Vera Therapeutics Announces Appointment of Industry Veteran David L. Johnson as Chief Operating Officer

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BRISBANE, Calif., July 01, 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 the appointment of David L. Johnson as Chief Operating Officer, effective immediately.

“We are excited to have David join our executive team at this important time for our clinical program of atacicept for the treatment of IgAN. We expect long-term 96-week data from the Phase 2b ORIGIN trial later this year and primary endpoint results from our pivotal Phase 3 clinical trial in the first half of 2025, and we look forward to planning for atacicept’s potential commercial launch,” said Marshall Fordyce, M.D., Founder and CEO of Vera Therapeutics. “David brings a wealth of operational and commercial experience in the biotech industry, including the successful commercial launches for a number of therapies. We look forward to partnering with him to ensure we can bring atacicept to patients in need.”

“I am pleased to join the Vera team to help advance the company’s plans for atacicept in its initial indication, the treatment of IgAN. We have a unique opportunity based on both the promising clinical data generated from this program to date, as well as a timeline that positions atacicept as one of the first B cell modulators to be approved for IgAN,” commented Mr. Johnson.

Mr. Johnson brings more than 30 years of commercialization and operational experience in the biopharmaceutical industry. Prior to joining Vera, he served as the Chief Commercial Officer at Global Blood Therapeutics (GBT) until it was acquired by Pfizer in 2022, during which time he established the company’s global commercial functions and led the launch of Oxbryta. Prior to GBT, Mr. Johnson spent 15 years at Gilead Sciences, Inc., in roles of increasing responsibility. His most recent position was as Vice President of Sales and Marketing for Gilead’s Liver Disease Business Unit, where he was responsible for building and leading the company’s liver disease franchises, including commercially launching four industry leading medicines to treat hepatitis. Prior to that position, he was Vice President of Sales and Marketing for Gilead’s Antiviral Business Unit, where he helped launch and oversee the HIV franchise. Mr. Johnson previously had an 11-year tenure at GSK plc, where he held various positions in sales, product marketing, business development, global commercial strategy and portfolio development. Mr. Johnson currently serves on the board of directors of Caribou Biosciences, a public gene therapy company. He received a B.A. in business marketing from the University of Puget Sound and an M.B.A. from the Kenan-Flagler Business School at the University of North Carolina.

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.

About the Phase 2b ORIGIN clinical trial
The Phase 2b ORIGIN clinical trial (NCT04716231) is a global, multicenter, randomized, double-blind, placebo-controlled trial evaluating the safety and efficacy of atacicept in 116 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 a renin-angiotensin-aldosterone system inhibitor (RAASi) for at least 12 weeks that is the maximum labeled or tolerated dose. The Phase 2b ORIGIN clinical trial evaluated three dose strengths of atacicept versus placebo, administered weekly by prefilled syringe. Patients were randomized 2:2:1:2 to atacicept 150 mg, atacicept 75 mg, atacicept 25 mg, or matching placebo. Upon completion of the 36-week blinded treatment period, all patients were offered open-label atacicept 150 mg for an additional 60 weeks.

The primary endpoint was the change in proteinuria as evaluated by urine protein to creatinine ratio (UPCR) at week 24 and the key secondary endpoint was the change in proteinuria as evaluated by UPCR at week 36. Additional exploratory endpoints include change in proteinuria as evaluated by UPCR at weeks 12, 48, and 96; change in estimated glomerular filtration rate (eGFR); change in serum immunoglobulin levels, and serum galactose-deficient IgA1 (Gd-IgA1) levels; safety and tolerability; and serum pharmacokinetics (PK).

For more information about the Phase 2b ORIGIN clinical trial, please visit www.clinicaltrials.gov.

About the Pivotal Phase 3 clinical trial (ORIGIN 3)
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 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.

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

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 expectations regarding presenting 96-week data from the Phase 2b ORIGIN trial in 2024, Vera's plans to receive and share topline data from the pivotal Phase 3 trial in the first half of 2025, Vera's plans to commercially launch atacicept 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," "may," "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.

For more information, please contact:

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

Media Contact:
Mari Purpura
LifeSci Advisors
mpurpura@lifesciadvisors.com