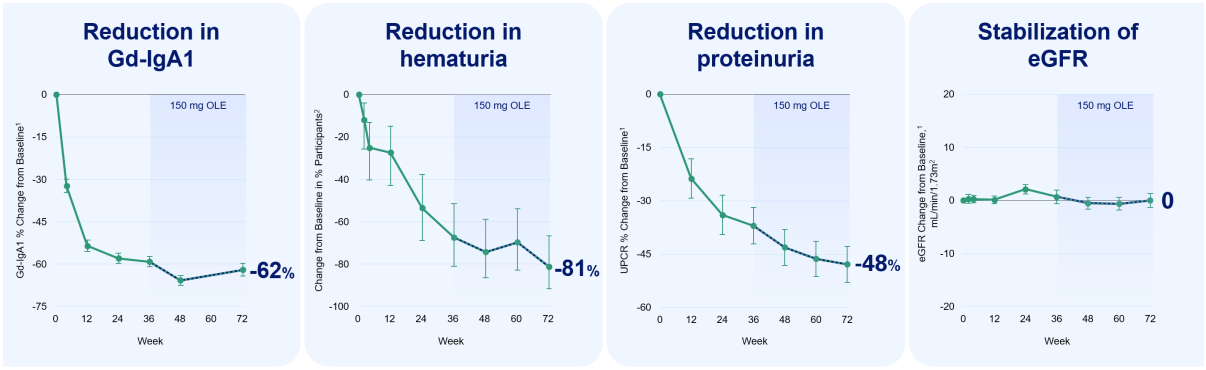


Atacicept Led to Significant Hematuria Resolution and Rapid Shifts to Lower Hematuria Grade

"For the first time in this field, we presented 72-week data from our Phase 2b ORIGIN trial showing stable kidney function over the duration of treatment. In addition, we presented data showing that atacicept leads to hematuria resolution in significantly more patients compared with placebo. The impact on hematuria was seen as early as 4 weeks after treatment initiation, which could have important implications for patients with acute kidney inflammation. The evolving atacicept data package supports our belief that atacicept may offer comprehensive disease modification to patients with IgAN," said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics. "We look forward to presenting the full 96-week data from the Phase 2b ORIGIN trial, which are expected in the fourth quarter of this year."

Participants who received atacicept for 72 weeks had stable eGFR, as well as consistent and sustained reductions in Gd-IgA1, hematuria and UPCR. Participants who switched from placebo to atacicept also demonstrated stable eGFR, as well as similar reductions in Gd-IgA1, hematuria, and UPCR as compared with participants randomized to atacicept during the first 36 weeks of the trial. The cumulative safety profile of atacicept was similar to the randomized period, with a 91% retention rate through 72 weeks. The Company believes these data support the potential for atacicept to offer long-term, comprehensive IgAN disease modification and support the ongoing pivotal Phase 3 ORIGIN 3 trial of atacicept in IgAN.

