Vera Therapeutics Announces Phase 3 Clinical Trial for Atacicept in Lupus Nephritis

Jan 18, 2022

- Positive feedback from FDA to initiate Phase 3 trial of atacicept in patients with LN -

BRISBANE, Calif., Jan. 18, 2022 (GLOBE NEWSWIRE) -- Vera Therapeutics, Inc. (Nasdaq: VERA), a late-stage biotechnology company focused on developing and commercializing transformative treatments for patients with serious immunological diseases, announced plans to initiate a Phase 3 clinical trial of its lead product candidate atacicept in lupus nephritis (LN).

This announcement comes after positive feedback from the U.S. Food and Drug Administration (FDA)'s review of the proposed Phase 3 trial. Lupus nephritis, a severe renal manifestation of systemic lupus erythematosus (SLE), causes kidney inflammation, which leads to blood and protein in the urine, high blood pressure, impaired kidney function, and eventually approximately 25 percent of LN patients develop end stage renal disease.

"Fewer than half of patients treated for LN have a complete response to current therapies, and among patients without a complete response, more than half will have non-functioning kidneys within five years," said Vera founder and CEO Marshall Fordyce, MD. "Atacicept has the potential to offer a significant improvement over standard of care for patients who currently have limited options. Atacicept has been administered to more than 1,400 patients in clinical studies across different indications. We look forward to initiating this Phase 3 trial and working with the FDA and other regulators to evolve the standard of care for LN patients."

The Phase 3 randomized, double-blinded, placebo-controlled trial will evaluate the efficacy and safety of atacicept in subjects with LN by assessing 150 milligrams of once-weekly subcutaneous injections of atacicept versus placebo. The clinical trial consists of a 52-week double-blind treatment period, followed by a 104-week open-label treatment period and a 26-week safety follow-up period. The primary endpoint for the trial is complete renal response at 52 weeks.

Additional Clinical Trials
Atacicept is also currently being evaluated for the treatment of immunoglobulin A nephropathy (IgAN) in the Phase 2b ORIGIN trial, which Vera expects will complete enrollment in mid-2022. If the data from this trial are positive, Vera plans to seek an accelerated approval path from the FDA and European Medicines Agency (EMA) for IgAN while initiating a pivotal Phase 3 clinical trial in 2023.

Vera also plans to initiate a Phase 2b or Phase 3 trial for MAU868 in kidney transplant patients with BK virus (BKV) viremia, a potentially first-in-class monoclonal antibody designed to treat BKV infections. In December 2021, Vera obtained worldwide, exclusive development and commercial rights to MAU868 from Amplyx Pharmaceuticals, Inc., a wholly owned subsidiary of Pfizer. In an interim analysis of Phase 2 data among kidney transplant recipients, MAU868 was shown to be well-tolerated and showed a greater proportion of subjects with decrease in BK plasma viral load versus placebo. Vera expects to share full results from the interim analysis in mid-2022 and initiate the next clinical trial in 2023.

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 lymphocyte stimulator (BlyS) 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 IgA nephropathy and lupus nephritis. Atacicept showed a dose-dependent effect on key biomarkers and clinical markers in a Phase 2a clinical study. 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 1,400 patients in clinical studies across different indications.

About Vera
Vera Therapeutics is a late-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 atacicept, a fusion protein self-administered as a subcutaneous injection once weekly that blocks both B lymphocyte stimulator (BLyS) and a proliferation inducing ligand (APRIL), which stimulate B cells and plasma cells to produce autoantibodies contributing to certain autoimmune diseases, including IgA nephropathy (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, a polyomavirus that can have devastating consequences in certain settings such as kidney transplant. 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 continued tolerability of Vera’s product candidates, research and clinical development plans and timing, the scope, progress, and results of developing Vera’s product candidates, strategy, and regulatory matters, including the timing and likelihood of success of obtaining drug approvals. 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 “plans,” “will,” “expects,” “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, risks and uncertainties associated with Vera’s business in general, the impact of the COVID-19 pandemic, and the other risks described in Vera’s filings with the Securities and Exchange Commission, including in its latest Form 10-Q filed with the Securities and Exchange Commission on November 10, 2021, particularly under the caption “Risk Factors.” 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.

Contacts
Investor Contact:
IR@veratx.com

Media Contact:
Kathy Vincent
Greig Communications, Inc.
kathy@greigcommunications.com