



Vera Therapeutics Announces Atacicept Achieved 46% Proteinuria Reduction in ORIGIN Phase 3 Trial in Adults with IgA Nephropathy

Jun 2, 2025

- *Atacicept ORIGIN Phase 3 trial met the primary endpoint of reduction in proteinuria (UPCR) at week 36; participants receiving atacicept achieved a 46% reduction from baseline and 42% reduction compared to placebo at week 36 ($p < 0.0001$)*
- *Other prespecified endpoints achieved similar or better results compared to the ORIGIN Phase 2b clinical trial — per FDA guidance, Vera is not sharing eGFR results at this time while the ORIGIN 3 placebo-controlled trial continues*
- *The safety profile of atacicept was favorable, and comparable to placebo*
- *Vera plans to meet with FDA in the coming weeks to discuss these results and the regulatory pathway; Vera currently plans to submit a Biologics License Application (BLA) for accelerated approval to the FDA in 4Q 2025; ORIGIN 3 trial continues with two-year results expected in 2027*
- *Vera will host a conference call and webcast at 8:00 am ET on Monday, June 2*

BRISBANE, Calif., June 02, 2025 (GLOBE NEWSWIRE) -- Vera Therapeutics, Inc. (Nasdaq: VERA) today announced that the primary endpoint was met in the ORIGIN Phase 3 trial of atacicept for the treatment of immunoglobulin A nephropathy (IgAN) in adults.

Participants treated with atacicept achieved a 46% reduction from baseline in proteinuria as measured by 24-hour urine protein-to-creatinine ratio (UPCR), with a statistically significant and clinically meaningful 42% reduction in UPCR compared to placebo ($p < 0.0001$) at week 36. For other prespecified endpoints, atacicept treatment also demonstrated results that were consistent with or better than those previously observed in the ORIGIN Phase 2b trial.¹ The safety profile of atacicept in this analysis was favorable, and comparable to placebo. Vera plans to share these results with the FDA in the coming weeks, and full results will be submitted to the American Society of Nephrology Kidney Week.

"ORIGIN 3 is the first Phase 3 clinical trial in IgAN to demonstrate this magnitude of UPCR reduction compared to placebo at week 36. These results convincingly demonstrate the impact of atacicept to reduce proteinuria," said Richard Lafayette, M.D., F.A.C.P., Professor of Medicine, Nephrology and Director of the Glomerular Disease Center at Stanford University Medical Center, and a primary investigator for both ORIGIN 2b and ORIGIN 3.

"If approved, we believe that atacicept has the potential to advance the standard of care in IgAN as the first dual BAFF/APRIL inhibitor. We currently plan to submit a BLA for atacicept in IgAN to the FDA in the fourth quarter of this year, which may allow for US approval and commercial launch in 2026. We are grateful to the study participants, their families and caregivers, the study investigators and staff, our research partners, and the Vera team for their ongoing commitment and dedication to this important research," said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics. "Vera aspires to evolve the practice of kidney medicine with the hope that, one day, patients may no longer face a future of dialysis or transplantation. Vera is poised for potential commercial launch of atacicept in 2026 and to pursue development in additional indications in other autoimmune kidney diseases and beyond."

"Patients with IgA nephropathy, as well as their families and care partners, suffer from clinical uncertainty and the horrible outcome of kidney failure. In addition to clinical signs and symptoms, IgAN has a devastating impact on quality of life and mental wellbeing. I'm thrilled with the progress that is being made in developing new treatments for patients," said Bonnie Schneider, Director and Cofounder of the IgA Nephropathy Foundation.

ORIGIN 3 is an ongoing global, multicenter, randomized, double-blind, placebo-controlled Phase 3 trial of 431 adults with IgA nephropathy. Participants were randomized 1:1 to atacicept 150 mg, self-administered at home via once weekly subcutaneous injection, or placebo. The primary efficacy endpoint was the change in 24-hour UPCR compared to placebo at the 36-week interim analysis. The trial continues in a placebo-controlled blinded manner to evaluate the change in kidney function over two years as measured by eGFR and is expected to complete in 2027.

For more information about the ORIGIN 3 clinical trial (NCT04716231), please visit <http://www.clinicaltrials.gov>.

The Company will host an investor call and webcast to discuss the data update at 8:00 AM ET on Monday, June 2.

Investors Dial-in: 1-877-425-9470

Int'l Investors Dial-in: 1-201-389-0878

Conference ID: 13754147

Webcast: https://viaid.webcasts.com/starthere.jsp?ei=1722931&tp_key=818ddad936

The live webcast will be available on the Company's [Investor Calendar](#), with the recording and presentation available immediately following the event.

References

1. Barratt J, et al. JASN 2024

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, other autoimmune kidney diseases and lupus nephritis.

The ORIGIN Phase 2b clinical trial of atacicept in IgAN met its primary and key secondary endpoints, with statistically significant and clinically meaningful proteinuria reductions and stabilization of eGFR versus placebo through 36 weeks. The safety profile during the randomized period was comparable between atacicept and placebo. Through 96 weeks, atacicept demonstrated further improvements in Gd-IgA1, hematuria, and proteinuria, as well as stabilization of eGFR reflecting a profile consistent with that of the general population without IgAN.

Atacicept has received FDA Breakthrough Therapy Designation for the treatment of IgAN, which reflects the FDA's determination that, based on an assessment of data from the ORIGIN Phase 2b clinical trial, atacicept may demonstrate substantial improvement on a clinically significant endpoint over available therapies for patients with IgAN. Vera believes atacicept is positioned for best-in-class potential, targeting B cells to reduce autoantibodies and having been administered to more than 1,500 patients in clinical trials 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 BAFF and APRIL, which stimulate B cells to produce autoantibodies contributing to certain autoimmune diseases, including IgAN and lupus nephritis. In addition, Vera is evaluating additional diseases where the reduction of autoantibodies by atacicept may prove medically useful. Vera also holds an exclusive license agreement with Stanford University for a novel, next generation fusion protein targeting BAFF and APRIL, known as VT-109, with wide therapeutic potential across the spectrum of B cell mediated diseases. 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, atacicept's potential as a treatment for indications beyond IgAN, Vera's expectations concerning other predefined endpoints in the Phase 3 ORIGIN trial, as well as the two-year data therefrom, Vera's plans to meet with, and submit a BLA for atacicept to, the FDA, and to potentially receive FDA approval for atacicept in IgAN and launch it commercially, and, in each case, the timing thereof, the potential for atacicept to bring value for patients and to change the standard of care in IgAN, if approved, and other statements that are not historical fact. Because such statements are subject to risk and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "anticipate," "believe," "expect," "plan," "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, preliminary or interim results may not be predictive of final study 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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