Vera Therapeutics Completes Full Enrollment in Pivotal ORIGIN Phase 3 Trial for Atacicept in IgAN

Apr 3, 2025

- *On track to announce primary endpoint result from ORIGIN 3 trial this quarter (2Q 2025)*
- *U.S. FDA BLA submission for accelerated approval planned for 2H 2025*

BRISBANE, Calif., April 03, 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 that it has completed full enrollment in the pivotal ORIGIN Phase 3 trial of atacicept in patients with IgA Nephropathy (IgAN).

“We are grateful for the IgAN community’s strong interest in the clinical development of atacicept that helped drive us towards completing full enrollment in the ORIGIN 3 trial with a total of 431 participants. Complete enrollment represents another key milestone on the path to potential approval of the first B cell modulator targeting both BAFF and APRIL for IgAN,” said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics. “We anticipate the 36-week primary efficacy endpoint data from the trial this quarter, which supports our planned Biologics License Application for an accelerated approval to the U.S. FDA in the second half of 2025. ORIGIN 3 follows the positive long-term results from the ORIGIN Phase 2b trial that demonstrated sustained and substantial reductions in Gd-IgA1, hematuria and proteinuria, and showed stabilized kidney function through 96 weeks, positioning atacicept as a potential best-in-class IgAN therapy. Pending the submission and thorough FDA review of the BLA, we would look forward to a potential PDUFA date and commercial launch in 2026.”

The ORIGIN 3 trial (NCT04716231) is a global, multicenter, randomized, double-blind, placebo-controlled Phase 3 trial evaluating the safety and efficacy of atacicept in patients with IgAN who have persistent proteinuria and remain at high risk of disease progression. Participants are randomized 1:1 to at-home self-administered once-weekly subcutaneous injections of atacicept 150 mg or placebo for a 104-week double-blind period, followed by a 52-week open-label extension.

The primary efficacy endpoint is the change in proteinuria as evaluated by urine protein to creatinine ratio (UPCR) through 36 weeks in an interim analysis of at least 200 participants. The key secondary efficacy endpoint is change in kidney function as measured by estimated glomerular filtration rate (eGFR) through 104 weeks in the full study population.

For more information about the ORIGIN 3 clinical trial, please visit http://www.clinicaltrials.gov.

In addition, the Company is currently conducting the ORIGIN Extend trial, which provides extended access to atacicept for participants from the ORIGIN Phase 2b or Phase 3 trials until commercial availability in their region, and captures longer-term safety and efficacy data.

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.

The Phase 2b ORIGIN 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 reductions 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 Phase 2b ORIGIN 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 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 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. 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. 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, Vera's plans to receive and report primary endpoint results in the Phase 3 ORIGIN 3 trial, to submit a Biologics License Application to the FDA, to potentially receive a PDUFA date, and potentially receive FDA approval for atacicept in IgAN and launch it commercially. 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," "may," "on track," "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 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.

For more information, please contact:

Investor Contact:
Joyce Allaire
LifeSci Advisors
212-915-2569
jallaire@lifesciadvisors.com

Media Contact:
Madelin Hawtin
LifeSci Communications
MHawtin@lifescicomms.com