Atacicept 72 Week Results Are Consistent With a Disease-Modifying IgAN Profile

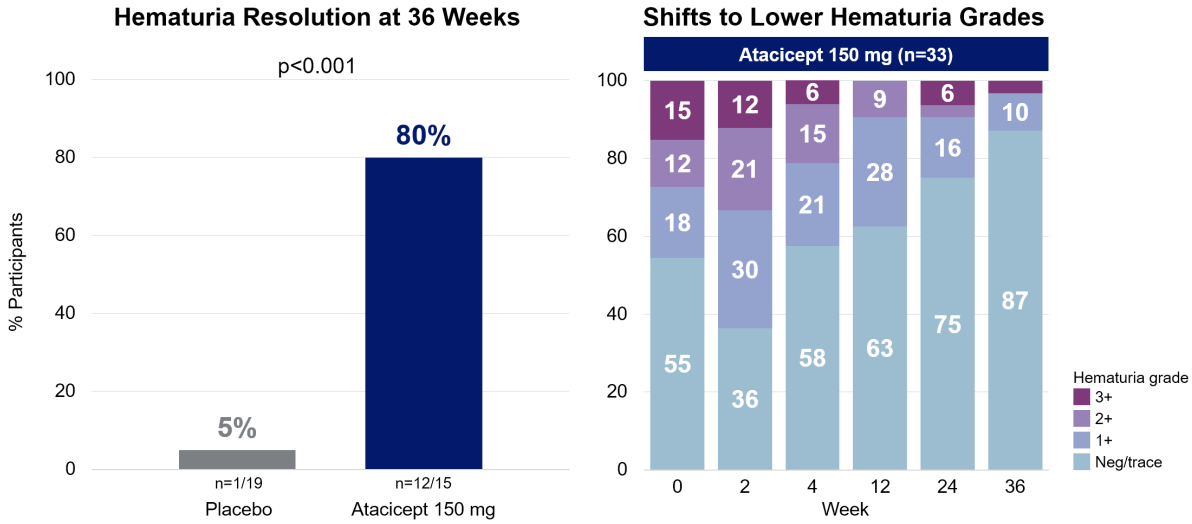


1. Mean ± SE; 2. Change from baseline in percentage of participants with hematuria at each visit out of those with baseline hematuria. Data from participants originally randomized to any atacicept group in the double-blind period in the intent-to-treat analysis for galactose-deficient IgA1 (Gd-IgA1), hematuria, and estimated glomerular filtration rate (eGFR), and in week 36 per-protocol analysis for urine protein-creatinine ratio. UPCR % change from baseline was -45% in the intent-to-treat analysis.

The 72-week abstract was selected as a best-ranked abstract by the ERA24 Congress Paper Selection Committee. The Free Communication oral presentation, titled "Phase 2b ORIGIN Study Open Label Extension with Atacicept in Patients with IgA Nephropathy and Persistent Proteinuria: Week 72 Interim Analysis" was delivered by Dr. Richard Lafayette, Professor of Medicine, Nephrology and Director of the Stanford Glomerular Disease Center at Stanford University Medical Center.

A post-hoc analysis of the 36-week data from the Phase 2b ORIGIN clinical trial showed that atacicept treatment led to hematuria resolution in a large majority of participants as compared with placebo (80% vs 5%, p<0.001). The atacicept group experienced rapid and sustained reductions in hematuria grade, with shifts to lower hematuria grades seen as early as 4 weeks after treatment initiation, while participants in the placebo group had minimal changes in hematuria grade throughout the randomized 36-week period. These results add to the growing body of evidence supporting atacicept as a potential disease-modifying treatment in IgAN.

Atacicept Led to Significant Hematuria Resolution and Rapid Shifts to Lower Hematuria Grade



Hematuria was evaluated via urine dipstick at a centralized lab, and hematuria levels were graded negative/trace, 1+, 2+, or 3+. Participants with hematuria grade of 1+ or higher at baseline were evaluated for resolution (defined as decrease to negative/trace). Fisher exact test was used to compare proportions between treatment groups.

The hematuria data was presented in a focused oral titled “Impact of Atacicept on Hematuria in IgA Nephropathy: Post-Hoc Analysis of The Phase 2b ORIGIN Study,” by Dr. Jürgen Floege, MD, Senior Professor, Division of Nephrology and Rheumatology at University of Aachen.

Upcoming milestones:

- Plan to present topline 96-week data from Phase 2b ORIGIN clinical trial of atacicept in IgAN in the fourth quarter of 2024
- Pivotal Phase 3 ORIGIN 3 trial on track to complete enrollment for primary endpoint in the third quarter of 2024; primary endpoint data available in the first half of 2025

The presentations will be available on the Company’s website at https://veratx.com/publications/.

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 a renin-angiotensin-aldosterone system inhibitor (RAASi) for at least 12 weeks that is the maximum labeled or tolerated dose. 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 were offered open-label atacicept 150 mg for an additional 60 weeks.

The primary endpoint was the change in proteinuria as evaluated by urine protein to creatinine ratio (UPCR) at week 24 and the key secondary endpoint was 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 galactose-deficient IgA1 (Gd-IgA1) levels; safety and tolerability; and serum pharmacokinetics (PK).

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. The safety profile was comparable between atacicept and placebo.

For more information about the Phase 2b 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 renin-angiotensin system inhibitors (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 kidney 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 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 kidney disease (ESKD) 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 IgAN and lupus nephritis. 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 clinical-stage biotechnology company focused on developing treatments for serious immunological diseases. Vera's mission is to advance treatments that target the source of immunological 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 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, atacicept's potential to be a best-in-class therapy for patients with IgAN, Vera's expectations regarding presenting 96-week data from the Phase 2b ORIGIN trial in the fourth quarter of 2024, Vera's plans to complete enrollment of its pivotal Phase 3 ORIGIN 3 trial in the third quarter of 2024, Vera's plans to receive and share topline data from the pivotal Phase 3 trial in the first half of 2025 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," "may," "expected," "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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Photos accompanying this announcement are available at:

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