



Vera Therapeutics Announces Appointment of Industry Veterans Robert Brenner, M.D. as Chief Medical Officer and William D. Turner as Chief Development Officer

January 8, 2024

BRISBANE, Calif., Jan. 08, 2024 (GLOBE NEWSWIRE) -- Vera Therapeutics, Inc. (Nasdaq: VERA), a late clinical-stage biotechnology company developing and commercializing transformative treatments for patients with serious immunologic diseases, today announced the appointments of two industry veterans to help lead the development of the company's drug programs including its late-stage product candidate, atacicept, to treat autoimmune diseases, currently in a Phase 3 clinical trial for IgA nephropathy (IgAN). The company has appointed Robert M. Brenner, M.D., as Chief Medical Officer to succeed Dr. Celia Lin, M.D.; and William D. Turner as Chief Development Officer, effective immediately.

"We are excited to enrich our leadership team by appointing these two seasoned industry executives. Rob and Bill each have successfully guided multiple therapies through late clinical development, regulatory approval and commercial launch. This is a key moment for Vera as we continue to advance the strategy for our late-stage clinical program," said Marshall Fordyce, M.D., Chief Executive Officer of Vera Therapeutics. "These executives add valuable experience to the execution of our clinical development program. We appreciate Dr. Lin's many contributions and leadership developing the Vera pipeline over the past three years and wish her all the best in her future endeavors."

Dr. Brenner brings more than 25 years of experience as a respected nephrologist and a successful biotechnology executive. Dr. Brenner has previously served in executive roles in several clinical-stage biotech companies, including Chief Medical Officer at Orionis Biosciences and SVP of Medical Affairs at AMAG Pharmaceuticals, contributing to the company's first therapeutic approval and launch for iron deficiency anemia (Feraheme). Previously, Dr. Brenner held several positions of expanding responsibility in the nephrology franchise at Amgen. During this time, he led kidney related global development programs, and supported two product approvals (Aranesp and Sensipar) and oversaw the establishment of the nephrology medical affairs organization. Dr. Brenner received his B.A. from Johns Hopkins University and his M.D. from Albert Einstein College of Medicine. He completed his medical residency at Brigham and Women's Hospital and his nephrology fellowship at Stanford University Medical Center.

Mr. Turner has nearly 30 years of drug development and commercialization experience, leading multiple organizations through all phases of product development including the development of the final commercial drug process, method, facility, and process validations, all phases of clinical programs, numerous drug application filings and the transition and establishment of several critical commercialization processes. Prior to joining Vera, Mr. Turner served as the Chief Regulatory and Technical Operations Officer at Sierra Oncology, Inc. (acquired by GSK), overseeing regulatory affairs, quality assurance, technical operations, analytical development/quality control, and technical/medical writing. During this time, he prepared these functional areas for the expected commercial launch, as well as directed the compilation, review and filing of the U.S. New Drug Application (NDA) and European Marketing Authorization Application (MAA) for Ojjaara (momelotinib). Prior to Sierra Oncology, Mr. Turner was Senior Vice President of Technical Operations and Regulatory Science at Aimmune Therapeutics (acquired by Nestlé) for several years culminating in the commercial launch of Palforzia, the first product approved to treat peanut allergy. Prior to his time at Aimmune, he served as Vice President of Regulatory Affairs and Global Quality at Dynavax Technologies Corporation, as well as several years in a leadership position at MedImmune (now AstraZeneca). He has significant experience in both small molecule and biologic development and has led teams in multiple therapeutic areas including vaccinology, oncology, hematology, allergy and respiratory. Mr. Turner received his B.S. in Medical Microbiology with a minor in Chemistry from California State University at Long Beach.

About the Pivotal Phase 3 clinical trial (ORIGIN 3)

The ORIGIN 3 clinical trial ([NCT04716231](https://clinicaltrials.gov/ct2/show/study/NCT04716231)) is a global, multicenter, randomized, double-blind, placebo-controlled Phase 3 trial evaluating the safety and efficacy of atacicept 150 mg in patients with IgAN who continue to have persistent proteinuria and remain at high risk of disease progression despite being on a stable prescribed regimen of renin-angiotensin system inhibitors (RASi) (ACEi or ARB) for at least 12 weeks that is the maximum labeled or tolerated dose. The objectives of the trial are to determine the effect of atacicept on proteinuria and preservation of renal kidney function compared to placebo.

The Phase 3 trial is composed of up to a 4-week screening period, a 104-week double-blind treatment period, a 52-week open-label extension and 26 weeks of follow-up. Participants will be randomized 1:1 to atacicept 150 mg once weekly subcutaneous injections (N=188) or placebo once weekly subcutaneous injections (N=188) for 104 weeks, followed by a 52-week open-label extension. The primary endpoint is the change from baseline in proteinuria as evaluated by urine protein to creatinine ratio (UPCR) at week 36. The key secondary endpoint is annualized rate of change in estimated glomerular filtration rate (eGFR) up to week 104. Additional secondary endpoints are the change in Gd-IgA1, change in eGFR up to week 52, and time from randomization to first occurrence of composite kidney failure endpoint event.

Robert M. Brenner



Robert M. Brenner, M.D., Chief Medical Officer

William D. Turner



William D. Turner, Chief Development Officer

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

About IgA nephropathy (IgAN), or Berger's disease

IgAN, also known as Berger's disease, is a serious and progressive autoimmune disease of the kidney, for which there remains a high unmet medical need. IgAN is driven by the production of immunogenic galactose-deficient IgA1 (Gd-IgA1), which triggers autoantibodies that lead to the formation of pathogenic immune complexes, which become trapped in the kidney's glomeruli, causing inflammation and progressive damage. In up to 50 percent of patients, IgAN can lead to end-stage renal disease (ESRD) or kidney failure, which has considerable morbidity and impact on patients' lives.

About Atacept

Atacept 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 atacept in IgAN met its primary endpoint and showed a statistically significant reduction in mean proteinuria versus baseline at weeks 24 and 36. Vera believes atacept 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.

About Vera Therapeutics

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 immunologic diseases in order to change the standard of care for patients. Vera's lead product candidate is atacept, 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 atacept 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 including kidney transplantation. Vera retains all global developmental and commercial rights to atacept 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 ability to execute against strategy for Vera's programs, the therapeutic potential of atacept's dual inhibitor approach to treating the cause of IgAN, Vera's plans to enroll and complete the pivotal Phase 3 ORIGIN 3 trial, the design and management of Vera's clinical trials, 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," 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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