Vera Therapeutics Announces Positive ORIGIN Phase 3 Data for Atacicept in IgA Nephropathy Presented at ASN Kidney Week 2025 and Published in the New England Journal of Medicine

Nov 6, 2025

- *Atacicept 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)*
- *The safety profile of atacicept across the ORIGIN program appears favorable, and comparable to placebo*
- *Biologics License Application (BLA) submission through the Accelerated Approval Program to the U.S. FDA expected in Q4 2025; potential PDUFA date in 2026*
- *ORIGIN 3 trial continues with two-year results expected in 2027*

BRISBANE, Calif., Nov. 06, 2025 (GLOBE NEWSWIRE) -- Vera Therapeutics, Inc. (Nasdaq: VERA) today announced data from the ORIGIN Phase 3 trial of atacicept in IgA nephropathy (IgAN) were presented as a featured late-breaking oral presentation during the opening plenary session of the American Society of Nephrology (ASN) Kidney Week 2025 and simultaneously published in *The New England Journal of Medicine* (NEJM).

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. Proteinuria efficacy was consistent across prespecified subgroups of age, sex, race, region, baseline proteinuria, baseline eGFR, and baseline SGLT2i use. Atacicept treatment also led to improvements in secondary endpoints: Gd-IgA1 was reduced by 68% and hematuria was resolved in 81% of participants with baseline hematuria.

Across the ORIGIN program in IgAN, the safety profile of atacicept appears favorable, and comparable to placebo. In the ORIGIN 3 full analysis set, the incidence of adverse events was generally balanced between the atacicept and placebo groups, with fewer serious adverse events reported with atacicept (n=1 [0.5%]) than placebo (n=11 [5%]), and no safety signals indicating immunosuppression. There were no deaths in either treatment group.

“ORIGIN 3 is the first Phase 3 clinical trial of a B-cell modulator in IgAN to show clinical improvements in proteinuria, Gd-IgA1, and hematuria. The consistent benefit for key disease markers and favorable safety profile across the ORIGIN program suggests that dual BAFF and APRIL inhibition with atacicept may modify disease course by targeting the underlying pathophysiology. I look forward to the full two-year results of the trial,” 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.

“We are grateful to the study participants, their families and caregivers, the study investigators and staff, our research partners, and the Vera Therapeutics team for their ongoing commitment and dedication to this important research. These results support our planned BLA submission to the FDA for atacicept in IgAN, and we look forward to a potential approval and US commercial launch in 2026. If approved, we believe that atacicept has the potential to advance the standard of care in IgAN as the first dual BAFF/APRIL inhibitor,” said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics. “Vera Therapeutics is laser focused on delivering atacicept to IgAN patients and to further investigating the potential of atacicept to treat other autoimmune kidney diseases.”

“For decades, patients with IgA nephropathy, as well as their families and care partners, have suffered from the fear of horrible outcomes like kidney failure, without many treatment options. Patients have been waiting far too long for innovation that can make a meaningful impact not only on the clinical signs and symptoms, but also on their quality of life and mental well-being. Since starting the IgAN Foundation in 2004, I have never had more hope for the future because of the medicines in development,” 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 trial results at 4:30 PM EST. To register, click here.

The live webcast will be available on the Company’s Investor Calendar, with the recording and presentation available immediately

following the event. Visit NEJM to view the article.

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 IgAN, lupus nephritis, and other autoimmune kidney diseases.

About the Atacicept Clinical Program
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.

The ORIGIN Phase 3 trial met the primary endpoint with a statistically significant and clinically meaningful reduction in proteinuria at week 36. Across the ORIGIN program in IgAN, the safety profile of atacicept appears favorable, and comparable to placebo.

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 Therapeutics 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 disease areas.

The ORIGIN Extend study provides ORIGIN study participants with extended access to atacicept until its commercial availability in their region and captures longer-term safety and efficacy data. Atacicept is also being evaluated in expanded IgAN populations, anti-PLA2R positive primary membranous nephropathy, and anti-nephrin positive focal segmental glomerulosclerosis (FSGS) and minimal change disease (MCD) patients in the PIONEER trial.

About Vera Therapeutics
Vera Therapeutics is a late clinical-stage biotechnology company focused on developing treatments for serious immunological diseases. Vera Therapeutics' mission is to advance treatments that target the source of disease in order to change the standard of care for patients. Vera Therapeutics' lead product candidate is atacicept, a fusion protein self-administered at home as a subcutaneous once weekly injection that blocks both BAFF and APRIL, which stimulate B cells to produce autoantibodies contributing to certain autoimmune diseases, including IgAN and lupus nephritis. Beyond IgAN, Vera Therapeutics is evaluating additional diseases where the reduction of autoantibodies by atacicept may prove clinically meaningful. In addition, Vera Therapeutics 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 Therapeutics is also developing MAU868, a monoclonal antibody designed to neutralize infection with BK virus, which can have devastating consequences in kidney transplant recipients. Vera Therapeutics retains all global developmental and commercial rights to atacicept, VT-109, 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, the potential approval of atacicept by the FDA, the related timing of such approval and the timing of a potential PDUFA date; the expected timing for two-year results from ORIGIN 3 trial; the ability of atacicept to modify disease course; the potential commercial launch of atacicept in 2026; the potential for atacicept to advance the standard of care in IgAN; the potential for atacicept to treat other autoimmune kidney diseases; the expected completion date of ORIGIN 3; the potential for atacicept to be best-in-class; and the plans, commitments, aspirations and goals under the caption "About Vera Therapeutics". Words such as "believe," "expect," "may," "plan," "potential," "will" and similar expressions are intended to identify forward-looking statements. These forward-looking statements are based upon Vera Therapeutics' 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 Therapeutics' business in general, the impact of macroeconomic and geopolitical events, and the other risks described in Vera Therapeutics' filings with the U.S. 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 Therapeutics 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.

For more information, please contact:

Investor Contact:
Joyce Allaire
LifeSci Advisors
212-915-2569

jallaire@lifesciadvisors.com

Media Contact:
Debra Charlesworth
Vera Therapeutics
415-854-8051
corporatecommunications@veratx.com