Vera Therapeutics Announces New Atacicept Phase 2 Clinical Data in Two Oral Presentations at the 59th European Renal Association Congress

May 20, 2022

- *Atacicept is the first known investigational therapy to decrease both circulatory Gd-IgA1 and anti-Gd-IgA1 autoantibodies which correlate with increased risk of IgA nephropathy disease progression*
- *New analysis shows atacicept improved renal function in patients with mild-to-moderate renal disease in Phase 2 study of atacicept in systemic lupus erythematosus*

BRISBANE, Calif., May 20, 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 disease, today announced new clinical data for its lead product candidate, atacicept, from the Phase 2a JANUS trial in patients with IgA nephropathy (IgAN) and first-time results from a post-hoc analysis of the Phase 2 APRIL-SLE study in patients with systemic lupus erythematosus (SLE). These data were included in two oral presentations at the European Renal Association - European Dialysis Transplant Association (ERA-EDTA) Congress being held May 19-22, 2022 in Paris, France, in person and virtually.

“We are excited to share these new data from the Phase 2a JANUS clinical trial which we believe make atacicept the first known investigational therapeutic to reduce IgG autoantibodies as well as its autoantigen, Gd-IgA1. Increased levels of both have been shown to correlate with increased risk of progression. We expect the ongoing Phase 2b ORIGIN trial evaluating up to atacicept 150 mg in patients with IgAN to help determine how these reductions in Gd-IgA1 and anti-Gd-IgA1 translate to measures of renal function, including proteinuria and GFR,” said Celia Lin, M.D., Chief Medical Officer at Vera Therapeutics.

Dr. Lin continued, “We also presented new data from a post-hoc analysis from our double-blind, placebo-controlled Phase 2 study which suggested atacicept has the potential to improve renal function in patients with mild-to-moderate SLE renal disease. We anticipate the planned Phase 3 COMPASS clinical trial evaluating atacicept 150 mg to help determine whether atacicept improves renal function in moderate-to-severe lupus nephritis. We look forward to continuing to advance our clinical program for atacicept in these serious kidney diseases so that we can help patients in need as quickly as possible.”

Details of the oral presentations are as follows:

Title: Atacicept Reduces Serum Anti-Gd-IgA1 Levels in Patients with Immunoglobulin A Nephropathy (IgAN)
Presenter: Jonathan Barratt, PhD, FRCP, The Mayer Professor of Renal Medicine, University of Leicester, UK
Abstract Number: FC 051

In the Phase 2a randomized, placebo-controlled JANUS trial in 16 IgAN patients, patients were evaluated for serum anti-Gd-IgA1 at baseline, weeks 4, 12, 24, 48, and 72. Results showed a decrease in serum anti-Gd-IgA1 levels was observed in both atacicept 25 mg and 75 mg groups over time. At 24 weeks, the mean percent change from baseline was a 24 percent decrease for atacicept 25 mg and a 29 percent decrease for atacicept 75 mg. At 72 weeks, a 28 percent decrease for atacicept 25 mg and 39 percent decrease for atacicept 75 mg was observed.

“It is well-known that Gd-IgA1 plays a central role in the pathogenesis of IgAN. As a result, it is exciting to report that, based on our knowledge, the Phase 2a JANUS trial is the first study to show a therapeutic substantially reduced serum Gd-IgA1 in patients with IgAN. In addition, we know that IgAN patients also develop antibodies against this Gd-IgA, which is another key factor in disease pathogenesis and progression,” said Dr. Barratt. “The ability of atacicept to decrease both circulatory Gd-IgA1 and anti-Gd-IgA1 autoantibodies, both of which are central to the pathogenesis and progression of IgAN, support its potential as a disease-modifying therapy for patients with IgAN.”

Title: Effect of Atacicept on Renal Function in Patients With Systemic Lupus Erythematosus (SLE)
Presenter: David Isenberg, M.D., ARC Diamond Jubilee Professor and director of the Centre for Rheumatology and Bloomsbury Rheumatology Unit, University College London, UK
Abstract Number: FC 055

APRIL-SLE was a double-blind, placebo-controlled, Phase 2 study that randomized patients with moderate-to-severe SLE to atacicept 75 mg, atacicept 150 mg, or placebo twice-weekly for 4 weeks, then weekly for 48 weeks. In total, 111 patients in the placebo group, 112 patients in the atacicept 75 mg group, and 62 patients in the atacicept 150 mg group completed 52 weeks of treatment. Results showed the estimated glomerular filtration rate (eGFR) time course was stable for the atacicept groups compared to a 4.4 percent decline in the placebo group from baseline at week 52. The urine protein creatine ratio (UPCR) from baseline at week 52 declined in the atacicept groups and increased in the placebo group.

“Results from this post-hoc analysis of the Phase 2 trial of atacicept in SLE suggest atacicept may improve renal function in patients with mild-to-moderate SLE renal disease. These data are encouraging and supportive of further investigating atacicept to treat lupus nephritis in a planned pivotal Phase 3 clinical trial, which is expected to be initiated in 2022,” said Dr. Isenberg.

The presentations are available on the Vera Therapeutics website.

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, Vera’s expectations regarding the ongoing Phase 2b ORIGIN trial and Vera’s clinical program for atacicept. 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. 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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