Vera Therapeutics Completes Enrollment for Primary Endpoint in Pivotal Phase 3 ORIGIN 3 Trial of Atacicept in IgAN

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- *On track to announce topline results from ORIGIN 3 trial in Q2 2025*
- *Expect to present 96-week data from ORIGIN Phase 2b clinical trial of atacicept in IgAN in Q4 2024*

BRISBANE, Calif., Sept. 12, 2024 (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 enrollment ahead of schedule for the primary endpoint in the pivotal Phase 3 ORIGIN 3 trial of atacicept in patients with IgAN. The enrollment of 200 participants in this initial cohort of the trial will provide data for the 36-week UPCR primary efficacy endpoint, supporting the subsequent submission for regulatory approval.

“We are excited to complete enrollment of 200 participants for the primary endpoint in our pivotal ORIGIN 3 trial, with topline data expected in Q2 2025. We’re grateful to the investigators and participants for their enthusiasm for our clinical program, enabling rapid enrollment and progress towards our goal of bringing a potentially transformative treatment to patients,” said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics. “Atacicept continues to generate broad interest following the release of positive data from the ORIGIN Phase 2b trial, including the most recent results where patients receiving atacicept showed stabilized kidney function through 72 weeks and rapid reductions in hematuria, demonstrating atacicept’s potential to transform the treatment of IgAN and potentially keep patients from needing dialysis. These results were presented to FDA and atacicept was granted Breakthrough Therapy Designation earlier this year. In addition, we look forward to presenting the long-term 96-week data from our ORIGIN Phase 2b trial in the fourth quarter of 2024. We believe atacicept is well positioned to be one of the first B cell modulators to be approved for IgAN and provide a new foundation for treating this organ-threatening disease.”

The ORIGIN 3 clinical 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 continue to have persistent proteinuria and remain at high risk of disease progression. The objectives of the trial are to determine the effect of atacicept on proteinuria and preservation of renal kidney function compared to placebo.

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

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 and plasma 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. For more information, please visit www.veratx.com.

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 72 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 and plasma cells to reduce autoantibodies and having been administered to

more than 1,500 patients in clinical studies across different indications.

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 anticipated presentations of clinical trial data, and Vera's product candidates, strategy, and regulatory matters. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Words such as "potential," "will," "plan," "expect," "on track" 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.

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