Vera Therapeutics Announces Alignment with U.S. FDA on Earlier ORIGIN Phase 3 Analysis to Support Potential Full Approval for Atacicept in Adults with IgA Nephropathy

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- Prescription Drug User Fee Act (PDUFA) date of July 7, 2026 for Biologics License Application (BLA) for accelerated approval of atacicept in patients with IgA Nephropathy (IgAN)
- Revised ORIGIN 3 eGFR analysis now planned for Q3 2026, pulled forward from 2027
- Pending positive eGFR analysis, plans to submit a supplemental Biologics License Application (sBLA) in Q4 2026, with potential full approval in 2027

BRISBANE, Calif., June 02, 2026 (GLOBE NEWSWIRE) -- Vera Therapeutics, Inc. (Nasdaq: VERA), a biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunological diseases, today announced it has aligned with the U.S. Food and Drug Administration (FDA) on a revised, earlier ORIGIN 3 eGFR analysis plan to support full approval for atacicept in adults with IgAN. The eGFR results are now expected in the third quarter of 2026. Pending these results, Vera Therapeutics plans to submit an sBLA for full approval in the fourth quarter of 2026.

Alignment with the FDA on a revised eGFR analysis plan follows a recent workshop hosted by the National Kidney Foundation which included clinicians, researchers, regulators, and patient advocates. In addition, the alignment with the FDA has been supported by the eGFR results from the ORIGIN Phase 2b trial of atacicept in IgAN.

“We are excited for the potential to deliver the first approved therapy targeting both BAFF and APRIL in adults with IgAN, and to bring forward the eGFR analysis to potentially support full approval of atacicept in this indication at an earlier date,” said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics.

About Atacicept

Atacicept is an investigational soluble recombinant fusion protein that contains the native human 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 promote B-cell survival and autoantibody production associated with IgAN and other autoimmune diseases.

About the Atacicept Clinical Program in IgAN

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, in the prespecified interim analysis. Across the ORIGIN program in IgAN, the safety profile of atacicept appears favorable, and comparable to placebo. The trial continues in a placebo-controlled blinded manner to evaluate the change in kidney function as measured by eGFR, with results expected in 2026. For more information about ORIGIN 3, please visit http://www.clinicaltrials.gov.

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.

The atacicept monthly dose range finding study was initiated in 2025 to explore the effectiveness, safety, and tolerability of different dosing regimens of atacicept. Enrollment in the study has been completed.

About Vera Therapeutics

Vera Therapeutics is a 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 evaluating development of 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, approval of atacicept by the FDA, including expected timing; the expected timing of the results of the ORIGIN 3 eGFR analysis; the potential for Vera Therapeutics to submit an sBLA for full approval of atacicept in adult patients with IgAN and the timing for such submission; the potential for atacicept to be the first approved therapy targeting both BAFF and APRIL in adult IgAN patients; timing of completion of ORIGIN 3; atacicept's positioning for best-in-class potential; and the plans, commitments, aspirations and goals under the caption "About Vera Therapeutics". Words such as "anticipate," "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.

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