Vera Therapeutics Submits Biologics License Application to U.S. FDA through Accelerated Approval Program for Atacicept for the Treatment of Adults with IgA Nephropathy

Nov 7, 2025

- *Atacicept received FDA Breakthrough Therapy Designation for the treatment of IgAN*
- *ORIGIN Phase 3 trial met its primary endpoint at the prespecified interim analysis of proteinuria reduction with 46% reduction from baseline and 42% reduction vs placebo at week 36 (p<0.0001)*
- *If approved, atacicept would be the first B cell modulator targeting both BAFF and APRIL for IgAN; potential FDA approval in 2026*

BRISBANE, Calif., Nov. 07, 2025 (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 it has submitted a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) through the Accelerated Approval Program for atacicept for the treatment of adults with immunoglobulin A nephropathy (IgAN).

The BLA submission for atacicept is supported by data from a prespecified interim analysis of the ORIGIN 3 trial, which met the primary endpoint of reduction in proteinuria at week 36. 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. The safety profile of atacicept across the ORIGIN program appears favorable, and comparable to placebo. Results of the interim analysis were presented as a late-breaking oral presentation at the opening plenary session of the American Society of Nephrology Kidney Week meeting and published in a manuscript in the New England Journal of Medicine on November 6.

“The submission of our first BLA marks an inflection point in our journey as a company, bringing us closer to delivering a breakthrough treatment that could change the standard of care for patients with IgAN and other autoimmune kidney diseases,” said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics. **“**Atacicept has the potential to address the unmet medical need in IgAN as the first dual BAFF/APRIL inhibitor. We look forward to working with the U.S. regulatory authorities to bring this treatment to patients. We are energized about the path forward and thankful to the patients, caregivers, HCPs, and the Vera Therapeutics team, whose contributions made this submission possible.”

IgAN is a serious and progressive autoimmune disease of the kidney, for which there remains a high unmet need for new disease-modifying treatments that target the upstream source of the disease. In at least 50% of patients, IgAN can lead to end-stage kidney disease or kidney failure, which has considerable morbidity and impact on patients’ lives. Atacicept is being developed as an at-home self-administered subcutaneous once-weekly injection that inhibits B-cell Activating Factor (BAFF) and A Proliferation-Inducing Ligand (APRIL), cytokines that drive B-cell production of autoantibodies associated with IgAN and potentially other autoimmune kidney diseases.

ORIGIN 3 (NCT04716231) 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 of the prespecified 36-week interim analysis was the change in 24-hour UPCR compared to placebo. 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 ORIGIN 3, please visit http://www.clinicaltrials.gov.

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 potential 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 and related timing of such approval; Vera Therapeutics' ability to change the standard of care for patients with IgAN and other autoimmune kidney diseases; atacicept's potential to address the unmet medical need in IgAN; 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